## SECURITIES AND EXCHANGE COMMISSION

# **FORM 10-Q/A**

Quarterly report pursuant to sections 13 or 15(d) [amend]

Filing Date: 1995-07-28 | Period of Report: 1995-04-02 SEC Accession No. 0000912057-95-005730

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## **FILER**

## **CHIRON CORP**

CIK:706539| IRS No.: 942754624 | State of Incorp.:DE | Fiscal Year End: 1231

Type: 10-Q/A | Act: 34 | File No.: 000-12798 | Film No.: 95556975

SIC: 2835 In vitro & in vivo diagnostic substances

Business Address 4560 HORTON ST EMERYVILLE CA 94608 5106558730

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

FORM 10-Q/A Amendment No. 1

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

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For Quarterly Period Ended April 2, 1995 Commission File Number: 0-12798

CHIRON CORPORATION

\_ -----

(Exact name of registrant as specified in its charter)

Delaware 94-2754624 \_ \_\_\_\_\_\_

(state or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

4560 Horton Street, Emeryville, California \_ \_\_\_\_\_\_

94608

(Address of principal executive offices)

(Zip code)

(510) 655-8730

\_ \_\_\_\_\_\_

(Registrant's telephone number, including area code)

Not Applicable

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(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by section 13 or 15(d) of the Security 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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

> Class Outstanding at April 2, 1995 \_\_\_\_\_

Common Stock, \$.01 par value

40,045,138

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Accounts receivable		140,476
Inventories		47,592
Other current assets	39 <b>,</b> 472	23,252
Total current assets		433,815
Noncurrent investments in marketable debt securities	135,783	171,328
Property, equipment and leasehold improvements, at cost:		
Land and buildings	168,000	60,930
Laboratory, production and office equipment	230,094	140,438
Leasehold improvements	86,536	82 <b>,</b> 145
Construction in progress	76 <b>,</b> 662	78 <b>,</b> 998
		362,511
Less: accumulated depreciation and amortization	90,297	76,337
Net property, equipment and leasehold improvements	470 <b>,</b> 995	286,174
Intangible assets, net	164,132	85,803
Investments in equity securities and affiliated companies	31,165	51,425
Other assets		21,197
	\$ 1,483,943	\$ 1,049,742
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES AND STOCKHOLDERS' EQUITY  Current liabilities:		
~	\$ 74,349	\$ 27,778
Current liabilities:	\$ 74,349 54,484	
Current liabilities: Accounts payable		24,010
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt	54,484	24,010  3,461
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable	54,484 84,786	24,010  3,461
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt	54,484 84,786 3,478 25,610 150,644	24,010  3,461 10,060 54,332
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable	54,484 84,786 3,478 25,610 150,644	24,010  3,461 10,060
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable Other current liabilities  Total current liabilities	54,484 84,786 3,478 25,610 150,644	24,010  3,461 10,060 54,332
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable Other current liabilities	54,484 84,786 3,478 25,610 150,644 393,351 405,994	24,010  3,461 10,060 54,332  119,641 338,061
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable Other current liabilities  Total current liabilities Long-term debt	54,484 84,786 3,478 25,610 150,644 393,351 405,994	24,010  3,461 10,060 54,332  119,641
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable Other current liabilities  Total current liabilities Long-term debt Other noncurrent liabilities	54,484 84,786 3,478 25,610 150,644 393,351 405,994	24,010  3,461 10,060 54,332  119,641 338,061
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable Other current liabilities  Total current liabilities Long-term debt Other noncurrent liabilities Commitments and contingencies	54,484 84,786 3,478 25,610 150,644 393,351 405,994	24,010  3,461 10,060 54,332  119,641 338,061
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable Other current liabilities  Total current liabilities Long-term debt Other noncurrent liabilities Commitments and contingencies Stockholders' equity:	54,484 84,786 3,478 25,610 150,644 393,351 405,994 51,999	24,010  3,461 10,060 54,332  119,641 338,061 19,409
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable Other current liabilities  Total current liabilities  Long-term debt Other noncurrent liabilities Commitments and contingencies Stockholders' equity: Common stock Additional paid-in capital Accumulated deficit	54,484 84,786 3,478 25,610 150,644 393,351 405,994 51,999	24,010  3,461 10,060 54,332  119,641 338,061 19,409
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable Other current liabilities  Total current liabilities  Long-term debt Other noncurrent liabilities Commitments and contingencies Stockholders' equity: Common stock Additional paid-in capital Accumulated deficit Cumulative foreign currency translation adjustment	54,484 84,786 3,478 25,610 150,644 	24,010  3,461 10,060 54,332  119,641 338,061 19,409 334 1,161,942 (575,236) (1,719)
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable Other current liabilities  Total current liabilities  Long-term debt Other noncurrent liabilities Commitments and contingencies Stockholders' equity: Common stock Additional paid-in capital Accumulated deficit	54,484 84,786 3,478 25,610 150,644 	24,010  3,461 10,060 54,332  119,641 338,061 19,409 334 1,161,942 (575,236) (1,719) (12,690)
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable Other current liabilities  Total current liabilities  Long-term debt Other noncurrent liabilities Commitments and contingencies Stockholders' equity: Common stock Additional paid-in capital Accumulated deficit Cumulative foreign currency translation adjustment	54,484 84,786 3,478 25,610 150,644 	24,010 3,461 10,060 54,332 119,641 338,061 19,409  334 1,161,942 (575,236) (1,719) (12,690) 572,631
Current liabilities: Accounts payable Accrued compensation and related expenses Short-term borrowings Current portion of long-term debt Taxes payable Other current liabilities  Total current liabilities  Long-term debt Other noncurrent liabilities Commitments and contingencies Stockholders' equity: Common stock Additional paid-in capital Accumulated deficit Cumulative foreign currency translation adjustment Unrealized loss from investments	54,484 84,786 3,478 25,610 150,644 	24,010 3,461 10,060 54,332 119,641 338,061 19,409  334 1,161,942 (575,236) (1,719) (12,690) 572,631

</TABLE>

SEE ACCOMPANYING NOTES.

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CHIRON CORPORATION
CONSOLIDATED STATEMENT OF OPERATIONS
(UNAUDITED)

(IN THOUSANDS, EXCEPT PER SHARE DATA)

\_ \_\_\_\_\_\_

	Three Months Ended		
	March 31, 1995	March 31, 1994	
<\$>	<c></c>	<c></c>	
Revenues:			
Product sales, net	\$ 183 <b>,</b> 909	\$ 45,484 15,487	
Equity in earnings of unconsolidated joint businesses	18,178	15,487	
Collaborative agreement revenues	5,567		
Other revenues	10,592	7,948	
Total revenues	218,246	91,381	
Expenses:			
Research and development	99,055	38,409	
Cost of sales	90,282	21,724	
Selling, general and administrative	84,894	23 <b>,</b> 518	
Write-off of purchased in-process technologies	230,657		
Costs related to Ciba transaction	49,520		
Restructuring and reorganization costs	37,641		
Other operating expenses	2,280	906	
Total expenses	594 <b>,</b> 329	84,557	
Income (loss) from operations	(376,083)	6,824	
Other income (expense), net	(1,389)	282	
Income (loss) before income taxes	(377,472)	7,106	
Provision for income taxes	8,306 	2,289	
Net income (loss)	\$ (385 <b>,</b> 778) 	\$ 4,817 	
Net income (loss) per share		\$ 0.14	
Weighted average number of shares used in computing per share amounts	40,013	34,606	

Three Months Ended

</TABLE>

SEE ACCOMPANYING NOTES.

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CHIRON CORPORATION
STATEMENT OF CASH FLOWS
(UNAUDITED)
(IN THOUSANDS)

\_ \_\_\_\_\_\_

	Three Months Ended		
	March 31,	March 31, 1994	
<\$>	<c></c>	<c></c>	
Cash flows from operating activities:	<b></b>	νο,	
Net income (loss)	\$ (385,778)	\$ 4,817	
Adjustments to reconcile net income (loss)			
to net cash used in operating activities:			
Write-off of purchased in-process technologies	230,657		
Reserves and write-offs	28,370	1,944	
Depreciation and amortization	22,666	10,031	
Deferred income taxes	(557)		
Undistributed earnings of affiliates	(189)	(247)	
Changes, excluding the effect of acquisitions, to:			
Accounts receivable	63,604	(15, 263)	
Inventories	(26,749)	(3,295)	
Other current assets	2,771	(2,182)	
Accounts payable	3,035	(7,187)	
Current portion of unearned revenue		(3,347)	
Accrued compensation and related expenses	4,670	(5,998)	
Taxes payable	7,906	1,906	
Other current liabilities	45,369	(2,201)	
Other noncurrent liabilities	(2,053)	(201)	
Net cash used in operating activities	(4,323)	(21,223)	
Cash flows from investing activities:	44.0 0.000	(0.550=)	
Purchase of investments in marketable debt securities	(19,877)		
Sale and maturities of investments in marketable debt securities	86,880	51,486	
Capital expenditures	(28,586)		
Purchase of IOLAB	(96,013)		
Cash acquired from the Acquisitions, net of cash paid	14,225		
Investments in equity securities and affiliates		(18,500)	
Distributions from affiliates		518	
Increase in other assets	(12,204)	(5,939)	
Net cash used in investing activities	(58,225)	(93,883)	
Cash flows from financing activities:	40.074		
Borrowings under line of credit arrangements	42,971		
Repayment of notes payable and capital leases	(2,450)	(77)	
Proceeds from capital contribution from Ciba	24,845		
Proceeds from issuance of common stock	3,060 	7,326	
Net cash provided by financing activities	68,426 	7 <b>,</b> 249	
Effect of exchange rate changes on cash and cash equivalents	368		
Net increase (decrease) in cash and cash equivalents	6 <b>,</b> 246	(107,857)	
Cash and cash equivalents at beginning of the period	84 <b>,</b> 876	156 <b>,</b> 516	
Cash and cash equivalents at end of period	\$ 91,122	\$ 48,659	

</TABLE>

SEE ACCOMPANYING NOTES.

## CHIRON CORPORATION NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## MARCH 31, 1995

## 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

## BASIS OF PRESENTATION

The information at March 31, 1995, and for the periods ended March 31, 1995 and 1994, is unaudited, but includes all adjustments which Chiron's management believes to be necessary for fair presentation of the periods presented. The consolidated balance sheet amounts at December 31, 1994, have been derived from audited financial statements. Certain 1994 balances have been reclassified to conform to the 1995 presentation. Interim results are not necessarily indicative of results for a full year. The consolidated financial statements should be read in conjunction with Chiron's audited consolidated financial statements for the year ended December 31, 1994, and with Amendment No. 1 to the Company's filing on Form 8-K dated January 4, 1995.

The consolidated financial statements include the accounts of the Company and its subsidiaries. Investments in joint ventures, partnerships and interests in other companies in which Chiron has an equity interest of 50 percent or less are accounted for by the equity method, cost method or in accordance with Statement of Financial Accounting Standards No. 115, as appropriate. All significant intercompany transactions and balances have been eliminated.

## FISCAL YEAR

Effective for fiscal year 1995, the Company adjusted its fiscal year end from December 31 to the 52 or 53-week period that ends on the Sunday nearest December 31. As a result, the first quarter of 1995 represents the thirteen-week period ended April 2, 1995. For presentation purposes, dates used in the consolidated financial statements and notes refer to the calendar month end.

## INVENTORIES

Pharmaceutical inventories are stated at the lower of cost or market using the average cost method or, in the case of vaccine products, using the last-in, first-out ("LIFO") method. Diagnostic and ophthalmic products are valued at cost using the first-in, first-out ("FIFO") method which is less than fair value. Inventories consist of the following:

	MARCH 199	•		BER 31,
		(IN MIL	LIONS)	
Finished goods	\$	98	\$	24
Work in process		23		9
Raw materials		38		15
	\$	159	\$	48

## INCOME TAXES

Income tax expense for the quarters ended March 31, 1995 and 1994, includes a provision for federal, state and foreign taxes based on the annual estimated effective rates applicable to certain of the Company's subsidiaries.

## PER SHARE DATA

Per share information is based on the weighted average number of common shares and dilutive common share equivalents outstanding. Shares issuable upon the exercise of stock options and certain warrants are included in the calculations, utilizing the treasury stock method, to the extent they are dilutive. Shares assumed to be issued upon conversion of the Company's convertible debentures and certain warrants are not included since their inclusion would be antidilutive. Fully diluted per share data has not been presented as the amount would not differ materially from primary per share data.

## REVENUE RECOGNITION

Revenue from product sales consists of shipments of ophthalmic products, therapeutics, diagnostic materials and instruments and other biologicals and is generally recognized upon shipment. Revenue from service contracts is recognized ratably over the life of the contract. Revenue from the sale of equipment under sales-type leases is recognized at the inception of the lease. All of the above revenues are included in "Product sales, net" in the Consolidated Statement of Operations.

## 2. BUSINESS COMBINATIONS

## TRANSACTION WITH CIBA-GEIGY LTD. AND AFFILIATES ("CIBA")

Effective January 1, 1995, Chiron entered into a series of agreements with Ciba, including an investment agreement, a cooperation and collaboration agreement and a governance agreement (collectively "agreements"). Ciba now holds approximately a 49.5 percent ownership interest in Chiron common stock, partially through a tender offer for approximately 38 percent of Chiron's outstanding common stock for \$117 per share. At the same time, Chiron acquired all of the outstanding common stock of Ciba Corning Diagnostics Corp. ("CCD") and Ciba's interests in The Biocine Company and JV Vax B.V. (a Netherlands company which owns Biocine SpA) in exchange for 6.6 million newly-issued Chiron common shares and a cash payment of \$24 million. These two acquisitions of Chiron common stock by Ciba, together with Ciba's prior holdings of approximately 1.4 million shares, result in the aforementioned 49.5 percent ownership of the Company's common stock.

Under the terms of the agreements, Ciba is entitled to name three new members to Chiron's Board of Directors and has limited rights to review and approve certain Chiron transactions. In connection with these agreements, Ciba has agreed to guarantee \$425 million of new debt for Chiron and has agreed to provide \$250 million (and up to \$300 million subject to certain reductions in the debt guarantee) over five years in support of research at Chiron, and Chiron has the option of issuing up to \$500 million of new equity to Ciba. In the event Chiron utilizes this research funding, Chiron will be obligated to offer to Ciba the opportunity to share in the market opportunities of any resulting

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products. Alternatively, Chiron is entitled to reacquire all rights to any resulting products by repaying to Ciba, in cash or common stock, an amount equal to the funding plus an agreed upon return.

The acquisitions of CCD and Ciba's interests' in The Biocine Company and JV Vax B.V. (the "Acquisitions") were accounted for by the purchase method. The purchase price of approximately \$433 million was allocated to the acquired assets and assumed liabilities based upon their estimated fair value on the acquisition date. The fair value of the net assets acquired in the Acquisitions, including in-process technology, was estimated based on an independent valuation of the acquired net assets. The aggregate purchase price of approximately \$433 million was less than the fair value of the net assets acquired by approximately \$62 million. This amount was ratably allocated as a reduction of the noncurrent assets of the acquired companies.

The Acquisitions include the following components:

	(IN MILLIONS)
Fair value of assets acquired	\$ 692
Common stock issued	(408)
Cash paid	(24)
Acquisition costs	(1)
Liabilities assumed	\$ 259

As required under generally accepted accounting principles, Chiron recognized as an expense the amount allocated to in-process technology in the first quarter of 1995. This resulted in a noncash charge against earnings of \$220 million. Other transaction-related charges totaling \$50 million related to employee payments and the related taxes, and legal and investment advisor fees were also recognized as expenses in the first quarter of 1995. Ciba has agreed to reimburse the Company \$25 million for a portion of the employee payments and such reimbursement has been recorded as a capital contribution. Other purchased intangible assets of approximately \$33 million consisting of a customer list and base technology will be amortized over their estimated useful lives of 10 to 15 years, using the straight-line method.

The results of operations of CCD, JV Vax B.V. and The Biocine Company are included in Chiron's consolidated operating results from January 1, 1995, forward. Chiron's interest in the operating results of JV Vax B.V. and The Biocine Company were included in the Company's 1994 operating results under the equity method of accounting. The following unaudited proforma consolidated financial information for the three months ended March 31, 1994, gives effect to the terms of the agreements as if such transactions had been consummated on January 1, 1994.

THREE MONTHS ENDED MARCH 31, 1994

(IN MILLIONS, EXCEPT PER SHARE DATA)

Total revenues	\$	203
Net income		3
Net income per share	(	0.07

The above proforma financial information does not purport to be indicative of actual financial results which would have been obtained had the acquisitions occurred on January 1, 1994, and should not be construed as representative of future results of operations. Also, the proforma financial information does not include the write-off of purchased inprocess technology of \$220 million or other

transaction-related costs totaling \$50 million (related to employee payments and the related taxes, and investment advisor and legal fees) which were recognized as expense in the first quarter of 1995.

## ACQUISITION OF IOLAB

Effective March 31, 1995, Chiron Vision acquired the surgical division of IOLAB from Johnson & Johnson. The purchase price of approximately \$96 million was allocated to the acquired assets and assumed liabilities based upon their estimated fair value on the acquisition date. The fair value of the net assets acquired, including in-process technology, was estimated based on independent valuations of the acquired net assets.

The acquisition includes the following components:

	(IN	MII	LLIONS)
Fair value of assets acquired		\$	109
Cash paid			(95)
Acquisition costs			(1)
Liabilities assumed		\$	13

The acquisition was accounted for by the purchase method, and the amount allocated to in-process technology of \$10 million was charged against earnings in the first quarter of 1995. Other purchased intangible assets of approximately \$46 million consisting of base technology, goodwill, trade name and a customer list will be amortized over their estimated useful lives of 10 to 15 years using the straight-line method. IOLAB's results of operations are included in Chiron's results of operations from March 31, 1995, forward.

Also, the Company recorded additional charges for restructuring and integration-related expenses totaling \$17 million in the first quarter of 1995. Of this amount, approximately \$8 million was related to write-downs of assets. The remaining \$9 million consists primarily of \$6 million in employee costs and \$3 million for the cost of lease terminations. The majority of the accrued costs are expected to be paid over the next two years.

## 3. RESTRUCTURING AND REORGANIZATION COSTS

Costs totaling \$38 million related to restructuring and reorganization plans, including \$17 million arising from the acquisition and integration of IOLAB (Note 2), represent the expected costs of integrating the acquired businesses (Note 2) with Chiron's existing businesses, as well as costs related to the idling of the Company's Puerto Rico manufacturing facility and the scale-back of manufacturing operations at the Company's Amsterdam facility, the write-down of duplicate facilities and the postponement of plans to expand the Company's research and administrative facilities.

Of the approximately \$21 million in charges for actions other than the integration of IOLAB, approximately \$15 million related to write-downs of assets. The remaining costs of approximately \$6 million consist primarily of employee costs of \$1 million and \$5 million related to additional tax obligations and lease termination costs. The majority of the accrued costs are expected to be paid over the next two years.

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## 4. COLLABORATIONS AND JOINT BUSINESS ARRANGEMENTS

GENERAL

The Company has entered into a number of collaborative arrangements with other pharmaceutical and biotechnology companies for the development and marketing of certain technologies and products. The majority of these collaborations are in the development or clinical trial phase. Chiron and its collaborative partners generally contribute certain technologies and research efforts to the collaboration. In addition, Chiron and its collaborative partners commit, subject to certain limitations and cancellation clauses, to share in the funding of the collaboration's ongoing research and clinical trial costs. Chiron, under certain of the arrangements, has purchased equity securities, including common and preferred stock and warrants to purchase common and preferred stock, of the collaborative partner. During the first quarter of 1995 the Company entered into the following new collaborations:

## PROGENITOR, INC.

In March 1995, the Company reached an agreement with Progenitor, Inc. ("Progenitor"), a subsidiary of Interneuron Pharmaceuticals, Inc., to collaborate in the development and commercialization of therapeutic and vaccine products incorporating Progenitor's proprietary gene therapy technology. Under the agreement, Chiron received a license to Progenitor's nonviral gene expression system for use in the development of products for the treatment of certain cancers and cardiovascular disorders, development of infectious disease vaccines and for development of certain other gene therapy products. Chiron will have the right to manufacture and market any resulting products of the collaboration. In return for the license and other rights, Chiron made an initial license payment of \$2.5 million to Progenitor, which was expensed in the first quarter of 1995, and agreed to make an additional funding payment of \$0.5 million and make additional license payments totaling \$1.0 million to retain certain rights to development of infectious disease vaccines. Also, Chiron has agreed to pay to Progenitor various product development milestone payments which could total approximately \$3 million per product plus certain other milestone payments which would be treated as prepaid royalties. In addition, Progenitor will receive a royalty from any commercial sales of products resulting from the collaboration.

## GENELABS TECHNOLOGIES, INC.,

In March 1995, the Company reached an agreement with Genelabs Technologies, Inc. ("Genelabs"), whereby Chiron and Genelabs cross-licensed certain rights to hepatitis C virus ("HCV"), hepatitis G virus ("HGV"), a novel hepatitis virus discovered by Genelabs, human T-cell leukemia virus-I ("HTLV-I") and human T-cell leukemia virus-II ("HTLV-II") diagnostic tests. Under the agreement, Chiron acquired certain rights to develop and market diagnostic products for the detection of HGV, HTLV-I and HTLV-II. In return, Genelabs acquired development and marketing rights in Asia, except Japan, for certain products incorporating Chiron's HCV technology. Chiron has agreed to pay \$5.0 million in up front license fees and up to \$9.0 million in HGV development milestones. Chiron also agreed to invest a total of \$10 million in equity securities of Genelabs at the closing. Of an initial payment of \$5.0 million, approximately \$4.2 million was expensed in the first quarter of 1995, while the remainder was recorded as an investment in securities of Genelabs. Also, under the terms of the agreement, Chiron has the option to acquire substantially all of the diagnostics business of Genelabs in the year 2000 at the then fair market value through the conversion of the \$10 million equity investment for approximately one-half of the business and an additional payment in an amount to be

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determined for the remaining half. Chiron's agreement to provide the HCV license is subject to the approval of Ortho, Chiron's joint diagnostic

business partner. Chiron intends to offer Ortho participation in the collaboration with Genelabs as an equal partner, whereby Ortho would share equally in all payments under the agreement.

## NEW YORK UNIVERSITY

In March 1995, the Company reached an agreement with New York University ("NYU"), for the license of optical mapping technology for use by Chiron and its sublicensee, Ciba, in development of diagnostics, therapeutics and vaccines, and Chiron also acquired the right to commercialize a potential optical mapping instrument. Under the terms of the agreement, Chiron made a \$5.0 million initial payment to NYU, which was expensed in the first quarter of 1995, for the license and for funding certain research facilities at NYU. If Chiron decides to continue development of the instrument, Chiron will be obligated to make a \$4.0 million milestone payment to NYU and will make royalty payments to NYU based upon any future product sales of the instrument, subject to certain minimum royalties. In addition, Ciba has agreed to make certain further research payments to NYU in connection with development of the instrument in exchange for the sublicense and in exchange for royalty payments by Chiron to Ciba based upon sales of the instrument.

## 5. DEBT OBLIGATIONS

## ACQUIRED DEBT OF CCD

As part of the Acquisitions, the Company assumed approximately \$96 million in debt of CCD. This debt consists primarily of short-term borrowings under revolving foreign line of credit arrangements totaling \$41 million at March 31, 1995, and a note payable to Ciba in the amount of \$56 million which is due in the year 2000. The foreign line of credit arrangements bear interest at local interest rates ranging from 3 percent to 17 percent. The note payable to Ciba bears interest at a variable rate (6.45 percent at March 31, 1995).

## LINE OF CREDIT ARRANGEMENT

On March 24, 1995, the Company entered into a revolving, unsecured line of credit arrangement with an international bank under which the Company may borrow up to \$50 million. This credit facility is guaranteed by Ciba and bears interest at a rate based on LIBOR (6.33 percent on the \$40 million outstanding at March 31, 1995).

## 6. CONTINGENCIES

See Item 1, Legal Proceedings, on page 24 of this Form 10-Q for a discussion of certain lawsuits filed against the Company.

## 7. SUBSEQUENT EVENT - PROPOSED ACQUISITION OF VIAGENE, INC.

On April 23, 1995, the Company entered into an agreement to acquire by merger Viagene, Inc. ("Viagene") by making a payment of 0.155 share of Chiron Common Stock or a cash payment of \$9 for each Viagene common share equivalent for a total consideration of approximately \$95 million (based on the closing price of Chiron Common Stock on April 23, 1995 and the assumption that all Viagene options and warrants not held by Chiron are exercised prior to the transaction). The agreement stipulates that 40 percent of the aggregate consideration will be in cash and the

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remaining 60 percent will be in Chiron Common Stock. The Company anticipates that the aggregate consideration will not exceed approximately \$38 million in cash and will result in the issuance of approximately 1 million shares of Chiron Common Stock. The Company has an ongoing

collaboration with Viagene in the area of gene therapy and, due to an earlier investment as part of the collaboration arrangement, currently holds approximately 17 percent of the outstanding voting stock of Viagene (which had a carrying value of approximately \$14 million on Chiron's books at March 31, 1995). The proposed merger is subject to regulatory approval and approval by Viagene stockholders and is expected to close in the third quarter of 1995. If the proposed merger is completed, the Company will account for the merger using the purchase method, and accordingly will record an expense for the amount of the purchase price allocated to inprocess technology.

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

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#### GENERAL

Chiron Corporation (the "Company" or "Chiron"), a human healthcare company, applies biotechnology and other techniques of modern biology and chemistry to develop, produce and sell products intended to improve the quality of life by diagnosing, preventing and treating human disease. Chiron participates in the global healthcare industry in four markets: diagnostics, including immunodiagnostics, critical care diagnostics and quantitative probe diagnostics; therapeutics, including Betaseron-Registered Trademark- (interferon beta 1-b) for multiple sclerosis and Proleukin-Registered Trademark- (Aldesleukin) for metastatic kidney cancer; vaccines, including a recombinant acellular pertussis vaccine and other pediatric vaccines, and vaccines under development for genital herpes, cytomegalovirus ("CMV"), human immunodeficiency virus ("HIV"), and hepatitis C virus ("HCV"); and ophthalmic surgical products.

Effective January 1, 1995, Chiron entered into a series of agreements with Ciba-Geigy Limited of Basel, Switzerland ("Ciba"), including an investment agreement, a cooperation and collaboration agreement and a governance agreement (collectively the "agreements"). Ciba now holds approximately a 49.5 percent ownership interest in Chiron common stock, partially through a tender offer for approximately 38 percent of Chiron's outstanding common stock for \$117 per share. At the same time, Chiron acquired all of the outstanding common stock of Ciba Corning Diagnostics Corp. ("CCD") and Ciba's interests in The Biocine Company and JV Vax B.V. (a Netherlands company which owns Biocine SpA) in exchange for 6.6 million newly-issued Chiron common shares and a cash payment of \$24 million. These two acquisitions of Chiron common stock by Ciba, together with Ciba's prior holdings of approximately 1.4 million shares, result in the aforementioned 49.5 percent ownership of the Company's common stock.

Under the terms of the agreements, Ciba is entitled to name three new members to Chiron's Board of Directors and has limited rights to review and approve certain Chiron transactions. In connection with these agreements, Ciba has agreed to guarantee \$425 million of new debt for Chiron and has agreed to provide at least \$250 million (and up to \$300 million subject to certain reductions in the debt guarantee) over five years in support of research at Chiron, and Chiron has the option of issuing up to \$500 million of new equity to Ciba. In the event Chiron utilizes Ciba's research funding, Chiron will be obligated to offer to Ciba the opportunity to share in the market opportunities of any resulting products. Alternatively, Chiron is entitled to reacquire all rights to any resulting products by repaying to Ciba, in cash or common stock, an amount equal to the funding plus an agreed upon return.

The acquisitions of CCD and Ciba's interests' in The Biocine Company and JV Vax B.V. ("the Acquisitions") were accounted for by the purchase method in the first quarter of 1995. The purchase price of approximately \$433 million was allocated to the acquired assets and assumed liabilities based upon their estimated fair value on the acquisition date. As required under generally accepted accounting principles, Chiron recognized as an expense the amount allocated to in-process

January 1, 1995, forward. Chiron's share of the operating results of Biocine SpA and The Biocine Company were included in the Company's 1994 operating results under the equity method of accounting.

Effective March 31, 1995, Chiron Vision acquired the surgical division of IOLAB from Johnson & Johnson for approximately \$96 million. The acquisition was accounted for by the purchase method, and resulted in a \$10 million charge to earnings in the first quarter of 1995 to expense purchased in-process technology. Chiron Vision plans to consolidate its intraocular lens manufacturing in Lyon, France and at IOLAB's plant in Claremont, California. The Company recorded additional charges for restructuring and integration-related expenses totaling \$17 million. IOLAB's results of operations are included in Chiron's consolidated operating results from March 31, 1995, forward.

On April 23, 1995, the Company entered into an agreement to acquire by merger Viagene, Inc. ("Viagene") by making a payment of 0.155 share of Chiron common stock or a cash payment of \$9 for each Viagene common share equivalent for a total consideration of approximately \$95 million. The agreement stipulates that 40 percent of the aggregate consideration will be in cash and the remaining 60 percent will be in Chiron common stock. The Company anticipates that the aggregate consideration will not exceed approximately \$38 million in cash and will result in the issuance of approximately 1 million shares of Chiron Common Stock. The Company has an ongoing collaboration with Viagene in the area of gene therapy and, due to an earlier investment as part of the collaboration arrangement, currently holds approximately 17 percent of the outstanding voting stock of Viagene (which had a carrying value of approximately \$14 million on Chiron's books at March 31, 1995). The proposed merger is subject to regulatory approval and approval by Viagene stockholders and is expected to close in the third quarter of 1995. If the proposed merger is completed, the Company will account for the merger using the purchase method, and accordingly will record an expense for the amount of the purchase price allocated to in-process technology.

## RESULTS OF OPERATIONS

## REVENUES

## PRODUCT SALES

The Company's revenues are derived from a variety of sources, including product sales, collaborative agreements, product royalty agreements and joint business arrangements. Product sales, Chiron's largest revenue category, consists of the following product lines in the human healthcare industry for each of the three-month periods ended March 31:

	1	995	1994
		(IN	MILLIONS)
Diagnostic products	\$	127	\$ 4
Ophthalmic products		24	22
Betaseron-Registered Trademark- sales		2	11
Oncology products		13	8
Vaccine products		16	
Other products		2	

As a result of the January 1995 acquisition of CCD, diagnostic product sales now represent the largest component of product sales. CCD had sales of \$120 million for the three months ended March 31, 1995. CCD's product sales for the first quarter of 1994, which are not included in Chiron's 1994 results, were approximately \$101 million. CCD product sales include direct sales and salestype leases of CCD's fully-automated random-access immunodiagnostic testing systems and reagents for these systems, as well as sales of critical blood analyte systems, clinical chemistry products and manual immunodiagnostic systems. CCD's sales increased from the prior year primarily due to increased sales of the immunodiagnostic and critical blood analyte product lines and due to favorable foreign currency exchange rates. Sales of diagnostic systems often include the sale of service and maintenance contracts. Revenue from these service contracts is included in product sales revenue and is recognized ratably over the life of the contracts.

Diagnostic product sales also include sales of nucleic acid probe products and instrumentation and sales of antigens and RIBA-Registered Trademark- HCV tests. Nucleic acid probe products are sold at cost to Daiichi Pure Chemical Co., Ltd. ("Daiichi"), which markets the product in Japan and pays Chiron a royalty based upon its sales of the product. Nucleic acid probe products are also sold by Chiron on a research-use only basis in the United States and Europe. Antigens and RIBA-Registered Trademark- HCV test kits are sold at cost to Ortho Diagnostic Systems, Inc. ("Ortho"), Chiron's partner in a joint diagnostic business.

Sales of ophthalmic surgical products increased between years largely due to the impact of the May 1994 acquisition of Laboratoires Domilens S.A. ("Domilens") and due to favorable foreign currency rate fluctuations. For the quarter ended March 31, 1995, sales of intraocular lenses by Domilens contributed \$6 million in incremental revenues. Offsetting these increases were lower sales of refractive surgery products, particularly of ophthalmic surgical knives used in radialkeratotomy procedures. Sales of surgical knives have decreased as refractive surgery procedures are increasingly shifting towards newer technologies, including the use of corneal shapers and excimer lasers in place of surgical knives.

During 1994, Chiron operated under an amended Betaseron-Registered Trademarksupply agreement whereby Chiron recognized substantially all of its Betaseron - -Registered Trademark- revenue at the time of shipment to its marketing partner, Berlex Laboratories, Inc. ("Berlex"). Chiron was required to revert to the terms of the original Betaseron-Registered Trademark- supply agreement by sometime in 1995 or no later than June of 1996. Chiron exercised its option to revert to the terms of the original Betaseron-Registered Trademark- supply agreement effective January 1, 1995. Under those original terms, Chiron will earn a partial payment for Betaseron-Registered Trademark- upon shipment to Berlex and a subsequent final payment based upon Berlex's net sales of the product. Further, because adequate inventory levels had been built by Berlex, Chiron's Betaseron-Registered Trademark- revenue dropped between years as no commercial-use vials were shipped during the first quarter of 1995. Total 1995 shipments of Betaseron-Registered Trademark- to Berlex are expected to be roughly comparable to, or slightly above or below 1994 levels. Assuming comparable 1994 and 1995 annual vial shipments to Berlex, total 1995 revenues from Betaseron-Registered Trademark- shipments will be lower than 1994 revenues by approximately \$25 million to \$30 million as a result of the reversion to the original supply agreement.

Sales of oncology products, principally Proleukin-Registered Trademark-, increased by approximately \$5 million between 1994 and 1995 as the number of

vials sold increased in both the European and domestic markets. Average selling prices were comparable between periods.

Vaccine product sales totaling approximately \$16 million consist of sales of pediatric and adult vaccines primarily in Italy and to public health organizations by the Company's Biocine SpA subsidiary. Biocine

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SpA's product sales for the first quarter of 1994, which are not included in Chiron's 1994 results, were approximately \$11 million. Biocine SpA's vaccine products include Acelluvax-Registered Trademark-, a recombinant acellular pertussis vaccine, Agrippal-Registered Trademark-, a flu vaccine, and Polioral-Registered Trademark-, an oral polio vaccine. Sales of certain of Biocine SpA's vaccines are seasonal, particularly the flu vaccine, with strong sales generally occurring during the pre-flu season in the fourth quarter of the year.

The Company markets many of its commercial products internationally. As a result, product revenues are affected by fluctuating foreign currency exchange rates. Foreign product sales were approximately \$118 million and \$12 million for the three months ended March 31, 1995 and 1994, respectively, with international sales of diagnostic products by CCD and vaccine sales by Biocine SpA accounting for substantially all of the increase in foreign product sales. Product sales would have been approximately 4 percent lower in 1995 if currency exchange rates had remained the same as in 1994. The Company's other revenues, discussed below, are largely denominated in U.S. dollars.

## EQUITY IN EARNINGS OF JOINT BUSINESSES

As of March 31, 1995, Chiron had a 50 percent equity interest in three joint businesses: a joint diagnostic business with Ortho, a generic cancer chemotherapeutics business with Ben Venue Laboratories, Inc., and a German ophthalmic excimer laser business. Chiron's one-half interest in the pretax operating earnings of its joint diagnostic business with Ortho represents the largest component of joint business revenues. Approximately 80 percent of the sales of the Chiron-Ortho joint business arise from sales of HCV blood screening tests. The joint business also receives a royalty from Abbott Laboratories ("Abbott") for Abbott's sales of HCV tests which use the Chiron technology and which compete directly with tests marketed by Ortho. Chiron's share of the profits of the joint business increased by approximately \$3 million from the prior year as lower margins on domestic sales of diagnostic kits by the joint business were more than offset by increased profits from sales by Ortho's foreign affiliates and lower research and development spending by the joint business.

## COLLABORATIVE AGREEMENT REVENUES

Collaborative agreement revenues consist of fees received for research services as they are performed, fees received for completed research or technology, fees received upon attainment of benchmarks specified in the related research agreements, and proceeds of sales of biological materials to research partners for clinical and preclinical testing. Collaborative agreement revenues decreased from the prior year period due to the January 1995 acquisition of Ciba's interest in The Biocine Company, Chiron's joint vaccine venture with Ciba. Prior to the acquisition, Chiron received reimbursement for its vaccine research expenses from The Biocine Company and recorded such reimbursement as collaborative agreement revenue. After the acquisition, The Biocine Company became a wholly owned subsidiary of Chiron and thus no longer provides research revenues to Chiron. In the first quarter of 1994, Chiron recognized revenues of \$11 million from The Biocine Company. Further contributing to the decrease in collaborative agreement revenues was the completion of a nucleic acid probe development program with Daiichi, which had provided first quarter 1994 revenues of \$3 million.

As part of the agreements with Ciba, Ciba has agreed to provide research funding to Chiron of \$250 million over the next five years. Annual funding amounts are subject to certain limitations and the specific programs to be funded are subject to Ciba's approval. In the event Chiron utilizes this research funding arrangement, Chiron will be obligated to offer to Ciba the opportunity to share in the market opportunities of any resulting products.

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In addition, Chiron is entitled to re-acquire all rights to any resulting products by repaying to Ciba, in cash or common stock, an amount equal to Ciba's funding plus interest. During the first quarter of 1995, no research funding was earned from Ciba under this arrangement.

## OTHER REVENUES

Other revenues consist principally of product royalties, government grants and sales fees earned by the Company for sales and marketing services rendered on behalf of its generic chemotherapeutics joint venture and on behalf of Ciba. Sales fees received from Ciba for sales of Aredia-Registered Trademark-, for which Chiron began earning sales fee revenue in late 1994, accounted for the increase in other revenues for the first quarter of 1995 as compared with the first quarter of 1994. Royalty revenue, the largest component of other revenues, was comparable between periods.

#### COST AND EXPENSES

#### RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses increased significantly between 1994 and 1995 due to the acquisitions of CCD and Biocine SpA, which on a combined basis added \$21 million in incremental research and development expenses. In addition, the Company entered into new collaboration agreements and funded development expenses in a number of its existing collaborative arrangements with other pharmaceutical and biotechnology companies for the research, development and marketing of certain technologies and products. As part of these collaborative arrangements, Chiron has made various investments in the equity securities of the collaborative partners and, in some cases, agreed to provide specified levels of funding to the collaboration. During the first quarter of 1995, new collaborative arrangements include the following:

In March 1995, the Company reached an agreement with Genelabs Technologies, Inc. ("Genelabs"), whereby Chiron and Genelabs cross-licensed certain rights to hepatitis C virus ("HCV"), hepatitis G virus ("HGV"), a novel hepatitis virus discovered by Genelabs, human T-cell leukemia virus-I ("HTLV-I") and human T-cell leukemia virus-II ("HTLV-II") diagnostic tests. Under the agreement, Chiron acquired certain rights to develop and market diagnostic products for the detection of HGV, HTLV-I and HTLV-II. In return, Genelabs acquired development and marketing rights in Asia, except Japan, for certain products incorporating Chiron's HCV technology. Chiron has agreed to pay \$5 million in up front license fees and up to \$9 million in HGV development milestones. Chiron also agreed to invest a total of \$10 million in equity securities of Genelabs at the closing. Of an initial payment of \$5 million, approximately \$4 million was expensed in the first quarter of 1995, while the remainder was recorded as an investment in securities of Genelabs. Also, under the terms of the agreement, Chiron has the option to acquire substantially all of the diagnostics business of Genelabs in the year 2000 at the then fair market value through the conversion of the \$10 million equity investment for approximately one-half of the business and an additional payment in an amount to be determined for the remaining half. Chiron's agreement to provide the HCV license is subject to the approval of Ortho, Chiron's joint diagnostic business partner. Chiron intends to offer Ortho participation in the collaboration with Genelabs as an equal partner, whereby Ortho would share equally in all payments under the agreement.

-- An agreement with Progenitor, Inc. ("Progenitor"), a subsidiary of Interneuron Pharmaceuticals, Inc., to collaborate in the development and commercialization of therapeutic and vaccine products incorporating Progenitor's proprietary gene therapy technology. Under the agreement, Chiron received a license to Progenitor's nonviral gene expression system for use in the development of products for the

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treatment of certain cancers, cardiovascular disorders, development of infectious disease vaccines and for development of certain other gene therapy products. Chiron will have the right to manufacture and market any resulting products of the collaboration. In return for the license and other rights, Chiron made an initial payment of \$2.5 million to Progenitor, agreed to make an additional funding payment of \$0.5 million, agreed to make additional license payments totaling \$1 million to retain certain rights to development of infectious disease vaccines and agreed to make additional product development milestone payments which could total approximately \$3 million for each of the resulting products plus certain other milestone payments which are treated as prepaid royalties. In addition, Progenitor will receive a royalty from any commercial sales of products resulting from the collaboration.

An agreement with New York University ("NYU") under which Chiron acquired rights to optical mapping technology for use by Chiron and its sublicensee, Ciba, in development of diagnostics, therapeutics and vaccines, and Chiron also acquired the right to commercialize a potential optical mapping instrument. Chiron made a \$5 million payment to NYU for the license and for funding of certain research facilities at NYU. If Chiron decides to continue development of the instrument, Chiron will be obligated to make a \$4 million milestone payment to NYU and will make royalty payments based on a percentage of sales of the instrument, subject to certain minimum amounts. In addition, Ciba has agreed to make certain further research payments to NYU in connection with development of the instrument in exchange for the sublicense and in exchange for royalty payments by Chiron to Ciba based upon sales of the instrument.

Incremental research and development expense recognized as a result of the Company's funding of its collaborations, including the new agreements with Genelabs, Progenitor and NYU, during the first quarter of 1995 totaled \$31 million. In addition to these new agreements, the Company exercised an option to fulfill its funding requirement through 1996 in a collaboration with G.D. Searle & Co. ("Searle") by making a \$9 million payment to Searle in return for a lower overall funding amount and the exclusive option to negotiate for the manufacturing rights to certain of Searle's products. Chiron also made a \$4 million payment to DepoTech, Inc. ("DepoTech") related to the attainment of a development milestone in a therapeutic collaboration and made a \$1.5 million payment to CytoMed, Inc. ("CytoMed") for funding of a collaboration utilizing complement inhibitors for use in therapeutic and diagnostic applications and for the purchase of additional equity securities of CytoMed. In addition, beginning in the first quarter of 1995, the Company began funding 100 percent of the expenses of its neurological disease collaboration with Cephalon, Inc. ("Cephalon"), resulting in a \$6 million expense for the first quarter collaborative expenses.

With respect to Chiron's in-house research and development programs, Chiron continued to devote substantial resources to its vaccine programs, growth factor and nucleic acid therapeutics programs and internal biological therapeutics programs. In particular, spending in the vaccines program increased by approximately \$4 million (excluding the impact of the acquisition of Biocine SpA) over the prior year due to clinical trial and manufacturing expenses for herpes simplex type 2 vaccines and other vaccines currently in development. The Company also recognized \$1.5 million in expense during the first quarter from

the purchase of an option from Johnson & Johnson to participate in a home-access HIV testing business. During the remainder of 1995, the Company expects that research and development expense will remain significantly higher than prior years due to the impact of the acquisitions and to continued expenses in all of its collaborations. Product development, manufacturing start-up, and regulatory expenses may also increase in future periods as Chiron's products in development advance towards commercialization.

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#### COST OF SALES

Cost of sales increased consistent with the increase in product sales between years. Gross profit margins decreased slightly from the prior year to 51 percent from 52 percent. Margins on existing product sales decreased from the prior year due to increased obsolescence reserves on ophthalmic products and operating expenses associated with the idled Puerto Rico facility. Partially offsetting these decreases in gross profit margins was the addition of CCD's and Biocine SpA's product sales which have higher margins than those of the Company's existing products. Gross profit margins will be adversely impacted during the remainder of 1995 due to the impact of the reversion to the original terms of the Betaseron-Registered Trademark- supply agreement which will result in lower revenues over the next two to three quarters. Further, gross profit margin percentages may fluctuate significantly in future periods as the Company's product mix continues to evolve, as the increased costs of new manufacturing facilities are included in cost of goods sold and as the restructurings of the Company's ophthalmic, diagnostics, and vaccine businesses are completed.

## SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses ("SG&A expenses") increased between 1994 and 1995, largely due to the impact of the acquisitions of CCD and Biocine SpA, which together added \$46 million in SG&A expenses. SG&A expenses were higher in the ophthalmic business due to the acquisition of Domilens and increased costs related to the ophthalmic sales force arising from the anticipated integration of Chiron Vision's operations with IOLAB. SG&A expenses also increased due to increased selling costs for the Company's therapeutic product lines and due to increased professional fees arising from ongoing patent litigation.

## OTHER EXPENSES

The write-off of purchased in-process technology includes \$220 million for the acquisitions of CCD, Biocine SpA and The Biocine Company and \$10 million for the acquisition of IOLAB. The fair value of the net assets acquired in these acquisitions, including in-process technology, was estimated based on valuations of the acquired net assets.

Other costs related to the Ciba transaction consist primarily of employee payments and related tax liabilities and legal and investment advisor fees. Under the agreements reached with Ciba, Ciba has agreed to reimburse the Company \$25 million for a portion of the employee payments and such reimbursement has been recorded as a capital contribution.

Restructuring and reorganization costs represent certain accrued costs of integrating the acquired businesses with Chiron's existing businesses, costs related to the idling of the company's Puerto Rico manufacturing facility and the scaling-back of manufacturing operations at the Company's Amsterdam facility, and costs related to the write-down of duplicate facilities at the Company's Emeryville, California headquarters. Also included is a charge related to the postponement of plans to expand the Company's Emeryville research and administrative facilities. Of the \$38 million in total charges,

approximately \$23 million related to write-downs of assets. The remaining charges of \$15 million consist of employee costs of \$7 million and other accrued costs of \$8 million primarily for lease termination costs and additional tax obligations. The majority of the accrued costs are expected to be paid over the next two years.

Other income (expense) consists primarily of investment income on the Company's cash and investment balances and interest expense accrued on debt and capital leases. Other income (expense) decreased

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between 1994 and 1995, due to increased interest expense resulting from the acquired debt of CCD and Biocine SpA and due to lower yields on the Company's investment portfolio.

The provision for income taxes in 1995 consists primarily of foreign taxes on certain foreign operations of the Company. Substantially all of the write-off of purchased in-process technologies is not deductible for income tax purposes and thus does not create a tax benefit in 1995. The provision for income taxes in 1994 was based on the estimated annual effective income tax rate. The income tax provision increased between periods primarily due to the acquisition of foreign operations which were not included in 1994 results.

#### OUTLOOK

Chiron may incur a loss in the second quarter of 1995 and expects to incur a loss in the third quarter of 1995 due to the continuing impact of integrating CCD, Biocine SpA, The Biocine Company and IOLAB, as well as significant charges associated with the planned acquisition of Viagene. Profitability of the Company beyond the third quarter of 1995 depends upon a number of factors. These factors include: successful integration of the newly acquired businesses with Chiron; substantial profit contribution from CCD and the newly integrated ophthalmic business; continuation of substantial profit contribution from the Chiron-Ortho joint business; continued product sales of Betaseron-Registered Trademark- in the United States and Proleukin-Registered Trademark- worldwide; the successful completion of clinical trials and subsequent FDA approval for commercialization of additional vaccines, diagnostics and pharmaceuticals under development; and expense reduction in several of the Company's businesses. There can be no assurance whether any combination of these factors can be achieved, or that any such combination will result in profitability of the Company. The integration of CCD, The Biocine Company, Biocine SpA and IOLAB will have a material impact on the results of operations of the Company going forward. Although the Company has recorded the majority of the expected cost of these integrations in the first quarter of 1995, the Company expects to incur additional charges in subsequent quarters as these integrations are completed. Profitability of the Company is also dependent on utilization of research funding available from Ciba. As part of the agreements with Ciba, Ciba agreed to provide the Company with funding totaling \$250 million over the next five years in support of the Company's research programs.

Achievement and maintenance of profitability are substantially dependent upon the success of Chiron's collaborations with others. Under the joint business agreement with Ortho, Chiron and Ortho together determine strategy and budgets for their joint diagnostics business, but Ortho conducts all commercial activities, except research and antigen manufacturing, and exercises broad control over the conduct of day-to-day operations. The Company is also dependent upon Schering AG, Germany, and its U.S. affiliate, Berlex, for development, marketing and distribution of Betaseron-Registered Trademark-. There can be no assurance that the corporate interests of Berlex and Ortho, or any other corporate partners, are or will remain consistent with those of Chiron or that any collaborator will succeed in developing new markets or retaining and expanding the markets served by the commercial collaborations.

In addition, Chiron's 50 percent share of the operating earnings of the Chiron-Ortho joint business has been a significant source of Chiron's revenues. The market for immunodiagnostic viral screening tests has evolved rapidly since the introduction of HCV tests by the Chiron-Ortho joint business and by Abbott. The joint business may be adversely affected in future periods by increasing margin pressures, the overall demand for current tests and new diagnostic products, and by the introduction of competing tests by unlicensed third parties.

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Furthermore, other Chiron programs will require substantial additional investment including the cost of funding collaborative research arrangements with third parties, the cost of clinical trials, the completion of commercial scale manufacturing facilities, and marketing and sales expenses associated with product introductions. Also, the planned merger with Viagene will result in a charge for the expensing of purchased in-process technology and will also result in increased research and development expenses in future periods. Chiron has significantly expanded its manufacturing capability to support both approved products and products in development which has resulted in higher levels of operating expenses and depreciation, and may result in even higher levels of operating expenses in future periods. The research, development and market introduction of new products will require the application of considerable technical and financial resources by Chiron, while revenues generated from such products, assuming they are successfully developed, may not be realized for several years. Other material and unpredictable factors which could affect operating results include the uncertainty, timing and costs associated with product approvals and commercialization; the issuance and use of patents and proprietary technology by Chiron or its competitors; the effect of technology and other business acquisitions or transactions; the increasing emphasis on controlling healthcare costs and potential legislation or regulation of healthcare pricing; and actions by collaborators, customers and competitors.

Chiron exercised its option to revert to the terms of the original Betaseron - Registered Trademark- supply agreement effective January 1, 1995. Under those original terms, Chiron will earn a partial payment for Betaseron - Registered Trademark- upon shipment to Berlex and a subsequent final payment based upon Berlex's net sales of the product. Total 1995 shipments of Betaseron - Registered Trademark- are expected to be roughly comparable to, or slightly above or below 1994 levels. Assuming comparable 1994 and 1995 annual vial shipments to Berlex, total 1995 revenues from Betaseron-Registered Trademark-shipments will be lower than 1994 revenues by approximately \$25 million to \$30 million as a result of the reversion to the original supply agreement.

In March 1995, the Company decided to idle its Puerto Rico facility and scale-back the manufacturing operations at the Company's Amsterdam facility. This decision was based on the belief that current demand for Betaseron -Registered Trademark- can be adequately supplied with the expanded manufacturing capacity at the Company's Emeryville, California facility. Utilization of this idled manufacturing capacity will require a significant increase in Betaseron - -Registered Trademark- demand and/or the introduction of new products which would require significant manufacturing capacity.

The market price of the Company's common stock is subject to significant volatility, particularly on a quarterly basis. Any shortfall in revenue or earnings from levels expected by securities analysts could have an immediate and significant adverse effect on the trading price of the Company's stock in any given period. Additionally, announcements of technological innovations by the Company or its competitors, developments concerning proprietary rights, public concern as to the safety of biotechnology and economic or other external factors may have a significant impact on the market price of the Company's common stock. The Company does not currently believe that inflation has a significant impact upon its business.

Chiron has financed product development, operations and capital expenditures primarily from public and private sales of equity and convertible debt, product sales, collaborative research revenues and from the earnings of the Chiron-Ortho joint business. In addition to these sources of capital, future cash requirements, including possible operating deficits, will be financed through a combination of debt, mortgage, leases, possible off-balance-sheet financing (such as R&D limited partnerships), and the use of existing cash and investment balances. In addition, Ciba has agreed to guarantee \$425 million of new debt

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for Chiron, and has agreed to provide \$250 million (and up to \$300 million subject to certain reductions in the debt guarantee) over five years in support of research programs at Chiron. Chiron also has the option of issuing up to \$500 million of new equity to Ciba. Until required for operations, Chiron's policy is to keep its cash and investments in a diversified portfolio of investment grade financial instruments, including money market instruments, corporate notes and bonds, government or government agency securities, or other debt securities. By policy, the amount of credit exposure to any one institution is limited. These investments are generally not collateralized and primarily mature within three years. Investments with original maturities in excess of one year are presented on the balance sheet as noncurrent investments.

Chiron's liquidity may be impacted in future periods by its decision to fund its share of expenses in certain of its joint ventures and collaboration arrangements. Over the next several years, Chiron anticipates funding collaborations with a number of its research partners, and may make additional equity investments in collaborative partners. During the first quarter of 1995 the Company funded \$34 million under third party collaborations for both additional equity investments and development expenses. Also, Chiron has agreed to provide one of its collaborative partners, Cephalon Inc., with an \$18 million credit facility through 1999 and has made advances to Cephalon Inc. totaling \$14 million through March 31, 1995.

During the quarter ended March 31, 1995, cash and cash equivalents increased by approximately \$6 million. Of this amount, approximately \$4 million was used in the Company's operating activities, compared to \$21 million used in operating activities in the first quarter of 1994.

Investing activities consumed cash of \$58 million in 1995, versus \$94 million in 1994. The first quarter of 1995 included the acquisition of IOLAB for \$96 million in cash. The first quarter of 1994 included net purchases of marketable debt securities of \$45 million, compared to net sales of marketable debt securities of \$67 million in the first quarter of 1995. Capital expenditures on plant and equipment were \$29 million during 1995 versus \$25 million in 1994. The Company also made investments in the equity securities of collaborative partners totaling \$3 million in the first quarter of 1995 and \$19 million in the first quarter of 1994.

Cash provided by financing activities in the first three months of 1995 of \$68 million includes a \$25 million capital contribution by Ciba to fund certain payments to employees which resulted from the agreements with Ciba and \$3 million from the issuance of common stock under the Company's employee benefit plans. Also, in March 1995, the Company borrowed \$40 million under a line of credit arrangement, representing the first utilization of the debt guarantee provided by Ciba. In addition, as part of the acquisitions, Chiron assumed approximately \$96 million in debt of CCD. This debt consists primarily of short-term borrowings under foreign line of credit arrangements and a long-term loan with Ciba.

The proposed acquisition of Viagene will require approximately \$38\$ million in cash and result in the issuance of approximately 1 million new shares of Chiron

More than 60 percent of the Company's product sales in the first quarter of 1995 were made in foreign countries primarily Western European countries and Japan. Foreign product sales are typically denominated in the currency of the country in which the sale occurs. To the extent that foreign activities give rise to receivable and payable balances that are denominated in foreign currencies, the Company's policy is to mitigate its exposure to fluctuating foreign currency exchange rates by hedging this exposure by entering into forward foreign currency contracts which are settled quarterly. The gains and losses on these hedging contracts are recorded in "Other income (expense)" in the consolidated statement of operations

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and serve to offset the loss and gain on the underlying exposures. At March 31, 1995, the Company had outstanding forward foreign currency contracts totaling approximately \$37 million.

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## ITEM 1. LEGAL PROCEEDINGS

MUREX DIAGNOSTICS, LTD. In a series of actions, the first of which was brought on March 2, 1992, Chiron together with Ortho Diagnostic Systems, Inc. ("Ortho") and Ortho Diagnostic Systems, Ltd., filed suit in the High Court for England and Wales against Murex Diagnostics, Ltd. ("Murex"), alleging infringement of Chiron's U.K. Patent No. 2,212,511 ("the '511 patent") as a result of Murex's manufacture and sale of HCV immunoassay kits in the U.K. Murex is a subsidiary of International Murex Technologies Corp., a Canadian company. Chiron and Ortho sought injunctive relief and unspecified damages. On May 27, 1994, the court granted judgment for Chiron and Ortho, holding the '511 patent valid and infringed, and ordered Murex to pay damages in an amount to be determined. Chiron's and Ortho's request for an injunction was granted on November 30, 1994. Murex has appealed. Chiron is informed that officials within the British Ministry of Health have in the past raised the possibility of authorizing Murex's infringement of the `511 patent under the "Crown use" provisions of British law, with respect to the sale of HCV immunoassay kits to the British National Health Service. Further, Murex has stated that it will apply for a compulsory license under the '511 patent. Infringement proceedings against Murex on German and European patents corresponding to the '511 patent have also been filed by Chiron and Ortho in Germany, Italy, The Netherlands and Belgium. On January 23, 1995, Chiron and Ortho were granted an injunction in Germany. On May 8, 1995, Chiron was granted a cross-border preliminary injunction by the Dutch court preventing infringement by Murex and certain of its affiliates covering The Netherlands, Belgium, France, Spain and Luxembourg. Murex has brought an action in Australia seeking the revocation of the Australian counterpart of the '511 patent. Chiron has counterclaimed for infringement.

DANIEL W. BRADLEY. On December 20, 1994, Dr. Daniel W. Bradley, a former scientist at the U.S. Centers for Disease Control (the "CDC") brought suit in the United States District Court for the Northern District of California against Chiron, Ortho, certain employees of Chiron, and the United States government. Bradley, who collaborated with Chiron scientists on the research that led to the discovery of HCV, alleges he has been wrongly excluded as an inventor of HCV. He requests various forms of relief, including declarations that he is an inventor of Chiron's patents related to HCV and that these patents are unenforceable. Bradley further seeks monetary damages and a constructive trust on all past and future profits derived from Chiron's HCV invention, which are estimated by Bradley to be in excess of \$1 billion, as well as penalties under

federal and state Racketeering and Corrupt Organization (RICO) statutes. Chiron believes that this suit is without merit and that substantial defenses exist. In 1990, Bradley and the CDC entered into a settlement agreement regarding his claims of inventorship in which any rights either might have were assigned to Chiron. Chiron believes that the settlement agreement is valid and bars nearly all of the claims in the subject litigation. Chiron and the other defendants have filed a motion to dismiss.

SICOR. In April 1991, Alco Chemicals, Ltd. ("Alco") and Sicor, SpA ("Sicor"), Cetus Ben Venue Therapeutics' ("CBVT") former suppliers of bulk doxorubicin, filed suit in the United States District Court for the Northern District of California against Cetus Corporation ("Cetus"), Ben Venue Laboratories, Inc. ("Ben Venue"), CBVT and Erbamont, Inc. ("Erbamont") and its affiliates. Sicor had been prevented from manufacturing product for CBVT since September 1990, when Sicor's facilities in Italy were ordered closed by the government in connection with trade secret litigation in Italy. In March 1991, CBVT entered into an agreement with Erbamont which provided for, among other things, the settlement of several legal proceedings then pending relating to Erbamont's alleged doxorubicin proprietary rights, and the exclusive supply of doxorubicin to CBVT by Erbamont. The Sicor complaint alleges breach of the CBVT contract to purchase bulk doxorubicin from Sicor, as well as antitrust violations and interference with contract and prospective advantage and seeks unspecified damages. Cetus has denied any entitlement to recovery in this lawsuit and has filed a counterclaim against the plaintiffs for fraud and breach of contract based on Sicor's

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failure to deliver the bulk product. In an order filed on January 11, 1993, the judge granted summary judgment motions in favor of the Cetus parties and Erbamont with respect to the Sicor and Alco claims. Sicor appealed the summary judgment and, in August 1993, dismissed its claims against Erbamont. In an opinion issued April 3, 1995, the Ninth Circuit Court of Appeals affirmed the summary judgment on the antitrust claims, but reversed and remanded to the District Court for further proceedings the claims of breach of contract and interference with prospective advantage. The Cetus parties filed a motion for rehearing by the Ninth Circuit Court of Appeals, and, on May 3, 1995, the Court directed the Sicor parties to file a response to such motion. In the event that the Ninth Circuit Court of Appeals decision is not changed on rehearing, the Company believes it has substantial defenses to the remanded claims. A related arbitration before the International Chamber of Commerce in Paris brought by Sicor against Chiron, Cetus and Ben Venue has been stayed pending the resolution of the Cetus parties counterclaims in the above described litigation.

In February 1995, Sicor and Alco filed a further action in the United States District Court for the Northern District of California against CBVT for amounts allegedly owed by CBVT to Sicor and Alco for the supply of doxorubicin, plus interest and attorneys' fees. This case has been assigned to the same judge as the above referenced District Court case. Internal investigation of the claim is under way, and there has been no further action in this suit.

AMERICAN HOME PRODUCTS. On April 27, 1995, American Home Products Corporation ("AHP") filed suit against Chiron in the Superior Court in New Castle County, Delaware, claiming compensatory, consequential and punitive damages based on an alleged breach and repudiation by Chiron of a contract pursuant to which Chiron had agreed to purchase certain assets from AHP for a purchase price of \$9.75 million. Chiron has not yet answered the complaint. However, a preliminary review of the facts of the case indicates that Chiron has significant defenses.

BRILLIANT TRADING CO., WOLFSON. Following the announcement by Chiron of the signing of a definitive agreement to acquire Viagene, two lawsuits purporting to be class actions were filed on April 24 and May 1, 1995,

respectively, in the Court of Chancery of the State of Delaware against named directors and officers of Viagene and against Viagene and Chiron. In one case, Chiron is sued on a theory that it aided and abetted alleged breaches of fiduciary duty by Viagene's directors and officers in approving the proposed acquisition by Chiron; in the other case, Chiron is sued for alleged breaches of fiduciary duty as a controlling stockholder of Viagene. The defendants seek declaratory and injunctive relief, an accounting and costs and disbursements. Chiron believes these suits are without merit.

The Company is party to certain other lawsuits, each of which is described in Item 3, Legal Proceedings on page 9 of the Company's report on Form 10-K for the period ended December 31, 1994, and as to which lawsuits there have been no material developments since such Form 10-K was filed.

- ITEM 2. CHANGES IN SECURITIES. None.
- ITEM 3. DEFAULTS UPON SENIOR SECURITIES. None.
- ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS. None.
- ITEM 5. OTHER INFORMATION. None.
- ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.

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## (a) EXHIBITS.

- 2.01 Agreement and Plan of Merger, made as of February 6, 1987, incorporated by reference to Exhibit 2.01 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 4.01 Indenture, dated as of May 21, 1987, between Cetus Corporation and Bankers Trust Company, Trustee, incorporated by reference to Exhibit 4.01 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 4.02 First Supplemental Indenture, dated as of December 12, 1991, by and among Registrant, Cetus Corporation, and Bankers Trust Company, incorporated by reference to Exhibit 4.02 of the Registrant's Form 10-K report for fiscal year 1992.
- 4.03 Indenture, dated as of November 15, 1993, between Registrant and The First National Bank of Boston, as Trustee, incorporated by reference to Exhibit 4.03 of the Registrant's Form 10-K report for fiscal year 1993.
- A.04 Rights Agreement, dated as of August 25, 1994, between the Company and Continental Stock Transfer & Trust Company, which includes the Certificate of Designations for the Series A Junior Participating Preferred Stock as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C, incorporated by reference to Exhibit 4.04 of the Registrant's current report on Form 8-K dated August 25, 1994.
- 4.05 Amendment No. 1 to Rights Agreement dated as of November 20, 1994, between Chiron Corporation and Continental Stock Transfer & Trust Company, incorporated by reference to Exhibit 4.05 of the

Registrant's current report on Form 8-K, dated November 20, 1994.

- 4.06 \$1,000,000 County of Lorain, Ohio Variable Rate Industrial Revenue Bonds dated as of July 1, 1984, due July 1, 2014. The Registrant agrees to furnish to the Commission upon request a copy of such agreement which it has elected not to file under the provisions of Regulation 601(b)(4)(iii).
- 4.07 \$1,000,000 Walpole Industrial Development Authority 6.75% Industrial Revenue Bonds dated as of July 1, 1979, due July 1, 2004. The Registrant agrees to furnish to the Commission upon request a copy of such agreement which it has elected not to file under the provisions of Regulation 601(b)(4)(iii).

- 10.01 Lease between Registrant and BGR Associates, a California limited partnership, dated May 26, 1989, incorporated by reference to Exhibit 10.01 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.02 Lease between Registrant and BGR Associates II, a California limited partnership, dated May 26, 1989, incorporated by reference to Exhibit 10.02 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.03 Agreement and Plan of Merger dated as of April 23, 1995 between Viagene, Inc., a Delaware corporation, and Chiron Corporation, incorporated by reference to Exhibit 10.67 of the Registrant's current report on Form 8-K dated April 24, 1995.
- 10.04 Stockholders' Agreement dated as of April 23, 1995 among certain stockholders of Viagene, Inc., a Delaware corporation, and Chiron Corporation, incorporated by reference to Exhibit 10.68 of the Registrant's current report on Form 8-K dated April 24, 1995.
- 10.05 Stock and Asset Purchase Agreement dated as of March 6, 1995, by and among Johnson & Johnson, a New Jersey corporation, Site Microsurgical Systems, Inc., a Pennsylvania corporation, and Chiron Corporation and Amendment No. 1 to Stock and Asset Purchase Agreement, entered into March 31, 1995 by and among Johnson & Johnson, Site Microsurgical Systems, Inc. and Chiron Corporation.
- 10.06 Revolving Credit Facility dated as of March 24, 1995, between Chiron Corporation and Swiss Bank Corporation, San Francisco Branch.
- 10.07 Lease between Acorn Development, Inc., a West Virginia corporation, and IntraOptics, Inc., a Delaware corporation, dated September 12, 1991, incorporated by reference to Exhibit 10.06 of the Registrant's Form 10-K report for fiscal year 1992.
- 10.08 Joint Venture Agreement by and between Chiron Biocine Corporation, a California corporation, and CIBA-GEIGY

Biocine Corporation, a Delaware corporation, dated April 15, 1987 (with certain confidential information deleted), incorporated by reference to Exhibit 10.23 of the Registrant's Form 8 filed with the Commission on February 14, 1992.

- Amendment to Biocine Joint Venture Agreement by and between Chiron Biocine Corporation, a California corporation, and CIBA-GEIGY Biocine Corporation, a Delaware corporation, effective as of January 1, 1992, incorporated by reference to Exhibit 10.63 to Registrant's Form 10-Q report for the period ended June 30, 1992.
- 10.10 Research and License Agreement by and between Registrant and The Biocine Company, a Delaware partnership, dated April 15, 1987 (with certain confidential information deleted), incorporated by reference to Exhibit 10.24 of the Registrant's Form 8 filed with the Commission on February 14, 1992.
- License Agreement by and between CIBA-GEIGY Biocine Corporation, a Delaware corporation, and The Biocine Company, a Delaware partnership, dated April 15, 1987 (with certain confidential information deleted), incorporated by reference to Exhibit 10.25 of the Registrant's Form 8 filed with the Commission on February 14, 1992.
- 10.12 License Agreement by and between Chiron Biocine Corporation, a California corporation, and The Biocine Company, a Delaware partnership, dated April 15, 1987 (with certain confidential information deleted), incorporated by reference to Exhibit 10.26 of the Registrant's Form 8 filed with the Commission on February 14, 1992.
- 10.13 Letter Agreement signed by CIBA-GEIGY Corporation, dated April 15, 1987, incorporated by reference to Exhibit 10.13 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.14 Agreement between the Registrant and Ortho Diagnostic Systems, Inc., a New Jersey corporation, dated August 17, 1989, and Amendment to Collaboration Agreement between Ortho Diagnostic Systems, Inc. and Registrant, dated December 22, 1989 (with certain confidential information deleted), incorporated by reference to Exhibit 10.14 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- License and Supply Agreement between Ortho Diagnostic Systems, Inc., a New Jersey corporation, the Registrant and Abbott Laboratories, an Illinois corporation, dated August 17, 1989 (with certain confidential information deleted), incorporated by reference to Exhibit 10.15 of the Registrant's Form 10-Q report for the quarter ended June 30, 1994.

- 10.16 Chiron 1991 Stock Option Plan, as amended, incorporated by reference to Annex 1 of the Registrant's Proxy Statement dated April 18, 1995.\*
- 10.17 Forms of Option Agreements, Chiron 1991 Stock Option Plan, as amended, incorporated by reference to Exhibit 10.17 of the Registrant's Form 10-K report for fiscal year 1993.\*
- 10.18 Forms of Option Agreements, Cetus Corporation Amended and Restated Common Stock Option Plan, incorporated by reference to Exhibit 10.33 of Registrant's Form 10-K report for fiscal year 1991.\*
- 10.19 Forms of Supplemental Letter concerning the assumption of Cetus Corporation options by Chiron, incorporated by reference to Exhibit 10.34 of Registrant's Form 10-K report for fiscal year 1991.\*
- 10.20 Agreement and Plan of Reorganization dated as of October 11, 1991 by and among the Registrant, Chiron Ophthalmics, Inc., COI Acquisition Corp., IntraOptics, Inc. and James R. Cook, M.D., incorporated by reference to Exhibit 28.2 of Registrant's current report on Form 8-K dated October 14, 1991.
- 10.21 Indemnification Agreement between the Registrant and Dr. William J. Rutter, dated as of February 12, 1987 (which form of agreement is used for each member of Registrant's Board of Directors), incorporated by reference to Exhibit 10.21 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.22 Stock Purchase Agreement by and between the Registrant and Johnson & Johnson Development Corporation, a corporation organized and existing under the laws of the State of New Jersey, dated as of October 3, 1986, incorporated by reference to Exhibit 10.22 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.23 Stock Purchase Agreement between the Registrant and CIBA-GEIGY, Limited, a corporation organized and existing under the laws of Switzerland, dated November 14, 1988, incorporated by reference to Exhibit 10.23 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.24 Form of Debenture Purchase Agreement between the Registrant and CIBA-GEIGY, Limited, a corporation organized and existing under the laws of Switzerland, dated June 22, 1990,

incorporated by reference to Exhibit 10.25 of the Registrant's Form 10-K report for fiscal year 1994.

10.25 Chiron Corporation 1.90% Convertible Subordinated Note due 2000, Series B, incorporated by reference to

Exhibit 10.25 of the Registrant's Form 10-K report for fiscal year 1993.

- 10.26 Investment Agreement dated as of November 20, 1994 among Ciba-Geigy Limited, Ciba-Geigy Corporation, Ciba Biotech Partnership, Inc. and Chiron Corporation, incorporated by reference to Exhibit 10.54 of the Registrant's current report on Form 8-K dated November 20, 1994.
- 10.27 Governance Agreement dated as of November 20, 1994 among Ciba-Geigy Limited, Ciba-Geigy Corporation and Chiron Corporation, incorporated by reference to Exhibit 10.55 of the Registrant's current report on Form 8-K dated November 20, 1994.
- 10.28 Subscription Agreement dated as of November 20, 1994 among Ciba-Geigy Limited, Ciba-Geigy Corporation, Ciba Biotech Partnership, Inc. and Chiron Corporation, incorporated by reference to Exhibit 10.56 of the Registrant's current report on Form 8-K dated November 20, 1994.
- 10.29 Cooperation and Collaboration Agreement dated as of November 20, 1994, between Ciba-Geigy Limited and Chiron Corporation, incorporated by reference to Exhibit 10.57 of the Registrant's current report on Form 8-K dated November 20, 1994.
- 10.30 Registration Rights Agreement dated as of November 20, 1994 between Ciba Biotech Partnership, Inc. and Chiron Corporation, incorporated by reference to Exhibit 10.58 of the Registrant's current report on Form 8-K dated November 20, 1994.
- Market Price Option Agreement dated as of November 20, 1994 among Ciba-Geigy Limited, Ciba-Geigy Corporation, Ciba Biotech Partnership, Inc. and Chiron Corporation, incorporated by reference to Exhibit 10.59 of the Registrant's current report on Form 8-K dated November 20, 1994.
- 10.32 Amendment dated as of January 3, 1995 among Ciba-Geigy Limited, Ciba-Geigy Corporation, Ciba Biotech Partnership, Inc. and Chiron Corporation, incorporated by reference to Exhibit 10.60 of the Registrant's current report on Form 8-K dated January 4, 1995.

- 10.33 Supplemental Agreement dated as of January 3, 1995 among Ciba-Geigy Limited, Ciba-Geigy Corporation, Ciba Biotech Partnership, Inc. and Chiron Corporation, incorporated by reference to Exhibit 10.61 of the Registrant's current report on Form 8-K dated January 4, 1995.
- 10.34 Amendment with Respect to Employee Stock Option Arrangements dated as of January 3, 1995 among Ciba-Geigy Limited, Ciba-Geigy Corporation, Ciba Biotech Partnership, Inc. and Chiron Corporation, incorporated by reference to Exhibit 10.62 of the Registrant's current report on Form 8-K dated January 4, 1995.\*

- 10.35 Supplemental Benefits Agreement, dated July 21, 1989, between the Registrant and Dr. William J. Rutter, incorporated by reference to Exhibit 10.27 of the Registrant's Form 10-Q report for the period ended September 30, 1994.\*
- 10.36 Lease dated as of July 1, 1983 between Cetus Corporation and H.B. Chapman, Jr., incorporated by reference to Exhibit 10.28 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.37 Amendment to Lease, made as of March 20, 1990, amending Lease dated July 1, 1983, between Harold B. Chapman, Jr. and Cetus Corporation.
- 10.38 Lease commencing March 1, 1987, between EuroCetus B.V. and the Municipal Land Company of the City of Amsterdam (Translation), incorporated by reference to Exhibit 10(k) of Cetus Corporation's Form 10-K report for its fiscal year 1987 (Commission File No. 0-10003).
- 10.39 Form of Option Agreement (with Purchase Agreements attached thereto) between Cetus Corporation and each former limited partner of Cetus Healthcare Limited Partnership, a California limited partnership, incorporated by reference to Exhibit 10.31 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.40 Form of Option Agreement (with forms of Purchase Agreements attached thereto), dated December 30, 1986, between Cetus Corporation and each former limited partner of Cetus Healthcare Limited Partnership II, a California limited partnership, incorporated by reference to Exhibit 10.32 of the Registrant's Form 10-Q report for the period ended September 30, 1994.

- 10.41 Big-O Property Purchase and Leaseback Agreement, dated as of October 31, 1988, between Cetus Corporation and Richard K. Robbins, incorporated by reference to Exhibit 10.33 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- Triple Net Lease dated as of January 20, 1989, between Cetus Corporation and BGR Associates III, a California limited partnership, and Marin County Exchange Corporation, incorporated by reference to Exhibit 10.34 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.43 License Agreement between the Registrant and the Board of Trustees of the Leland Stanford Junior University, dated December 15, 1981, incorporated by reference to Exhibit 10.07 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.44 Stock Purchase and Warrant Agreement dated May 9, 1989, between Cetus Corporation and Hoffmann-La Roche Inc., incorporated by reference to Exhibit 10.36 of the Registrant's Form 10-Q report for the period ended September 30, 1994.

- 10.45 Letter Agreement, dated as of December 12, 1991, relating to Stock Purchase and Warrant Agreement between Registrant and Hoffmann-La Roche Inc., incorporated by reference to Exhibit 10.59 of Registrant's Form 10-K report for fiscal year 1991.
- 10.46 Agreement and Plan of Merger dated as of July 21, 1991, by and among Registrant, Chiron Acquisition Subsidiary, Inc. and Cetus Corporation, incorporated by reference to Exhibit 28.2 of Registrant's Form 8-K report dated July 22, 1991.
- 10.47 Letter Agreement dated September 26, 1990 between the Registrant and William G. Green, incorporated by reference to Exhibit 10.41 of the Registrant's Form 10-K report for fiscal year 1992.\*
- 10.48 Letter Agreement dated December 18, 1991 between Registrant and Jack Schuler, incorporated by reference to Exhibit 10.42 of the Registrant's Form 10-K report for fiscal year 1992.\*
- 10.49 Lease between Sclavo S.p.A. and Biocine Sclavo S.p.A., dated January 7, 1992.

- 10.50 Agreement made as of November 11, 1993 by and between Kodak Clinical Diagnostics Limited, a company registered in England, and Ciba Corning Diagnostics Corp., a Delaware corporation, and Letter dated October 7, 1994 from Kodak Clinical Diagnostics Limited to Ciba Corning Diagnostics Corp. [Certain information has been omitted from the Agreement pursuant to a request by Registrant for confidential treatment pursuant to Rule 24b-2.]
- 10.51 Letter Agreement dated September 9, 1991 between the Registrant and Walter Moos, incorporated by reference to Exhibit 10.47 of the Registrant's Form 10-K report for fiscal year 1992.\*
- 10.52 Letter Agreement between the Registrant and Walter Moos, dated February 1, 1993, incorporated by reference to Exhibit 10.48 of the Registrant's Form 10-K report for fiscal year 1992.\*
- 10.53 Letter Agreement between Registrant and Renato Fuchs, dated May 13, 1993, incorporated by reference to Exhibit 10.47 of the Registrant's Form 10-K report for fiscal year 1993.\*
- 10.54 Agreement made as of December 6, 1984, by and between Corning Glass Works, a New York corporation, and Bioanalysis Limited, a company incorporated in England and Wales, and Letter dated July 26, 1985 from Bioanalysis Limited to Corning Glass Works. [Certain information has been omitted from the Agreement pursuant to a request by Registrant for confidential treatment pursuant to Rule 24b-2.]
- 10.55 Description of Executive Variable Compensation Program., incorporated by reference to Exhibit 10.58 of the Registrant's Form 10-K report for fiscal year

- 10.56 Chiron Corporation 1995 Executive Officer Variable Cash Compensation Plan, incorporated by reference to Annex 2 of the Registrant's Proxy Statement dated April 18, 1995.\*
- 10.57 Regulatory Filing, Development and Supply Agreement between the Registrant, Cetus Oncology Corporation, a wholly owned subsidiary of the Registrant, and Schering AG, a German company, dated as of May 10, 1993 (with certain confidential information deleted), incorporated by reference to Exhibit 10.50 of the Registrant's current report on Form 8-K dated February 9, 1994.

- 10.58 Letter Agreement dated December 30, 1993 by and between Registrant and Schering AG, a German company (with certain confidential information deleted), incorporated by reference to Exhibit 10.51 of the Registrant's Form 10-K report for fiscal year 1993.
- 10.59 Guaranty, dated as of September 29, 1994, made by Registrant, in favor of Bankers Trust Company, as trustee, incorporated by reference to Exhibit 10.52 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.60 Guaranty, dated as of September 29, 1994, made by Cetus Corporation, in favor of The First National Bank of Boston, as trustee, incorporated by reference to Exhibit 10.53 of the Registrant's Form 10-Q report for the period ended September 30, 1994.
- 10.61 Letter Agreements dated September 11, 1992, July 15, 1994 and September 14, 1994 between the Registrant and Lewis T. Williams, incorporated by reference to Exhibit 10.54 of the Registrant's Form 10-Q report for the period ended September 30, 1994.\*
- 10.62 Letter dated January 4, 1995 to C. William Zadel., incorporated by reference to Exhibit 10.65 of the Registrant's Form 10-K report for fiscal year 1994.\*
- 10.63 Letter to Dino Dina dated April 24, 1984, incorporated by reference to Exhibit 10.66 of the Registrant's Form 10-K report for fiscal year 1994.\*
- 10.64 Research Agreement, dated as of July 15, 1985, between Ciba-Geigy Limited, a Swiss corporation, and Ciba Corning Diagnostics Corp., a Delaware corporation.
- Licensing Agreement, effective December 18, 1986, by and between Miles Laboratories, Inc., a Delaware corporation, and Ciba Corning Diagnostics Corp., a Delaware corporation, and Letter dated December 18, 1992 from Ciba Corning Diagnostics Corp. to Miles Laboratories, Inc. [Certain information has been omitted from the Agreement pursuant to a request by Registrant for confidential treatment pursuant to Rule 24b-2].

the Agreement pursuant to a request by Registrant for confidential treatment pursuant to Rule 24b-2].

- Turn-back License Agreement, dated as of May 30, 1986, by and between Ciba Corning Diagnostics Corp., a Delaware corporation, and Advanced Magnetics, Inc., a Delaware corporation. [Certain information has been omitted from the Agreement pursuant to a request by Registrant for confidential treatment pursuant to Rule 24b-2].
- 10.68 Settlement Agreement, dated August 30, 1989, between Ciba Corning Diagnostics Corp. and Advanced Magnetics, Inc. [Certain information has been omitted from the Agreement pursuant to a request by Registrant for confidential treatment pursuant to Rule 24b-2].
- 10.69 Lease made and entered into December 17, 1984 between BGR Associates, a California limited partnership, and Cetus Corporation and Amendment to Lease dated December 17, 1984 entered into effective February 1, 1986.
- 10.70 Agreement, effective as of December 21, 1988, by and between Hoffmann-La Roche Inc., a New Jersey corporation, and Cetus Corporation. [Certain information has been omitted from the Agreement pursuant to a request by Registrant for confidential treatment pursuant to Rule 24b-2].
- 10.71 Agreement, effective as of December 21, 1988, by and among F. Hoffmann-La Roche Ltd., a Swiss corporation, Cetus Corporation, and EuroCetus International, B.V., a Netherlands Antilles corporation. [Certain information has been omitted from the Agreement pursuant to a request by Registrant for confidential treatment pursuant to Rule 24b-2].
- 10.72 Agreement, by and between Cetus Oncology Corporation, EuroCetus International, N.V., and F. Hoffmann-La Roche Ltd.. [Certain information has been omitted from the Agreement pursuant to a request by Registrant for confidential treatment pursuant to Rule 24b-2].
- 10.73 Agreement commencing January 1, 1991, between EuroCetus B.V. and the Municipal Development Corporation (Translation), incorporated by reference to Exhibit 10.41 of the Registrant's Form 10-K report for fiscal year 1994.
- 11 Statement of Computation of Earnings per Share.
- 27 Financial Data Schedule.

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## (b) REPORTS ON FORM 8-K.

Chiron filed a current report on Form 8-K, dated January 4, 1995, reporting under Item 2 the completion of a transaction with Ciba-Geigy Limited ("Ciba") whereby Ciba acquired through a partial tender offer an approximate 49.5 percent interest in the Company and Chiron acquired all of the outstanding common stock of Ciba Corning Diagnostics Corp. and Ciba's interests in The Biocine Company and JV Vax B.V. in exchange for 6.6 million new shares of Chiron common stock and a cash payment of \$24 million. On March 17, 1995, Chiron filed Amendment No. 1 to its current report on Form 8-K, dated January 4, 1995, to include under Item 7 the audited financial statements of Ciba Corning Diagnostics Corp., The Biocine Company and JV Vax B.V. and pro forma combined condensed financial information.

Chiron filed a current report on Form 8-K, dated March 6, 1995, reporting under Item 5 the issuance of a press release announcing the reaching of an agreement to acquire the ophthalmic surgical division of IOLAB, a Johnson & Johnson company.

Chiron filed a current report on Form 8-K, dated March 10, 1995, reporting under Item 5 the issuance of a press release by Chiron and Genelabs Technologies, Inc. announcing they have signed a heads of agreement to form a worldwide diagnostic alliance.

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CHIRON CORPORATION

March 31, 1995

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 1 to the report to be signed on its behalf by the undersigned thereunto duly authorized.

## CHIRON CORPORATION

DATE: July 27, 1995

BY: /s/Edward E. Penhoet

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Edward E. Penhoet President and Chief Executive Officer

<sup>\*</sup>Management contract, compensatory plan or arrangement.

DATE: July 27, 1995

BY: /s/Dennis L. Winger

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Dennis L. Winger

Senior Vice President, Finance

and Administration

## [CONFIDENTIAL TREATMENT REQUESTED]

[Certain information has been omitted herein pursuant to a request for confidential treatment pursuant to Rule 24b-2.]

## AGREEMENT

This Agreement made as of the 11th day of November, 1993, by and between:

KODAK CLINICAL DIAGNOSTICS LIMITED, a company registered in England, having its principal office at Mandeville House, 62 The Broadway, Amersham, Buckinghamshire, HP7 OHJ, England, (hereinafter KCDL); and

CIBA CORNING DIAGNOSTICS CORP., a Delaware corporation, having its principal office at 63 North Street, Medfield, Massachusetts 02052, U.S.A. (hereinafter CCD).

WHEREAS, KCDL has acquired the full power, right, and authority to grant nonexclusive license under U.S. Patent 4,745,077 issued May 17, 1988, as well as corresponding patents and patent applications applied for in the European Patent Office and in the United Kingdom, France, Germany, and Japan relating to a method useful, in part, for the conduct of human, in vitro diagnostic immunoassays and genetic probe assays for detection of an analyte in a human sample contained in a liquid medium characterized by the use of a labelled reagent which forms a chemiluminescent label system and another reagent bound to magnetically attractable particles.

WHEREAS, CCD has requested a nonexclusive license under the above-referenced patents and patent applications for use in certain human, in vitro diagnostic immunoassay and genetic probe assay systems developed by CCD for the detection of analytes in human samples contained in a liquid medium, which are characterized by the use of a labelled reagent to form a chemiluminescent label system and another reagent bound to magnetically attractable particles.

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WHEREAS, KCDL and CCD acknowledge and agree that technology developments related to new and improved human, in vitro diagnostic assay

systems have recently been and are expected to continue to be numerous and rapid; and that new human, in vitro diagnostic immunoassay products and genetic probe products are complex systems involving many different technologies, including but not limited to biotechnology, chemistry, optics, electronics, fluid management, reagent handling, reaction detection, and equipment design; and that new human, in vitro diagnostic immunoassay and genetic probe assay systems must offer a sufficient number of different assays to be attractive to the marketplace and to be manufacturable on a cost-effective basis; [CONFIDENTIAL TREATMENT REQUESTED]

NOW, THEREFORE, the parties hereto agree as follows:

#### ARTICLE 1 -- DEFINITIONS

- A. "Licensed Patents" shall mean U.S. Patent 4,745,077 issued May 17, 1988, and any corresponding patents or patent applications applied for in the European Patent Office or in the United Kingdom, France, Germany, or Japan as listed in Schedule 1 hereto, and any continuation, continuation-in-part, reissue, re-examination, extension, substitution, or division of such patents and applications.
- B. "Class A Licensed Products" shall mean any human, in vitro diagnostic immunoassay products, including but not limited to instruments, instrument kits, systems, assays or chemical products (but excluding assay products using genetic probe reagents or a combination of immunoassay reagents and genetic probe reagents), employing a labelled reagent to form a chemiluminescent label and another reagent which is bound to magnetically attractable particles, the manufacture, use or sale of which would, but for the license granted in Article II hereof, infringe one or more of the License Patents.

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- C. "Class B Licensed Products" shall mean any human, in vitro diagnostic genetic probe products, including but not limited to instruments, instrument kits, systems, assays, or chemical products (including assay products using a combination of genetic probe reagents and immunoassay reagents), employing a labelled reagent to form a chemiluminescent label and another reagents which is bound to magnetically attractable particles, the manufacture, use or sale of which would, but for the license granted in Article II hereof, infringe one or more of the Licensed Patents.
- D. "Licensed Products" shall mean Class A Licensed Products and Class B Licensed Products.
- E. "Improvement Patent" shall mean any patent or patent application which (a) CCD or any of its Subsidiaries other than Biotrack,

Inc. owns or has the right to license as of the effective date of this Agreement, (b) relates to test elements, devices, or methods for the conduct of human, invitro diagnostic assays and (c) claims a filing priority date on or before the effective date of this Agreement; and all patents and patent applications in the U.S. or in any foreign country corresponding thereto, including any patent granted on any continuation, continuation-in-part, reissue, re-examination, extension, substitution, or division of such patents or applications. The term "Improvement Patent" does not include any patent or patent application or any claim of any patent or patent application relating to the chemical structure of a chemiluminescent label, any patent or patent application, or any claim of any patent or patent application relating to magnetic particle technology, any patent or patent application or any claim of any patent or patent application relating to the following genetic probe amplification methods: amplification of midivariant DNA templates, amplification of midivariant RNA templates, and nucleic acid amplification with DNA-dependent RNA polymerase activity of RNA replicases (but not excluding any patent application or any claim of any patent or any patent application to the extent that they may be applicable to other methods of genetic probe amplification), or any patent or patent application or any claim of any patent or patent application that is part of the patent estate acquired by CCD from Triton Diagnostics, Inc. and relating to cancer diagnostics, or that relates to any specific markers for measurement of cancer antigens. CCD hereby represents that, as of the date of this Agreement, no license under patent rights of any Affiliate of CCD that is not a

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Subsidiary of CCD is held by CCD or needed for the conduct of CCD's in vito diagnostics business.

"Net Sales" shall mean the actual total revenue received resulting from the transfer of licensed products, whether through sale, lease, or other commercial transaction, to a third party, less the following deductions: (i) actual cash discounts and/or quantity discounts allowed; (ii) actual credits for customers' returns and allowances; (iii) the value of the service components of an operating or capital lease which includes a transfer of licensed products; provided that the deduction for such service components shall not exceed the actual value (determined by a reasonable accounting method) or [Confidential Treatment Requested] (iv) actual, separately stated and billed charges for freight handling and transportation paid by CCD or its Affiliates; (v) actual, separately stated and billed charges for insurance charges; and (vi) actual, separately stated and billed sales and use taxes and other similar taxes incurred; provided, however, that (a) the value of such Net Sales received from a Royalty-Bearing Distributor which is used solely for the purpose of calculating ongoing royalty under this Agreement shall not be less than [Confidential Treatment Requested] of the actual total revenue received resulting from the transfer of the same quantity of the same licensed products to End-Users made by CCD and its Affiliates in the United

States during the same royalty reporting period less the appropriate deductions for items (i) through (vi) above, and (b) the foregoing information relating to the actual total revenue received from the transfer of licensed products to End-Users in the United States which is used solely for royalty calculation purposes hereunder shall be made available only to auditors of KCDL pursuant to Article V-E of this Agreement.

G. "Affiliate(s)" shall mean any company, partnership, joint venture, or other entity which directly or indirectly controls, is controlled by or is under common control with a party. Control shall mean the possession of [Confidential Treatment Requested] or more of the voting share capital or the power to direct or cause the direction of the management and policies of the controlled entity, whether through the ownership of shares, by contract or otherwise. In the case of CCD, the term "Affiliate" 1) shall also include Ciba Corning Diagnostics de Mexico, S.A. de C.V., a corporation of Mexico, having its principal office at Vito Allessio Robles #68 Primer Piso, Cal., Florida, CP01030, Mexico DF, Mexico, but only for so long as at least forty-nine percent (49%) of such company is

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controlled by CCD, and 2) shall exclude, Biotrack, Inc., a California corporation with a principal address at 1058 Huff Avenue, Mountain View, California 94043.

- H. "Authorized distributor(s)" shall mean any company, partnership, joint venture or other entity (other than an End-User) which is identified in subparagraph (1) below or meets the conditions of subparagraph (2) below:
- (1) The entity is CCD, an Affiliate of CCD, or a distributor of CCD diagnostics products as of the effective date hereof to be identified on Schedule 2 to be prepared by CCD and furnished to KCDL within three (3) months of the effective date of this Agreement; or
- (2) The entity meets each of conditions (a) through (c) below:
- (a) the entity is not, and no greater than [Confidential Treatment Requested] of the voting share capital of the entity is owned or controlled by, and no power to direct or cause the direction of the management policies of the entity is under the control of, a manufacturer of human in vitro diagnostic products with annual net sales revenue of human in vitro diagnostic products, during the fiscal year immediately prior to the fiscal year in which such entity is granted the right to sell Licensed Products, of greater than [Confidential Treatment Requested] as set forth in information reported by the Venture Planning Group,

- (b) in the fiscal year immediately prior to the fiscal year in which such entity is granted the right to sell Licensed Products, the entity has annual net sales revenue of human in vitro diagnostic products no greater than [Confidential Treatment Requested] as set forth in information reported by the Venture Planning Group, and
- (c) Kodak receives a written certification from CCD or the entity verifying (a) above.

The foregoing annual net sales revenue values of [Confidential Treatment Requested] as set forth in (a) and (b) above shall be adjusted annually

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in accordance with the change in the size of the worldwide in vitro diagnostic market from the effective date of this Agreement to January 1 of the year in question, as reported by Boston Biomedical Consultants.

- I. "Royalty-Bearing Distributor(s)" shall mean any company, partnership, venture or other entity which meets the conditions of both subparagraphs (1) and (2) below:
  - (1) is not an End Use or an Authorized Distributor; and
- of the voting share capital is owned or controlled by, and no power to direct or cause the direction of the management policies of the entity is under the control of, a manufacturer of human, in vitro diagnostic products with annual net sales revenue of human, in vitro diagnostic products, during the fiscal year immediately prior to the fiscal year in which such entity is granted the right to sell licensed products, of greater than [Confidential Treatment Requested] as set forth in information published annually by the Venture Planning Group; provided, however, that CCD may designate not more than two entities (in each case together with all affiliates of such entity) as Royalty-Bearing distributors, without regard to the condition set forth in this subparagraph (2), subject to the conditions that:
- (a) neither such entity nor any of its Affiliates has manufactured products which infringed the Licensed Patents; and
- (b) neither CCD nor any Affiliate of CCD obtains in connection with the designation of such an entity as a distributor of Licensed Products any right to use patented technology of such entity or any of its Affiliates in the manufacture of Licensed Products by or for CCDs, unless such license is extended to KCDL and its Affiliates at the same royalty rate and on the same terms and conditions.

Any Royalty-Bearing Distributor designated by CCD pursuant to the foregoing proviso to subparagraph (2) is hereinafter in this paragraph referred to as a "Special Royalty-Bearing Distributor" and also shall be considered included in all references in this Agreement to Royalty-Bearing Distributors. Satisfaction of the specified conditions

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(a) and (b) of the proviso to the foregoing subparagraph (2) shall be confirmed by a certificate signed by an officer of CCD and a certificate signed by an officer of the Special Royalty-Bearing Distributor, which certificate shall be given to the best of the knowledge of such officer in the case of CCD's certificate regarding satisfaction of said condition (a). It shall be presumed, subject to rebuttal by a preponderance of the evidence, that any license agreement entered into by CCD with a Special Royalty-Bearing Distributor after the date of this Agreement and within three years before or five years after the date that such Special Royalty-Bearing Distributor is authorized by CCD to sell Licensed Products, and before termination by CCD of such authorization to sell Licensed Products, is entered into in connection with such distribution arrangement, and CCD shall provide to KCDL upon request at any time during such period and at the end of such period a certificate of continued compliance with the specified condition (b) of the proviso to the foregoing subparagraph (2).

The foregoing annual net sales revenue value of [Confidential Treatment Requested] in subparagraph (2) above shall be adjusted annually in accordance with the change in the size of the worldwide in vitro diagnostic market from the effective date of this Agreement to January 1 of the year in question, as reported by Boston Biomedical Consultants.

J. "Special Authorized Distributor" shall mean an Authorized Distributor qualified as such pursuant to subparagraph (1) of Article I-H which is, or greater than [Confidential Treatment Requested] of the voting share capital is owned or controlled by, or the power to direct or cause the direction of the management policies of the entity is under the control of, a manufacturer of human in vitro diagnostic products with annual net sales revenue of human, in vitro diagnostic products, during the fiscal year immediately prior to the fiscal year in which this Agreement is executed, of greater than [Confidential Treatment Requested] as set forth in information reported by the Venture Planning Group. To the extent that Net Sales of Licensed Products by CCD and its Affiliates to Special Authorized Distributors in any calendar quarter exceed [Confidential Treatment Requested] of total Net Sales of Licensed Products by CCD and it Affiliates during such calendar quarter, such excess shall be treated as Net Sales to Royalty Bearing Distributors for purposes of Article V and Article III-H.

- K. "End-User(s)" shall mean the customers, such as hospitals, clinical laboratories, and doctors, who purchase Licensed Products for the conduct of diagnostic assays. End-Users shall exclude resellers, such as dealers, distributors, and other manufacturers of diagnostic products, who purchase diagnostic products for the purpose of reselling them to others.
- L. "Subsidiary" shall mean, with respect to CCD, any company in which more than [Confidential Treatment Requested] of the voting share capital is owned by CCD as of the date of this Agreement.

## ARTICLE II -- LICENSE GRANT

- A. KCDL grants to CCD and its Affiliates a non-exclusive license (without sublicensing rights) under Licensed Patents to make, have made, use, and sell or otherwise dispose of Licensed Products bearing the name and trademark of CCD or an Affiliate of CCD prominently displayed thereon to End-Users, Authorized Distributors and Royalty-Bearing Distributors.
- (1) The aforesaid nonexclusive license to have made Licensed Products includes the right for CCD and/or its Affiliates to work with third parties who either develop or manufacture, in whole or in part, Licensed Products, which are supplied for use, resale, or other commercial purposes solely to CCD and/or its Affiliates.
- (2) Under the aforesaid nonexclusive license, CCD and/or its Affiliates may include on the Licensed Products the name and trademark of an Authorized Distributor, together with the name and trademark of CCD or an Affliate of CCD, provided that the name and trademark of CCD or an Affliate of CCD is displayed on the Licensed Products at least as prominently as the name and the trademark of the Authorized Distributor.
- B. The license granted hereunder shall be subject to and is conditioned on KCDL's timely receipt of the applicable license payments as provided under Article III of this Agreement.

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C. Upon written request by CCD on or before December 31, 1996, KCDL is willing to [Confidential Treatment Requested] Licensed Products bearing prominently displayed thereon the name and trademark of CCD, an Affiliate of CCD, [Confidential Treatment Requested] or a combination of CCD (or an Affiliate of CCD) and [Confidential Treatment Requested] to End-Users and to distributors corresponding to those designated as Authorized Distributors, Royalty-Bearing Distributors, or Special Authorized Distributors (but who are defined in terms of [Confidential Treatment Requested] rather than CCD). KCDL will [Confidential Treatment Requested] on reasonable terms and conditions, including:.

- (1) an ongoing royalty based on a percentage of the net selling price of Licensed Products not to exceed the rates specified in attached Schedule 3;
- (2) a nonexclusive license grant to KCDL and its affiliates on reasonable terms and conditions under selected patents or patent applications [Confidential Treatment Requested] owns or has the right to license relating to human, in vitro diagnostic products; and/or
- (3) a combination of items (1) and (2) above, with or without any other license fees and payments.

In the event subparagraph (2) above does not apply, either because [Confidential Treatment Requested] does not own or have the right to license any such patents or patent applications or because KCDL and its Affiliates do not desire to be licensed under any such patents or patent applications, the KCDL will [Confidential Treatment Requested] on reasonable terms and conditions based on an ongoing royalty equal to a percentage of the net selling price of Licensed Products as specified in attached Schedule 3, an initial license payment not to exceed [Confidential Treatment Requested] and an annual minimum royalty payment not to exceed [Confidential Treatment Requested]

D. KCDL agrees to use reasonable efforts to conclude negotiation of license agreements pursuant to Article II-C within a period of time that is reasonably

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practical based on the circumstances. Following receipt of CCD's written request [Confidential Treatment Requested] KCDL shall have a period of four (4) months from receipt of a full written disclosure of all patents and patent applications [Confidential Treatment Requested] to December 31, 1996 or the then current date, whichever is earlier, relating to human, in vitro diagnostics to specify the patents or patent applications [Confidential Treatment Requested] with respect to which KCDL and/or its Affiliates wish In the even the KCDL and/or its Affiliates do not wish to obtain a license. to obtain a license under any selected patents or patent applications [Confidential Treatment Requested] KCDL shall use diligent efforts to conclude within an additional four (4) week period (following the end of the aforementioned 4 month period) a license agreement [Confidential Treatment Requested] based on the financial terms set forth in Article II-C. In the case of a license agreement [Confidential Treatment Requested] pursuant to Article II-C that involves a cross license, KCDL shall be under no obligation whatsoever to conclude such license agreement if [Confidential Treatment Requested] is unwilling to grant KCDL and/or its Affiliates a license under those patents or patent applications which it owns or has the right to license and which KCDL has selected for inclusion in such cross license.

E. KCDL hereby agrees that upon written request KCDL is willing to grant [Confidential Treatment Requested] on reasonable terms and conditions to be negotiated. KCDL agrees to use reasonable efforts to conclude negotiation of such licenses within a reasonable period of time.

# ARTICLE III - LICENSE PAYMENTS AND ROYALTIES

- A. CCD shall pay to KCDL an Initial License Payment of [Confidential Treatment Requested] which shall be payable no later than December 15, 1993, by electronic wire transfer to an account designated in writing by KCDL.
- B. In addition to the Initial License Payment under Article III-A, beginning on or before August 31, 1994, and continuing on or before August 31 each year thereafter through and including 2005, CCD shall pay to KCDL, in lieu of ongoing royalties on sales of Class A Licensed Products by CCD or its Affiliates to Authorized Distributors or End-Users, an annual, lump-sum license payment in an amount as shown in Table 1 below.

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<TABLE> <CAPTION>

Table 1 - Annual, Lump-Sum License Payments

	Calendar Year	Lump-Sum License Payment
		[Confidential Treatment Requested]
<s></s>		<c></c>
	[Confidential	[Confidential Treatment Requested]
	Treatment	[Confidential Treatment Requested]
	Requested]	[Confidential Treatment Requested]

  |  |C. Of the total of the annual, lump-sum license payments specified in Table 1 above, [Confidential Treatment Requested] of the payments specified in Table 1 represents the total of the annual, lump-sum

license payments to be paid by CCD to KCDL as set forth in Article III-B of this Agreement under the United States patent of the Licensed Patents. The remainder of the Payments specified in Table 1 represent the total of the annual, lump-sum license payments to be paid by CCD to KCDL as set forth in Article III-B of this Agreement under the non-Untied States patents and patent applications of the Licensed Patents.

- D. In the event that European patent 149565 B1 of Licensed Patents is revoked by the European Patent Office; KCDL shall promptly [Confidential Treatment Requested].
- E. In the event of a final decision of the Japanese Patent Office, including any appeal to the Japanese courts, as a result of which the Japanese Patent Office (1) does not lay open for opposition the Japanese patent application of Licensed

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Patents by December 31, 2000, or (2) does not grant a patent on the Japanese patent application (Kokoku) of the Licensed Patents following the opposition of such application (Kokoku) by December 31, 2000, CCD shall not be required to make any of the annual, lump-sum license payments specified in Table 1 after the year 2000; provided, however, that if a Japanese patent is granted on such Japanese patent application (Kokoku) after December 31, 2000, CCD shall make any payments which are specified in Table 1 for the year in which such Japanese patent is granted through the year 2005 (but excluding any payments specified in Table 1 for the year(s) after 2000 through the year immediately preceding the grant of such Japanese patent).

- F. In addition to the license payments specified in Article III-A through Article III-E above, with respect to any sales or other transfer of Class A Licensed Products and/or Class B Licensed Products on or after the effective date of this Agreement by CCD or its Affiliates to any Royalty-Bearing Distributors, CCD shall pay to KCDL an ongoing royalty of [Confidential Treatment Requested] of Net Sales of such Licensed Products.
- G. In addition to the license payments specified in Article III-A through III-E above, with respect to any sales or other transfer of Class B Licensed Products, on or after the effective date of this Agreement by CCD or its Affiliates to any End-Users or Authorized Distributors, CCD shall pay to KCDL an on going royalty of [Confidential Treatment Requested] of Net Sales of Class B Licensed Products.

## ARTICLE IV -- OPTION FOR LICENSE UNDER CCD PATENTS

A. In partial consideration of the license granted to CCD under this Agreement, CCD grants to KCDL an irrevocable option to obtain a non-exclusive, royalty-bearing license (without sublicensing rights) to KCDL and its

Affiliates to make, have made, use and sell or otherwise dispose of products under any [Confidential Treatment Requested] Improvement Patent including all patents in any other country corresponding to such Improvement Patent, subject to KCDL's payment to CCD of total cumulative payments for such license such that:

(1) In the case of an Improvement Patent whose claims have applicability to diagnostic assays in general, the present value of such total cumulative

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payments, calculated from the date of signing such license, does not exceed [Confidential Treatment Requested]

- (2) In the case of an Improvement Patent whose claims have applicability only to one or several specific diagnostic assays, [Confidential Treatment Requested]
  - B. In both subparagraphs (1) and (2) of paragraph IV-A above,
- 1. The present values of both streams of payments shall be calculated:
  - a. using a discount rate of 10%,
- b. on a monthly basis from the date of signing each such license, and
- 2. KCDL shall also pay an initial license payment of [Confidential Treatment Requested], due within thirty (30) days of KCDL exercising the option. The amount in the case of both clauses (1) and (2) of paragraph IV-A above shall be reduced if, with respect to the particular Improvement Patent for which KCDL exercises such option, CCD does not have corresponding patents in each of the United States, Europe, and Japan. The amount of such reductions shall be as follows: [Confidential Treatment Requested] if CCD does not have a corresponding patent in the United States, [Confidential Treatment Requested] if CCD does not have a corresponding European patent, and [Confidential Treatment Requested] if CCD does not have a corresponding Japanese patent.
- C. KCDL shall have the right to exercise the aforesaid option upon written notice to CCD of the Improvement Patent which KCDL wishes to license. The option granted under this Article IV-A shall become exercisable by KCDL upon signing this Agreement, and shall remain exercisable until the earlier of [Confidential Treatment Requested] or the termination of this Agreement (unless such termination is due to the material breach

of CCD in which case such option shall remain exercisable by KCDL until [Confidential Treatment Requested]. Upon KCDL's exercise of its option hereunder, the parties shall use diligent efforts to complete within three months negotiation of a license agreement containing the terms set forth in this Article, and any such additional terms not inconsistent therewith as are customary in similar agreements, provided that such additional terms shall be consistent with the corresponding provisions of this Agreement applicable to the license granted to CCD hereunder.

# ARTICLE V - STATEMENTS, RECORDS AND ACCOUNTS

- A. CCD shall furnish to KCDL two (2) times per year on or before February 28 and August 31 during the years in which license payments are made hereunder a written statement that CCD has continued to sell Class A Licensed Products to Authorized Distributors and End-Users during the preceding six (6) month periods ending, respectively, on December 31 and June 30.
- B. During February, May, August, and November, following each calendar quarter year, or portion thereof, in which this Agreement is in effect, CCD shall, with respect to Class A Licensed Products and/or Class B Licensed Products sold or otherwise transferred by CCD or its Affiliates to Royalty-Bearing Distributors and/or Class B Licensed Products sold or otherwise transferred by CCD or its Affiliates to End-Users and Authorized Distributors during the preceding quarter calendar year, furnish to KCDL.
  - (1) a written royalty statement separately setting forth:
- (a) in each geographic region (i.e., the Americas; Europe, Middle East, and Africa; and Asia/Pacific), the total Net Sales of all such Class A Licensed Products and Class B Licensed Products made by CCD and its Affiliates during the preceding calendar quarter-year, itemized by instrument model in the case of instruments, and by disease-specific or organ-specific assay group in the case of assays, the applicable class of Licensed Products to which it belongs, and the applicable ongoing royalty rate;

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- (b) the total royalty accruing on Net Sales of all such Class A and Class B Licensed Products; and
- (2) payment of any royalty owed for said Net Sales during the preceding calendar quarter-year.

- C. If no Net Sales of Class A Licensed Products or Class B Licensed Products to Royalty-Bearing Distributors and Class B Licensed Products to End-Users or Authorized Distributors shall have been made during any calendar quarter year, or portion thereof, this Agreement is in effect, CCD's royalty statement shall so report. The first such royalty statement submitted under this Agreement by CCD shall be due in May, 1994, and shall be applicable to all such Net Sales of Licensed Products made on or after the effective date of this Agreement.
- D. Within ninety (90) days after termination of this Agreement or any license under Article II, CCD shall furnish to KCDL a similar royalty statement covering all Net Sales of Class A Licensed Products to Royalty-Bearing Distributors and all Class B Licensed Products and Class B Licensed Products to End-Users and Authorized Distributors made prior to the termination date.
- E. CCD shall maintain complete and accurate records of Net Sales of Licensed Products made by CCD and its Affiliates under this Agreement, and shall retain such records for a period of three (3) years after submitting the royalty statement to which they pertain. Such records may, upon thirty (30) days prior written request by KCDL and at its expense, be audited once per calendar year during CCD's normal business hours by a public accounting firm selected by KCDL for the purpose of verifying CCD's compliance with this Agreement. The accounting firm shall execute a confidentiality agreement with CCD and shall report to KCDL only whether there is a royalty underpayment and, if so, the amount thereof. In the event of any underpayment, CCD shall promptly remit to KCDL all amounts due. If any such inspection discloses an aggregate underpayment of more than [Confidential Treatment Requested] during any calendar year, CCD shall reimburse KCDL for the cost of the audit and shall pay interest to KCDL on the back royalty due KCDL at an annual interest rate equal to [Confidential Treatment Requested].

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F. CCD may withhold from its license and royalty payments to KCDL any income taxes required to be withheld by CCD under the laws of foreign countries where Licensed Products are sold. Such amount shall be paid to the appropriate taxing authorities and CCD shall provide KCDL with official receipts issued by said taxing authority or such other evidence as is reasonabley available to establish that such taxes have been paid and are available for credit by KCDL for English income tax purposes. CCD shall cooperate with KCDL and take all actions reasonably necessary in order to secure a reduction or elimination of withholding taxes pursuant to applicable income tax treaties between England and such foreign countries.

## ARTICLE VI -- RELEASE OF LIABILITY

KCDL on its own behalf and on behalf of its Affiliates hereby fully, finally and forever releases CCD and its Affiliates from any and all

claims of liability for any infringement or alleged infringement of Licensed Patents resulting from the manufacture, use, or sale of Licensed Products prior to the effective date of this Agreement.

#### ARTICLE VII -- ENFORCEMENT OF LICENSED PATENTS

- A. During the pendency of any opposition proceeding with respect to the European patent of the Licensed Patents, KCDL will use reasonable efforts to enforce the United States patent of Licensed Patents upon receipt of credible evidence which constitutes a reasonable showing that a third party having annual worldwide net sales revenue of human in vitro diagnostic products in excess of [Confidential Treatment Requested] as set forth in information published annually by the Venture Planning Group is engaging in the conduct of activity which constitutes an infringement of such United States patent.
- B. Following the final decision of any opposition proceeding with respect to the European patent of the Licensed Patents which sustains the grant of a patent on such European patent, KCDL will use reasonable efforts to enforce the United Kingdom patent, the French patent, and the German patent of Licensed Patents upon receipt of credible evidence which constitutes a reasonable showing that a third party

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having annual worldwide net sales revenue of human in vitro diagnostic products in excess of [Confidential Treatment Requested] as set forth in information published annually by the Venture Planning Group is engaging in the conduct of activity which constitutes an infringement of any one of the foregoing United Kingdom, French, or German patents of the Licensed Patents.

In the event that within twelve (12) months following KCDL's receipt of such evidence, KCDL has not:

- (1) entered into a royalty-bearing license under Licensed Patents with such third party in regard to such infringing activity; or
- (2) filed and maintained a claim of patent infringement against such third party or company in a tribunal of competent jurisdiction in at least one of the foregoing countries in which such third party is continuing to engage in such infringing activity; or
- (3) taken other action such that the infringing activity of such third party constitutes a level of annual net sales revenue of less than [Confidential Treatment Requested];

then any subsequent license payments due KCDL by CCD as specified in Article III-B and Article III-D of this Agreement shall be reduced by [Confidential Treatment Requested] until such time as KCDL has taken the action specified in

at least one of clauses (1) through (3) of this paragraph. Thereafter, such license payments shall be paid in full to KCDL by CCD without any reduction.

C. Following the final decision of any opposition proceeding with respect to the Japanese patent application (Kokoku) of the Licensed Patents which results in the grant of a patent on such Japanese patent application (Kokoku), KCDL will use reasonable efforts to enforce the Japanese patent of Licensed Patents upon receipt of credible evidence which constitutes a reasonable showing that a third party having annual net sales revenue of human in vitro diagnostic products in Japan in excess of [Confidential Treatment Requested] as set forth in information published annually by the Venture Planning Group (or other similar source which is acceptable to

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both parties) is engaging in the conduct of activity which constitutes an infringement of such Japanese patent.

In the event that within twelve (12) months following KCDL's receipt of such evidence, KCDL has not:

- (1) entered into a royalty-bearing license under Licensed Patents with such third party in regard to such infringing activity; or
- (2) filed and maintained a claim of patent infringement against such third party in a tribunal of competent jurisdiction; or
- (3) taken other action such that the infringing activity of such third party constitutes a level of annual net sales revenue of less than [Confidential Treatment Requested];

then any subsequent license payments due KCDL by CCD as specified in Article III-B of this Agreement shall be reduced by [Confidential Treatment Requested] until such time as KCDL has taken the action specified in at least one of clauses (1) through (3) of this paragraph. Thereafter, such license payments shall be paid in full to KCDL by CCD without any reduction.

D. Any decision to file a claim of patent infringement against a third party under Licensed Patents shall be a matter within the sole discretion of KCDL. Upon request and at the expense of KCDL, CCD shall cooperate with KCDL in regard to prosecuting legal actions relating to such claims of patent infringement, including but not limited to the furnishing of information and witnesses and providing reasonable assistance in securing evidence in support of such actions.

ARTICLE VIII -- TERMINATION

A. Either party shall have the right to terminate this Agreement following any material breach or default in performance under this Agreement by the other party upon [Confidential Treatment Requested] prior written notice to the breaching party specifying the nature of the breach or default. Unless the breaching party has cured the breach or

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default prior to the expiration of such [Confidential Treatment Requested] period, the non-breaching party, at its sole option, may terminate this Agreement upon written notice to the breaching party. Termination of this Agreement shall become effective upon receipt of such notice by the breaching party.

- B. During the term of this Agreement, in the event that CCD and its Affiliates shall cease the manufacture, use, and sale of all Licensed Products for a continuous period of [Confidential Treatment Requested] or more, CCD shall have the right to terminate this Agreement.
- C. Upon termination of this Agreement for any reason, the license granted hereunder by KCDL shall terminate and CCD's obligations under this Agreement to pay any further license payments and ongoing royalties shall cease.
- Unless sooner terminated under the provisions of this Article D. VIII, all licenses granted hereunder shall continue in force for the full term of all patents licensed hereunder and this Agreement shall terminate on the expiration of the last such patent to expire. However, in the event that after [Confidential Treatment Requested], a Licensed Patent has been held permanently revoked, unenforceable or invalid in any country by a final decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, which is rendered in a proceeding other than the European and Japanese examination or opposition proceedings referenced in Article III of this Agreement, each of the license payments due as specified in Table 1 after such final decision shall be reduced by [Confidential Treatment Requested] for each such country in which such a final decision is made, except for the United Kingdom in which case such reduction shall be [Confidential Treatment Requested]. In the event that after August 31, 1996, such final decisions are effective as to all Licensed Patents, no further license payments in any amount shall be due as specified in Table 1 after the date the last such final decision becomes effective. In the event that at any time a Licensed Patent has been held permanently revoked, unenforceable or invalid in any country by a final decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, no further royalty payments shall be due as specified in Article III-F or Article III-G under such Licensed Patent in such country.

E. Termination of this Agreement shall not relieve the parties of any obligation accruing prior to the effective date of such termination.

## ARTICLE IX -- WARRANTIES AND REPRESENTATIONS

# A. KCDL represents and warrants that:

- (a) it is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it was incorporated;
- (b) it has the full right, power and authority to enter into this Agreement and to convey the non-exclusive license granted under this Agreement;
- (c) it has not previously granted, and will not grant to any third party during the term of this Agreement, any rights that are in conflict with the license granted to CCD herein; and
- (d) there are no patents corresponding to the Licensed Patents in any countries other than the United States, United Kingdom, France, Germany and Japan.

# B. CCD represents and warrants that:

- (a) it is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it was incorporated;
- (b) it has the full right, power and authority to enter into this Agreement and to convey the option for a non-exclusive license granted to KCDL under this Agreement; subject to the approval or ratification of CCD's Board of Directors, as set forth in Section XI below; and
- (c) it has not previously granted, and will not grant to any third party during the term of this Agreement, any rights that are in conflict with the option granted to KCDL herein; and

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(d) so far as its representatives negotiating this Agreement are aware, neither it nor any of its Affiliates have as of the effective date of this Agreement any existing distributor which constitutes a company, partnership, joint venture or other entity who is, or greater than [Confidential Treatment Requested] of the voting share capital is owned or controlled by, or the power to direct or cause the direction of the management

policies of the entity is under the common control of, a manufacturer of human, in vitro diagnostic products with annual net sales revenue of human, in vitro diagnostic products of greater than [Confidential Treatment Requested], except for [Confidential Treatment Requested].

# ARTICLE X -- ASSIGNMENT

This Agreement and the license, option and other rights and obligations hereunder may not be assigned or otherwise transferred, by either party without the written consent of the other party, which consent shall not be withheld unreasonably. Notwithstanding the foregoing, either party may assign this Agreement and the license, and other rights and obligations hereunder, in connection with the transfer or sale of all or substantially all of that portion of its business or assets relating to performance of its obligations hereunder, or in the event of its merger or consolidation with another company at any time during the term of this Agreement. Any purported assignment in violation of the preceding two sentences shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve either party of responsibility for the performance of any accrued obligation which such party then has hereunder.

#### ARTICLE XI -- MISCELLANEOUS

- A. No reference to this license and no trademark, trade name or trade dress or copyrighted work of either party or its Affiliates shall appear on product that is made, sold or used under this Agreement by the other party, or on its packaging or in advertising or promotional materials for such product.
- B. The specific terms and conditions of this Agreement shall be treated as confidential information by the parties hereto and shall not be disclosed to third parties during the term of this Agreement. Notwithstanding the foregoing, 1) neither

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party shall be required to maintain the fact or the extent of the license granted hereunder to CCD and its Affiliates in confidence, 2) KCDL may issue a press release, in form and content mutually agreeable to KCDL and CCD, disclosing the license grant hereunder, 3) CCD shall be permitted to disclose the terms and conditions of this Agreement on a confidential basis to Amersham International plc of England, and 4) either party hereto may be permitted to make disclosures relating to the terms and conditions of this Agreement on a confidential basis in contemplation of a permitted assignment of this Agreement pursuant to Article X hereof. Furthermore, the content of Schedule 2 to this Agreement and of the royalty statements delivered pursuant to Article V shall be treated as confidential information by KCDL and its Affiliates and shall not be

disclosed by KCDL or its Affiliates to third parties during the term of, or at any time following the termination of, this Agreement, unless required by operation of applicable law or regulatory requirements.

- C. Except as otherwise expressly provided herein, nothing contained in this Agreement shall:
- (1) Grant any license or sublicensing right or confer any right, by implication, estoppel or otherwise;
- (2) Impose any obligation or confer any right to enforce any patent; or
- (3) Constitute any representation, warranty, assurance, guarantee or inducement whatsoever by either party or any affiliate thereof.
- D. KCDL and CCD agree they are independent contractors and that the relationship between the parties shall not constitute a partnership, joint venture or agency. Neither party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written authorization of the other party to do so.
- E. Failure at any time to require strict performance of any of the provisions herein shall not waive or diminish a party's right thereafter to demand strict compliance therewith or with any other provision. Waiver of any default shall not waive

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any other default. A party shall not be deemed to have waived any rights hereunder unless such waiver is in writing and signed by a duly authorized officer of the party making such waiver.

F. All notices and other communications required or permitted under the Agreement must be in writing. They may be delivered personally or sent by telex, commercial courier, postage prepaid mail or facsimile, at the option of the sending party, except that CCD's Initial License Payment under Article III-A hereof shall be made by electronic wire transfer to an account designated in writing by KCDL. All communications and payments, other than the aforementioned CCD electronic wire transfer payment, must be sent to, and shall be effective on the date of delivery at, the receiving party's Address for Notice or Address for Statements and Payments. The initial Address for Notice and Address for Statements and Payments set forth below and any subsequent Address for Notice or Address for Statements and Payments may be changed by a communication as provided herein.

KCDL Address for Notices, Statement and Payments:

The Company Secretary
KODAK CLINICAL DIAGNOSTICS LIMITED
Mandeville House
62 The Broadway
Amersham
Buckinghamshire
HP7 OHJ, England
Facsimile No: 494-431-165

CCD Address for Notices and Payments:

Ciba Corning Diagnostics Corp. 63 North Street
Medfield, MA 02052
U.S.A.
Attn.: President
Facsimile No. 508-359-3879

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with a copy to:

Ciba Corning Diagnostics Corp.
63 North Street
Medfield, MA 02052
U.S.A.
Attn.: General Counsel
Facsimile No. 508-359-3885

- G. This Agreement, which shall be governed by the substantive laws of the State of New York, U.S.A. (without regard to its conflicts of law provisions), constitutes the entire Agreement between the parties with respect to the subject matter hereof. Any modification of this Agreement shall be set forth in writing and duly executed by both parties.
- H. The headings of the several articles of this Agreement are intended for convenience of reference only and are not intended to be part of or to affect the meaning of interpretation of this Agreement.
- I. If any provision of this Agreement is held invalid, illegal, or in any other way becomes void or unenforceable, this Agreement and the remaining provisions thereof shall not in any way be affected or be impaired and shall continue in full force and effect. In such event, however, at any time any provision of this Agreement violates or conflicts with, or otherwise does not satisfy, any provision of applicable law or regulation in any country or jurisdiction, including the competition laws of the European Communities, then the parties shall negotiate in good faith such changes or amendments to such

provision as are necessary to eliminate such violation or conflict, or satisfy such law or regulation, and in so doing, shall attempt to preserve as much as practicable the economic and other benefits to each party as set forth in such provision.

J. KCDL shall make those filings in the Commission of the European Community which are required in order to obtain approval of this Agreement by the Commission of the European Community. In addition, KCDL shall prepare responses within a reasonable period of time in writing to any communications from the Commission of the European Community regarding such filings. CCD shall reasonably cooperate with KCDL in the preparation of any such filings and responses.

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IN WITNESS WHEREOF, the parties have caused their respective corporate names to be affixed hereto and this instrument to be signed by their duly authorized officers, all as of the day and year first above written.

KODAK CLINICAL DIAGNOSTICS LIMITED

By /s/ Jose J. Coronas

Jose J. Coronas

Title Director

\_\_\_\_\_

CIBA CORNING DIAGNOSTICS CORP.

By /s/ Michael D. Webb

-----

Michael D. Webb

Title

\_\_\_\_\_

Vice President

SCHEDULE 1

LICENSED PATENTS

Country Number Issue Date or Filing Date -----United States P-4,745,077 5/17/88

European	P-149565 B1	12/23/92
German	P-3586909	2/4/93
France	P-149565	12/23/92
Japan Appln.	PA-85/7298	Filed 1/17/85
United Kingdom	P-149565	12/23/92

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P = Patent

PA = Patent Application

SCHEDULE 2 -- 11 pages

[CONFIDENTIAL TREATMENT REQUESTED]

#### SCHEDULE 3

- 1. The ongoing royalty for Class A Licensed Products is equal to the ongoing royalty percentage as specified in Table 1 or Most Favorable Terms granted to another licensee (other than CCD) as hereinafter defined in this Schedule.
- 2. The ongoing royalty for Class B Licensed Products shall be equal to [Confidential Treatment Requested] of the annual net sales of Class B Licensed Products or the Most Favorable Terms1 granted to another licensee (other than CCD) as hereinafter defined in this Schedule.

Table 1 -----

Annual net sales of Class A Licensed Products Ongoing Royalty Percentage 1

On the first [Confidential Treatment Requested] of annual net sales

[Confidential

On the second [Confidential Treatment Requested] of annual net

sales Treatment

On the third [Confidential Treatment Requested] of annual net sales

Requested]

On the fourth [Confidential Treatment Requested] of annual net sales

On any annual net sales in excess of [Confidential Treatment Requested]

- -----

1 Most Favorable Terms:

- A. If KCDL grants a license to another licensee (other than CCD) based on ongoing royalty percentages more favorable than those specified above in this Schedule 3, KCDL shall immediately reduce the above-noted ongoing royalty percentages to those granted to such other licensee.
- B. The provisions of Section A above shall not apply:
- (a) Where the consideration payable by such other licensee includes substantial rights or immunities in, to or under patent rights held by such licensee, including rights with respect to patent applications or other proprietary rights;
- (b) Where the more favorable royalty terms for license rights cover only past infringement or are the result of the settlement or compromise of a claim of past infringement;
  - (c) To any license which may be granted to any government;
- (d) To any license which may be granted by KCDL to any Affiliate or to an Affiliate of such Affiliate; or
  - (e) To any license granted by order of any court or any government agency.

[KODAK LETTERHEAD]

7 October 1994

General Counsel Ciba Corning Diagnostics Corp 63 North Street Medfield Massachusetts 02052 USA

Dear Sir or Madam

As you may be aware, Eastman Kodak Company ("Kodak") has agreed to sell the

business and assets of its Clinical Diagnostics Division, which includes the directly wholly owned subsidiary of Kodak Clinical Diagnostics Limited ("KCDL"), to Johnson & Johnson ("J&J").

In connections with the sale of the business, Kodak desires to assign to J&J, or to a subsidiary of J&J, all of KCDL's right, title and interest under the License Agreement, dated 11 November 1993, between you and KCDL, and J&J desires to assume and discharge or perform when due, or to cause a subsidiary of J&J to assume and discharge or perform when due, all liabilities or obligations of KCDL arising out of or relating thereto.

Please indicate your consent to the assignment described above by returning a signed copy of this letter to the undersigned at:

Legal Department, Kodak Limited, PO Box 66, Kodak House, Station Road, Hemel Hempstead, Herts HP1 1JU, England

no later than 24 October 1994. If you have any questions, please do not hesitate to telephone me.

Thank you for your co-operation.

Yours faithfully

CONSENTED TO:
CIBA CORNING DIAGNOSTICS CORP

/s/ Terence J. Charlton

By: /s/

\_\_\_\_\_

Title: SVP WW Marketing

\_\_\_\_\_

Date: 11/8/94

Terence J Charlton Legal Adviser Kodak Clinical Diagnostics Limited

# [CONFIDENTIAL TREATMENT REQUESTED]

[Certain information has been omitted herein pursuant to a request for confidential treatment pursuant to Rule 24b-2.]

## LICENSING AGREEMENT

THIS AGREEMENT shall be effective on the last date of execution hereof by and between MILES LABORATORIES, INC. (MILES), a corporation of the State of Delaware and having its principal place of business at 1127 Myrtle Street, Elkhart, Indiana 46515 and CIBA CORNING DIAGNOSTICS CORP. (CIBA CORNING), a corporation of the State of Delaware and having its principal place of business at 63 North Street, Medfield, Massachusetts 02052.

WHEREAS, MILES owns all rights to United States Patent No. 4,380,580 and its corresponding foreign-filed counterparts covering certain chemiluminescent specific binding assay methods and reagent systems;

WHEREAS, CIBA CORNING owns or controls patent rights and confidential know-how relating to certain chemiluminescent specific binding assay methods and reagent systems;

WHEREAS, MILES intends to research and develop reagent systems for performing chemiluminescent specific binding assays which incorporate the above CIBA CORNING patent rights and/or confidential know-how;

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WHEREAS, CIBA CORNING intends to develop and market instruments and reagent systems for performing chemiluminescent immunoassays and desires to receive a nonexclusive license under the above MILES patent rights;

WHEREAS, MILES is willing to grant such a license under the terms hereof which provide in part that MILES receive certain access and license rights to patent rights, know-how, and other proprietary rights owned or licensed to CIBA CORNING concerning its chemiluminescent immunoassay instrument and reagent systems; and

WHEREAS, CIBA CORNING is willing to grant MILES such access and licensing rights under the terms hereof.

NOW THEREFORE, in consideration of the mutual promises herein, the parties agree as follows:

## ARTICLE 1

#### **DEFINITIONS**

1.1 "CLAIM" shall mean a patent claim which defines an invention which the patentee has been granted the right to exclude others from making, using, or selling throughout the granting country. The term does NOT include any claim which has

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been disclaimed, cancelled, or held to be invalid by a court of competent jurisdiction in a final decision from which no appeal has or can be taken.

- 1.2 "LICENSED PATENTS" and "LICENSED PATENT APPLICATIONS" shall mean the patents and patent applications, including U.S. Patent No. 4,380,580 and its foreign filed counterparts, listed in Exhibit A attached hereto.
- 1.3 "LIQUID-PHASE" as applied to any assay shall mean an assay in which the assay reaction and/or the measurement of generated signal takes place in the presence of a bulk solution or liquid, and specifically shall NOT include a solid-phase assay in which an assay reaction and/or the measurement of generated signal takes place in or on a solid, porous or nonporous, carrier such as, without limitation, a reagent strip, which solid carrier is not in contact with a bulk solution or liquid during such reaction or measurement.
- 1.4 "CHEMILUMINESCENT IMMUNOASSAY" shall mean a LIQUID-PHASE heterogeneous chemiluminescent assay employing a chemiluminescent reactant as label and wherein the substance or condition to be determined, i.e., analyte of interest, is determined by binding thereto of an antibody or other specific binding protein.

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- 1.5 "CHEMILUMINESCENT BINDING ASSAY" shall mean a LIQUID-PHASE chemiluminescent assay employing a chemiluminescent reactant as label and wherein the analyte of interest is determined by binding of any kind of specific binding substance such as an antibody or other binding protein, nucleic acid, or the like. A CHEMILUMINESCENT IMMUNOASSAY is one type of CHEMILUMINESCENT BINDING ASSAY.
- 1.6 "LICENSED PRODUCT" shall mean a product for performing a CHEMILUMINESCENT IMMUNOASSAY only, and no other product, which when made, used, or sold would infringe a CLAIM of a LICENSED PATENT.
- 1.7 "INSTRUMENT SYSTEM" shall mean the hardware and software components of an instrument capable of running CHEMILUMINESCENT BINDING ASSAYS.
  - 1.8 "MILES" and "CIBA CORNING" shall include, unless expressly provided

otherwise herein, all of their respective Affiliates, and shall in the case of MILES specifically include Bayer AG, Germany, and its Affiliates. Affiliates shall mean any corporation or other business entity controlled by, controlling, or under common control with the affected party, wherein control means direct or indirect beneficial ownership of at least fifty

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percent (50%) of the voting stock or the maximum amount allowed under local law, or at least fifty percent (50%) interest in the income, of such corporation or other business entity.

- 1.9 "NET SALES" shall mean invoiced price for sales less actual credited allowances to customers for spoiled, damaged, outdated, or returned LICENSED PRODUCT.
- 1.10 "CONFIDENTIAL MATTER" shall mean information or material, whether of a technical, business, or other nature, which constitutes a trade secret, know-how or other confidential asset not within the public domain.
- 1.11 "PROPRIETARY TECHNOLOGY" shall mean patent rights and CONFIDENTIAL MATTER.

#### ARTICLE 2

## LICENSE TO CIBA CORNING

2.1 MILES grants to CIBA CORNING a worldwide, nonexclusive, nontransferable right and license, with no right to grant any sublicenses, to make, have made, use, and sell LICENSED PRODUCTS. Accordingly, the license to CIBA CORNING includes the right of CIBA CORNING and purchasers of its LICENSED PRODUCTS to practice

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methods covered by the LICENSED PATENTS and LICENSED PATENT APPLICATIONS only by using such LICENSED PRODUCTS.

# ARTICLE 3

## ROYALTY TO MILES

3.1 In consideration for the above license, CIBA CORNING shall pay MILES a royalty of [Confidential Treatment Requested] of NET SALES of LICENSED PRODUCTS by CIBA CORNING. LICENSED PRODUCT shall be considered as sold when invoiced to the customer. Royalty shall be due for sales to an Affiliate only if LICENSED PRODUCT is consumed by such Affiliate, in which case, royalty shall

be calculated from the invoiced price to such Affiliate or a reasonable arms-length invoice price if such Affiliate is treated on a more favorable basis than the general trade. Otherwise, royalty shall be due when sold by such Affiliate to a third party and NET SALES calculated based on the invoiced price to such party.

- 3.2 No royalty shall be due for sales of a LICENSED PRODUCT covered by a LICENSED PATENT APPLICATION but not by a LICENSED PATENT.
- 3.3 If during the term of the license granted to CIBA CORNING hereunder MILES grants a license to a third party other than an Affiliate to make, have made, use, or sell LICENSED

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PRODUCT at a royalty rate that is less than [Confidential Treatment Requested], MILES shall so notify CIBA CORNING in writing and the royalty rate set forth in Paragraph 3.1 above shall thereupon become the same as the royalty rate for such third party.

## ARTICLE 4

# PAYMENTS AND RECORDS

- 4.1 CIBA CORNING shall keep complete and accurate records containing all information required for the computation and verification of the royalties to be paid hereunder.
- 4.2 CIBA CORNING shall, upon request of MILES, permit an independent public accountant selected by MILES to have access during ordinary business hours to such records as may be necessary to determine either the accuracy of any report or the sufficiency of any payment made under this Agreement within two (2) years prior to such request. Such accountant shall disclose to MILES only information necessary to inform MILES of:
  - a) the accuracy of the reports of CIBA CORNING and payments to MILES; and
  - b) the extent of any inaccuracy or noncompliance.

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The accountant shall be paid by MILES unless a deficiency of greater than ten percent (10%) is reported, whereupon CIBA CORNING shall pay all such accountant costs and fees.

4.3 On or before thirty (30) days after March 31, June 30, September 30, and December 31 of each year throughout the term of this Agreement, CIBA CORNING shall deliver to MILES a quarterly written statement of account of

NET SALES of LICENSED PRODUCT. The first written statement delivered to MILES shall include an accounting of all NET SALES of LICENSED PRODUCT which occurred prior to the effective date hereof.

- 4.4 Payment of royalties shall accompany each statement submitted in accordance with Paragraph 4.3 above.
- 4.5 If the manufacture, use or sale of a LICENSED PRODUCT in a particular country infringes a dominant patent of a third party, CIBA CORNING shall, upon written notice to MILES, have the right to deduct from royalty due MILES on account of sales of such LICENSED PRODUCT in such country any royalty required to be paid to such third party to continue the manufacture, use and sale thereof, provided, however, that any such deduction shall not exceed fifty-percent (50%) of such royalty due MILES. For the purposes of this Paragraph, a dominant patent shall mean a patent having a claim that is of such breadth that there is no

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subject matter of any claim in the LICENSED PATENTS in such country that could be made, used and sold without infringing such patent.

- 4.6 If royalties are not paid when due, interest shall be accrued on the unpaid royalties from the date due until paid, at a rate per annum which shall be the lesser of either:
  - a) the prime rate of the Citibank, N.A., New York, then in force for short-term borrowing; or
  - b) the maximum legal rate then permitted under the laws of the Commonwealth of Massachusetts.
- 4.7 All amounts due hereunder shall be payable in United States dollars. All royalty due as a result of sales in countries foreign to the United States shall be converted for calculation purposes into equivalent United States dollars at the exchange rate of Citibank, N.A., New York, at the close of business on the last business day of the quarterly reporting period.

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## ARTICLE 5

# MILES' PATENTS

5.1 MILES shall pay for all expenses in prosecuting, maintaining, and litigating the LICENSED PATENTS and LICENSED PATENT APPLICATIONS. MILES shall

maintain the LICENSED PATENTS in all countries in which CIBA CORNING is selling LICENSED PRODUCT and paying MILES royalty therefor.

- 5.2 CIBA CORNING shall provide MILES with any reasonable assistance in furtherance of MILES' performance in Paragraph 5.1 above, provided that MILES requests such assistance in writing and is willing to either pay CIBA CORNING or credit CIBA CORNING against royalties for CIBA CORNING's reasonable expenses in providing such assistance.
- 5.3 MILES warrants that it has good, clear title to the LICENSED PATENTS and LICENSED PATENT APPLICATIONS.
- 5.4 MILES shall retain the exclusive right and power to institute and prosecute, at its sole discretion, actions for infringement of any LICENSED PATENT and to seek and receive any relief appropriate under the governing law. However, if during the term of the license granted to CIBA CORNING hereunder CIBA CORNING notifies MILES in writing of infringement by a third

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party of any LICENSED PATENT in a particular country on account of the manufacture, use or sale of a product substantially competitive with a then existing LICENSED PRODUCT sold by CIBA CORNING in such country, and MILES does not within a period of one (1) year from the date of such notice (a) institute legal action to attempt to abate such infringement or cause it to cease, or (b) cause such infringement to cease by means deemed appropriate by MILES other than legal action and including the grant of a license, then CIBA CORNING shall have the right to withhold any and all royalties due thereunder for sales of such LICENSED PRODUCT in such country after the end of such one (1) year period; provided, however, that if MILES shall institute legal action against one infringer of its LICENSED PATENTS, it shall not be obligated to institute legal action against a second or subsequent infringers during the pending of such action. If after CIBA CORNING has rightfully begun withholding royalty to MILES the infringement ceases for whatever reason, MILES shall have the right to reinstate the royalty due hereunder by written notice to CIBA CORNING, and if such cessation occurred as the result of legal action taken by MILES, CIBA CORNING shall, within ninety (90) days of such notice, pay MILES fifty-percent (50%) of all royalty withheld because of such infringement.

5.5 Except as provided expressly above, nothing in this Agreement shall be construed as:

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(a) A warranty or representation by MILES as to the scope or validity of any CLAIM in any LICENSED PATENT;

- (b) A warranty or representation by MILES that any product made, used, or sold by CIBA CORNING under any license granted hereunder is or will be free from infringement of patents of any third parties;
- (c) An obligation or requirement on the part of MILES to bring or prosecute any action or suit against any third party for infringement of any LICENSED PATENT;
- (d) Conferring a right to CIBA CORNING to use in advertising, publicity, or any other manner any trademark or trade name of MILES without specific written consent; or
- (e) A warranty or representation by MILES as to the safety or efficacy of any LICENSED PRODUCT made, used, or sold by CIBA CORNING.
- 5.6 CIBA CORNING shall mark LICENSED PRODUCTS with the appropriate patent numbers of the covering LICENSED PATENTS in compliance with the laws of the country in which such PRODUCTS are sold.

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#### ARTICLE 6

# TECHNOLOGY ACCESS

- 6.1 In further consideration of the license granted to CIBA CORNING under Article 2 above, MILES is granted limited, reasonable access, as defined by the provisions set forth below, to CIBA CORNING PROPRIETARY TECHNOLOGY to enable MILES at its discretion to develop and commercialize CHEMILUMINESCENT BINDING ASSAYS for use on INSTRUMENT SYSTEMS marketed by CIBA CORNING.
- 6.2 For so long as CIBA CORNING is engaged in research, development, manufacture, and/or marketing of CHEMILUMINESCENT IMMUNOASSAY products and/or INSTRUMENT SYSTEMS therefor, MILES and CIBA CORNING shall exchange information and materials under the confidentiality provisions of ARTICLE 8 hereof for the purpose of enabling MILES at its discretion to develop, commercialize and maintain CHEMILUMINESCENT BINDING ASSAYS for new analytes or using new assay methodologies (such new assays being referred to herein as MILES Assays, with the assays developed by CIBA CORNING being referred to herein as CIBA Corning Assays) which are compatible with CIBA CORNING INSTRUMENT SYSTEMS for CHEMILUMINESCENT IMMUNOASSAYS, while making CIBA CORNING aware in advance of such MILES Assays that MILES wishes to develop and commercialize. Examples of specific information and materials which are appropriate for exchange and which in

particular MILES shall need to know and/or have concerning the CIBA CORNING efforts are set forth in Exhibit B attached hereto.

- 6.3 MILES shall be granted [Confidential Treatment Requested] licenses and sublicenses under CIBA CORNING PROPRIETARY TECHNOLOGY relating to CHEMILUMINESCENT BINDING ASSAYS to perform research and development of MILES Assays as provided in Article 7 hereof.
- 6.4 Any materials needed by one party from the other in order to meet the above objectives shall be supplied in reasonable amounts and purchased at a [Confidential Treatment Requested].
- 6.5 The procedure for the exchanges referred to in Paragraph 6.2 above shall be as follows unless modified by an agreement in writing by both parties:
  - a) MILES and CIBA CORNING hereby designate Dr. Robert T. Buckler and Dr. Graham P. Lidgard as their respective Official Correspondents hereunder;
  - b) All documents shall be sent inter partes through the Official Correspondents;

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- c) All meetings shall be attended by the Official Correspondents or their designated alternate;
- d) Quarterly face-to-face meetings shall be scheduled through the Official Correspondents so as to discuss any progress by either party;
- e) Quarterly written reports of a summary nature on the progress by each party shall be exchanged between the Official Correspondents;
- f) Special interim meetings can be scheduled as needed and agreed upon through the agreement of the Official Correspondents; and
- g) Any change in Official Correspondent for a party shall be made by written notification to the other party.
- 6.6 In the event that MILES in cooperation with CIBA CORNING is successful in developing MILES Assays for the CIBA CORNING INSTRUMENT SYSTEMS and desires to proceed to have such Assay marketed for such INSTRUMENT SYSTEMS, the parties will engage in good faith discussions concerning the manufacture, labeling, and marketing of products for such Assays on a

case-by-case basis, it being understood that neither party shall require unreasonable terms in order to reach agreement. It is presently intended that:

- (1) The manufacture of Assay reagents and/or assembly of the finished product will be performed by the party which can do so most economically,
- (2) An appropriate MILES trade name or trademark will appear prominently on the product,
- (3) CIBA CORNING will use reasonable efforts to promote and market the product,
- (4) If the result of negotiation is that CIBA CORNING makes and sells a particular MILES Assay, then CIBA CORNING shall pay MILES [Confidential Treatment Requested] which in the normal case will be generally equal to the [Confidential Treatment Requested],
- (5) If the result of negotiation is that MILES makes and CIBA CORNING sells a particular MILES Assay, then a transfer price from MILES to CIBA CORNING shall be negotiated which in the normal course will provide

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Miles with a [Confidential Treatment Requested] and

- (6) If the result of negotiation is that each party makes one or more components of a particular MILES Assay and CIBA CORNING sells the finished product, then the transfer price or prices for goods transferred between the parties shall be negotiated and CIBA CORNING shall pay MILES a [Confidential Treatment Requested].
- 6.7 The design and development of the INSTRUMENT SYSTEMS and CIBA CORNING Assays shall be at the sole discretion of CIBA CORNING. MILES shall have no right to require any particular performance or design features, however, CIBA CORNING will reasonably consider the needs of MILES for performing MILES Assays on its INSTRUMENT SYSTEMS and if changes are made which incur additional costs to CIBA CORNING, MILES shall be required to pay its fair share of such costs which in appropriate cases may constitute the entire amount of such costs.

- 6.8 In the event that CIBA CORNING decides to end its marketing of INSTRUMENT SYSTEMS for which MILES Assays are being or have been developed, MILES shall have the right upon prompt written request to CIBA CORNING to receive the transfer of all necessary PROPRIETARY TECHNOLOGY from CIBA CORNING within a reasonable time to enable MILES to continue the manufacture and marketing of such INSTRUMENT SYSTEMS and the MILES and CIBA CORNING Assays. Appropriate compensation, including royalties, shall be paid by MILES for such transfer, which compensation shall be negotiated in good faith. CIBA CORNING shall have no obligation to transfer PROPRIETARY TECHNOLOGY to MILES for any INSTRUMENT SYSTEM that has no connection to any MILES Assay.
- 6.9 In the event that MILES decides to end its involvement with a particular MILES Assay after such has been commercially introduced for use on a CIBA CORNING INSTRUMENT SYSTEM, CIBA CORNING shall have the right upon prompt written request to MILES to receive the transfer of all necessary PROPRIETARY TECHNOLOGY from MILES within a reasonable time to enable CIBA CORNING to continue the manufacture and marketing of such MILES Assay, but only on INSTRUMENT SYSTEMS of CIBA CORNING. CIBA CORNING shall pay MILES appropriate compensation, including royalties, for such transfer, which compensation shall be negotiated in good faith.

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- 6.10 In the event that MILES sees a marketing opportunity for CHEMILUMINESCENT BINDING ASSAYS which would require the design and development of a new INSTRUMENT SYSTEM and [Confidential Treatment Requested] MILES shall pay CIBA CORNING appropriate compensation, including royalties, for such transfer, which compensation shall be negotiated in good faith.
- 6.11 ALL PROPRIETARY TECHNOLOGY resulting during the term hereof solely from the efforts of employees, officers or agents of one of the parties hereto shall be the property of such party and the other party hereto shall have no right or license with respect to such PROPRIETARY TECHNOLOGY except as expressly provided in this Agreement.
- 6.12 In the event that PROPRIETARY TECHNOLOGY results during the term hereof from the joint efforts of employees, officers, or agents of both parties, such PROPRIETARY TECHNOLOGY shall be the property of the party whose research and development efforts were most closely related to such PROPRIETARY TECHNOLOGY

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at the time of its creation. The other party hereto shall [Confidential Treatment Requested] If the owning party decides not to seek patent protection for such PROPRIETARY TECHNOLOGY, the other party shall have

the right to do so at its own expense and through counsel of its own choosing. If patent protection is sought, the non-filing party shall cooperate in the preparation, filing, and prosecution of covering patent applications without additional consideration. Furthermore, if the owning party declines to sue or license a third party for infringement after written notice by the other party, such other party shall have the right and power to do so at its own expense and through counsel of its own choosing.

## ARTICLE 7

#### LICENSES TO MILES

7.1 CIBA CORNING grants MILES [Confidential Treatment Requested] licenses and sublicenses under any PROPRIETARY TECHNOLOGY owned, controlled, or licensed to CIBA CORNING relating to chemiluminescent and instrument technology as used in CHEMILUMINESCENT BINDING ASSAYS needed by MILES to perform research and development of MILES Assays as contemplated under Paragraph 6.2 hereof.

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- 7.2 Any licenses and sublicenses to MILES pursuant to Paragraphs 6.6, 6.8 and 6.10 shall be negotiated in good faith and reduced to a written agreement. Neither party shall take a position in any such negotiations that would unreasonably restrict the commercialization of MILES Assays.
- 7.3 CIBA CORNING represents and warrants that it has the right and power to grant licenses and sublicenses to MILES under all PROPRIETARY TECHNOLOGY presently owned, controlled, or licensed to CIBA CORNING relating to CHEMILUMINESCENT BINDING ASSAYS, including, without limitation, the licenses held by CIBA CORNING [Confidential Treatment Requested]. Further, CIBA CORNING shall be obligated to use its best efforts to obtain the right to sublicense MILES under any PROPRIETARY TECHNOLOGY hereafter licensed to CIBA CORNING relating to CHEMILUMINESCENT BINDING ASSAYS. If hereafter CIBA CORNING negotiates with a third party to be granted a license under

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PROPRIETARY TECHNOLOGY relating to CHEMILUMINESCENT BINDING ASSAYS and such third party refuses to include a right to grant sublicenses in general, CIBA CORNING's best efforts shall require that [Confidential Treatment Requested].

#### CONFIDENTIALITY

- 8.1 All information and materials exchanged between the parties in performing hereunder shall be deemed CONFIDENTIAL MATTER as provided below.
- 8.2 CONFIDENTIAL MATTER received by a party from the other shall not be disclosed by such receiving party to any third party, or used by such receiving party for its benefit, or that of a third party, except as expressly provided herein.
  - 8.3 To be accorded treatment as CONFIDENTIAL MATTER, however, such MATTER:

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- (a) must be first disclosed to the receiving party in writing and plainly marked "Confidential", or similar words: or
- (b) if first disclosed orally, must be reduced to writing by the disclosing party and plainly marked "Confidential", or similar words, and delivered to the receiving party within ninety (90) days of its first oral disclosure to the receiving party; or
- (c) if a physical thing, must be marked "Confidential", or similar words, or be accompanied by a writing specifically identifying such thing as "Confidential".

Information and material provided by one party to the other hereunder which is not identified as "Confidential" as provided above shall be considered as given and received without any obligation of confidentiality or nonuse and the receiving party shall be free to use such information in any way it sees fit, subject only to any rights that the disclosing party may have under the Patent Laws.

8.4 The terms of this Agreement, including all Exhibits, shall be considered CONFIDENTIAL MATTER.

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8.5 This Agreement shall supersede the Letter of Confidentiality dated

May 13, 1986 between the parties, attached hereto as Exhibit C, and all information protected thereunder shall be considered CONFIDENTIAL MATTER hereunder and subject to the terms and conditions hereof.

- 8.6 The obligations of confidentiality and nonuse of this ARTICLE 8 shall not apply to information or material:
  - (a) Which is known by the receiving party prior to receipt from the disclosing party as evidenced by documents in the possession of the receiving party at the time of disclosure,
  - (b) Which, after receipt from the disclosing party, is disclosed to the receiving party by a third party having the legal right to do so,
  - (c) Which is available to the public at the time of receipt from the disclosing party,
  - (d) Which becomes available to the public after receipt from the disclosing party through no fault of the receiving party,

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- (e) Which is required, in the opinion of legal counsel of the receiving party, to be disclosed for securing approval of governmental health regulatory agencies, including but not limited to the U.S. Food and Drug Administration, to market products contemplated hereunder, provided that the receiving party shall use its reasonable efforts to seek to obtain from such agencies such protection for such information against public disclosure as may be legally available,
- (f) Which is required, in the opinion of legal counsel for the receiving party, to be disclosed for the filing of patent applications by the receiving party, provided that the disclosing party is timely advised of the receiving party's intention to include such information in a patent application of the receiving party and the disclosing party does not notify the receiving party within thirty (30) days of its objection to such disclosure,
- (g) Which is reasonably necessary to be disclosed by the receiving party to its individual agents or third parties who require knowledge hereof in order to perform their normal duties or services, such as legal counsel, certified public accountants, and the like.

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provided that such agents and third parties are advised of and acknowledge the confidential nature of such disclosure, or

(h) Which is otherwise reasonably necessary to be disclosed in order to

perform hereunder, including marketing and promotional activities relating to successfully developed Assays.

8.7 Each party shall use the same level of care in complying with the obligations hereof respecting CONFIDENTIAL MATTER as it does with respect to its own information of similar nature. The parties mutually represent and warrant that each and every employee who will have access to the other party's CONFIDENTIAL MATTER hereunder shall be under contractual obligation not to disclose or use such CONFIDENTIAL MATTER except as directed by such party.

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#### ARTICLE 9

### TERM AND TERMINATION

- 9.1 Either party may terminate this Agreement at anytime if the other party fails to perform any material covenant, condition, or limitation herein, provided such other party shall not have remedied its failure within sixty (60) days after receipt of written notice of such failure.
- 9.2 If performance of this Agreement or any part hereof by either party shall be rendered unenforceable or impossible under, or in conflict with any law, regulation, or official action by any government agency having jurisdiction over such party; then such party shall not be considered in default by reason of failure to perform and the validity of all remaining provisions hereof shall not be affected by such result.
- 9.3 CIBA CORNING may terminate that portion of this Agreement consisting of ARTICLES 2, 3, 4 and 5 concerning the nonexclusive license grant by MILES at any time for any reason upon ninety (90) days written notice to MILES, provided that any such termination shall not relieve CIBA CORNING of the obligation to pay royalties or make any other payments accruing to MILES prior to the effective termination date and further that the remaining

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portion hereof, particularly the provision of ARTICLES 6, 7 and 8 shall be unaffected and continue in full force and effect.

- 9.4 Unless earlier terminated by CIBA CORNING as provided in Paragraph 9.1 or 9.3 above, the provisions of ARTICLES 2, 3, 4 and 5 shall continue until the expiration of the last patent to expire in the LICENSED PATENTS.
- 9.5 The provisions of ARTICLES 6 and 7 shall remain in full force and effect until the parties mutually agree in writing to their termination, unless earlier terminated under the provisions of Paragraph 9.1 above,

provided, however, that the provisions of ARTICLES 6 and 7 shall terminate upon written notice by CIBA CORNING if MILES does not approach CIBA CORNING to negotiate for the commercialization of a MILES Assay under Paragraph 6.6 hereof within six (6) years of the effective date hereof or thereafter if no MILES Assays are sold for a continuous period of two (2) years. All obligations of confidentiality and nonuse created under ARTICLE 8 shall survive the termination of the provisions of ARTICLES 6 and 7 for three (3) years.

9.6 Neither party shall be liable to the other for any failure to perform or any delay in performance hereunder where such delay is occasioned by strikes or other labor difficulties, civil disorders, armed conflict, embargoes, fires, floods,

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accidents or other causes or any kind or extent beyond the control of such party.

## ARTICLE 10

#### NOTICES

10.1 Any notice required or permitted by this Agreement shall be in writing. A notice shall be considered served when deposited in the national postal system in a sealed envelope with sufficient postage affixed, registered, or certified with return receipt requested, and addressed to the party to whom such notice is directed at its post office address given below:

If to MILES: Miles Laboratories, Inc.

P.O. Box 40

Elkhart, IN 46515

Attention: (Official Correspondent)

and Director of Patents, Trademarks and Licensing

If to CIBA CORNING: Ciba Corning Diagnostics Corp.

67 North Street Medfield, MA 02051

Attention: (Official Correspondent)

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#### INTERPRETATION

- 11.1 This Agreement shall be construed and the rights of the parties hereunder shall be determined in the Commonwealth of Massachusetts, in accordance with the laws of the Commonwealth of Massachusetts.
- 11.2 All section captions or titles are inserted herein for ready reference only and are without contractual significance or effect.

#### ARTICLE 12

#### ASSIGNMENT

- 12.1 Except where the assignee is a successor in business, CIBA CORNING must have written consent from MILES in order to assign this Agreement.
- 12.2 Except where the assignee is a successor in business, MILES must have written consent from CIBA CORNING in order to assign this Agreement.

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### ARTICLE 13

## ENTIRE AGREEMENT

- 13.1 This writing constitutes the entire agreement between MILES and CIBA CORNING relating to the subject matter hereof. There are no understandings, representations, or warranties of any kind except as expressly set forth herein.
- 13.2 The Agreement may NOT be waived, altered, extended, or modified except by written agreement of the parties.

#### ARTICLE 14

## INDEPENDENT CONTRACTORS

14.1 The performance of each party thereunder is undertaken as an independent contractor and not as an agent or partner of the other party. Neither party shall enter into or incur, or hold itself out to third parties as having authority to enter into or incur on behalf of the other party, any contractual obligation, expense, or liability whatsoever.

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IN WITNESS WHEREOF, CIBA CORNING and MILES have duly signed and have made delivery to the other.

MILES LABORATORIES, INC.

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[CIBA-CORNING LETTERHEAD]

December 18, 1992

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Miles Laboratories, Inc. P.O. Box 40

Elkhart, IN 46515

Attention: Director of Patents, Trademarks and Licensing

RE: Licensing Agreement between Miles Laboratories, Inc. and Ciba Corning Diagnostics Corp.

Dear Sir or Madam:

Pursuant to Article 9.5 of our Agreement of December 18, 1986, Ciba Corning Diagnostics Corp. hereby gives Miles Laboratories, Inc. notice of termination of the provisions of ARTICLES 6 and 7 of that Agreement.

Sincerely,

Jeffrey Rudin Vice President and General Counsel

JR/gg

### [CONFIDENTIAL TREATMENT REQUESTED]

[Certain information has been omitted herein pursuant to a request for confidential treatment pursuant to Rule 24b-2.]

#### MAGNETOCLUSTER BINDING ASSAY TECHNOLOGY AGREEMENT

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by and between

BIOCLINICAL GROUP, INC.

and

CORNING GLASS WORKS

Dated as of January 21, 1983

# MAGNETOCLUSTER BINDING ASSAY TECHNOLOGY AGREEMENT

Dated as of January 21, 1983

BIOCLINICAL GROUP, INC. (herein called "BioClinical"), a Delaware corporation, having its principal place of business at 767-B Concord Avenue, Cambridge, Massachusetts 02138, and CORNING GLASS WORKS (herein called "Corning"), a New York corporation, having its principal place of business at Houghten Park, Corning, New York 14831, acting for and on behalf of its CORNING MEDICAL & SCIENTIFIC DIVISION, having its offices at Medfield Industrial Park, Medfield, Massachusetts 02052, hereby agree as follows:

1. BASIS FOR AGREEMENT. BioClinical has advised Corning (a) that BioClinical has developed methods and techniques for producing what are believed to be new and unique magnetically separable particles containing substances capable of binding other substances which, in turn, can be used for IN VITRO immunoassay and binding protein assay

systems (the "BioClinical Magnetocluster Binding Assay Technology"); and (b) that this development encompasses trade secrets and confidential information (the "BioClinical Confidential Information") as well as certain inventions on which BioClinical is applying for United States and foreign counterpart patent protection (the "BioClinical Patent Rights"). Corning has developed and markets world-wide a number of IN VITRO immunoassays and binding protein assay

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medical diagnostic products which Corning believes has advised BioClinical could benefit from use of the BioClinical Magnetocluster Binding Assay Technology. Upon verification of the applicability of the BioClinical Magnetocluster Binding Assay Technology to Corning's medical diagnostic products, Corning desires to acquire from BioClinical the exclusive right and license to use the BioClinical Confidential Information and BioClinical Patent Rights and to apply the BioClinical Magnetocluster Binding Assay Technology to IN VITRO diagnostic immunoassay and binding protein assay systems developed or to be developed by Corning. The purpose of this Magnetocluster Binding Assay Technology Agreement is to set forth the terms and conditions under which BioClinical is willing to grant such exclusive rights and licenses to Corning, and under which Corning is willing to receive such rights and licenses, for this field-of-use.

- 2. DEFINITIONS. For the purposes of this Agreement, the following terms, whether used in the singular or in the plural, shall have the following meanings:
- 2.1. AFFILIATE. The term "Affiliate" shall mean any entity in which a party owns or controls fifty percent (50%) or more of the voting securities, equity participation or beneficial interest.
- 2.2. BINDING ASSAY. The term "Binding Assay" shall mean a test to detect or measure the presence or amount of an analyte in a solution using as a mechanism the

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binding properties of the analyte and another substance for IN VITRO diagnostic testing.

2.3. BIOCLINICAL CONFIDENTIAL INFORMATION. The term "BioClinical Confidential Information" shall mean and collectively include all technical information which is owned by BioClinical, disclosed to Corning hereunder from time to time and which is included

in the BioClinical Magnetocluster Binding Assay Technology, to the extent that such information: (a) as of the date of disclosure to Corning, was not (1) known to Corning; or (2) disclosed in published literature; or (b) becomes generally available to industry; or (c) is subsequently obtained by Corning from a third party without binder of secrecy upon Corning, provided that Corning has no reason to believe that such third party is in breach of any confidentiality obligations to BioClinical. The term "BioClinical Confidential Information" does not include any confidential information relating solely to the Excluded Technology.

- 2.4. BIOCLINICAL IMPROVEMENTS. The term "BioClinical Improvements" shall mean and collectively include all improvements in or modifications to the BioClinical Magnetocluster Binding Assay Technology
- (a) which are made apart from any collaboration with Corning at any time either by BioClinical, by any BioClinical Affiliate, by any third party under contract to or for the benefit of

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BioClinical or any BioClinical Affiliate, or by any two or more of such parties; or

- (b) which are acquired by BioClinical or by any BioClinical Affiliate; or
- (c) which are licensed by any third party to BioClinical or to any BioClinical Affiliate with the right to grant sublicenses to non-affiliates without accounting to others.
- 2.5. BIOCLINICAL MAGNETIC PARTICLE TECHNOLOGY. The term "BioClinical Magnetic Particle Technology" shall mean and collectively include all technical information, including all inventions, methods, plans, processes, specifications, characteristics, raw material data, equipment design, know-how, experience, and trade secrets, (a) which was developed by or for BioClinical or any BioClinical Affiliate; and (b) which pertain to the production, processing and/or finishing of Uncoupled Magnetic Particles.
- 2.6. BIOCLINICAL MAGNETOCLUSTER BINDING ASSAY TECHNOLOGY. The term "BioClinical Magnetocluster Binding Assay Technology" shall mean and collectively include all technical information, including all inventions, methods, plans, processes, specifications, characteristics, raw material data, equipment design, know-how, experience and trade secrets (a) which was or which may be developed by or for BioClinical or any BioClinical Affiliate; and (b) which

pertains to (1) the production of magnetocluster particles used in Binding Assays or magnetically separable particles used in Binding Assays and/or (2) the use of such magnetocluster particles or magnetically separable particles in diagnostic kits and/or in components thereof, for IN VITRO immunoassays and/or protein-binding assays. The term "BioClinical Magnetocluster Binding Assay Technology" shall not include any technical information which relates solely to any of the Excluded Technology.

- 2.7. BIOCLINICAL PATENT RIGHTS. The term "BioClinical Patent Rights" shall mean and collectively include
- (a) all patentable inventions specifically pertaining to the BioClinical Magnetocluster Binding Assay Technology (1) which are subject to protection under the provisions of the Patent Act [Title 35, United States Code] and/or any foreign patent laws; (2) which were in existence on the effective date of this Agreement and/or which may be made at any time during the Contract Period prior to December 31, 1992; and (3) which are legally and/or beneficially owned and/or controlled by BioClinical; and
- (b) any and all applications for United States Letters Patent which may be filed at any time covering such patentable inventions, as well as any

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and all divisions, continuations, continuations-in-part and renewals thereof, any and all United States Letters Patent which may be granted thereon, any and all reissues and extensions thereof, and any and all foreign counterpart applications and/or Letters Patent granted thereon.

The term "BioClinical Patent Rights" shall not include any patentable inventions and/or patent rights relating solely to any of the Excluded Technology.

- 2.8. CONTRACT PERIOD. The term "Contract Period" shall mean the period beginning with the effective date of this Agreement and ending on the date on which this Agreement terminates in accordance with the provisions of Section 19 hereof.
- 2.9. CORNING CONFIDENTIAL INFORMATION. The term "Corning Confidential Information" shall mean and collectively include

- (a) all business information pertaining to Corning or to any Corning Affiliate which BioClinical may learn in connection with any audit of Corning's and/or any Corning Affiliate's records pursuant to the provisions hereof; and
- (b) all technical information which is disclosed by Corning to BioClinical to the extent that such information: (1) as of the date of disclosure to BioClinical, was not (i) known to BioClinical; or (ii)

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disclosed in published literature; or (2) becomes generally available to industry; or (3) is subsequently obtained by BioClinical from a third party without binder of secrecy upon BioClinical, provided that BioClinical has no reason to believe that such third party is in breach of any confidentiality obligations to Corning.

- 2.10. CORNING QUARTER. The term "Corning Quarter" shall mean the time encompassed by Period 1-3, 4-6, 7-10, and 11-13 of a Corning fiscal year, which approximates the calendar year. A Period shall mean a Corning standard four-week accounting period.
- 2.11. DESIGNATED BINDING ASSAYS. The term "Designated Binding Assays" shall mean and collectively include the Binding Assays listed in Schedule A.
- 2.12. EFFECTIVE DATE. The term "effective date of this Agreement" shall mean January 21, 1983.
- 2.13. EXCLUDED TECHNOLOGY. The term "Excluded Technology" shall mean and collectively include all technical information, including all inventions, methods, plans, processes, specifications, characteristics, raw material data, equipment design, know-how, experience, and trade secrets (a) which was or may be developed by or for BioClinical or any BioClinical Affiliate; and (b) which solely pertains to the use of Magnetocluster particles for any products (including any Excluded Products) other than

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for use as Magnetocluster Binding Assay Products. The term "Excluded Technology" shall not include any technical information which is contained in the BioClinical Magnetocluster Binding Assay Technology.

2.14. EXCLUDED PRODUCTS. The term "Excluded Products"

shall mean and collectively include any products made by coupling an organic or inorganic moiety to Uncoupled Magnetic Particles, to form Magnetocluster particles which are not Magnetocluster Binding Assay Products.

2.15. MAGNETOCLUSTER. The term "magnetocluster" shall mean those magnetic-gradient-dependent colloidal suspensions, within an appropriate solvent or carrier liquid, of ferrospinel compounds in which an organic and/or inorganic moiety is coupled by adsorptive and/or covalent bonding to a ferrospinel having the structure

## Fe(I)(I)(I)M(I)(I)(I)M(I)(I)M(O)(I)(I)O(4)

where the trivalent and divalent metal cations M(I)(I)(I) and M(o)(I)(I) each represents transition metals having an ionic radius small enough to fit within the interstitial sites located within such ferrospinel, the inorganic and/or organic moiety coupled to the ferrospinel being sufficiently insoluble in the solvent and/or carrier liquid to permit the magnetocluster to be separated from such solvent and/or carrier liquid by the application of a strong magnetic field gradient.

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- 2.16. MAGNETOCLUSTER BINDING ASSAY PRODUCTS. The term "Magnetocluster Binding Assay Products" shall mean and collectively include all products (a) which include Magnetoclusters used in a Binding Assay; and (b) which are used solely in diagnostic kits or components thereof for IN VITRO immunoassays and/or protein-binding assays. The term "Magnetocluster Binding Assay Products" shall not include any Excluded Products.
- 2.17. NET ROYALTIES. The term "Net Royalties" shall mean the net royalties actually received by Corning from non-affiliated third party licensees under any of the BioClinical Confidential Information and/or BioClinical Patent Rights after deduction of all reasonable legal costs actually incurred by Corning in the licensing of such BioClinical Confidential Information and/or BioClinical Patent Rights to such non-affiliated third party licensees.
- 2.18. NET SALES. The term "Net Sales" shall mean sales at the invoiced price of Magnetocluster Binding Assay Products after deduction of (a) all trade and quantity discounts actually allowed; (b) allowance or credits for returns; (c) sales commissions actually paid to non-affiliated third parties; and (d) sales or purchase or turnover taxes (if any) borne by Corning and its Affiliates but before any deduction for cash or prompt payment discounts.

- 2.19. PRIOR AGREEMENT. The term "Prior Agreement" shall mean the Agreement to Supply Information in Confidence, dated September 10, 1982, by and between Corning and BioClinical.
- 2.20. UNCOUPLED MAGNETIC PARTICLES. The term "Uncoupled Magnetic Particles" shall mean all magnetic ferrospinel particles (a) which embody or are made in accordance with the BioClinical Magnetic Particle Technology; and (b) which are suitable for utilization in Binding Assays.
- 3. REPRESENTATIONS AND WARRANTIES. The following provisions relate to representations and warranties by the parties:
- 3.1. BY BIOCLINICAL. BioClinical represents and warrants to Corning as follows:
- 3.1.1. CORPORATE STANDING. BioClinical is a corporation duly organized, validly existing, and in good standing under the laws of the State of Delaware.
- 3.1.2. CORPORATE POWER AND AUTHORIZATION. BioClinical has all necessary corporate power to enter into and perform its obligations under this Agreement and has taken all necessary corporate action under the laws of the State of Delaware and its certificate of incorporation and by-laws to authorize the execution and consummation of this Agreement.

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- $\,$  3.1.3. OWNERSHIP. BioClinical either legally or beneficially owns or controls the entire right, title, and interest in and to
- (a) the BioClinical Confidential Information, including the right (1) to grant licenses under any of the BioClinical Confidential Information; and (2) to preclude the unauthorized disclosure of any of the BioClinical Confidential Information; and
- (b) the BioClinical Patent Rights, including the right (1) to grant licenses under any of the BioClinical Patent Rights; and (2) to enforce any issued patent or patents of the BioClinical Patent Rights against any third parties infringing any claim or claims of any patents including in such Patent Rights.
- 3.1.4. NO LITIGATION. To the best of BioClinical's knowledge, there is no action, suit, claim, proceeding or governmental investigation pending or threatened against BioClinical with respect to

- 3.1.5. NO OPTIONS. There are no outstanding options or rights in any third party to acquire any of the BioClinical Confidential Information, BioClinical Improvements or the BioClinical Patent Rights to be licensed to Corning hereunder.
- 3.1.6. NO DEFAULT. To the best of BioClinical's knowledge, BioClinical is not in default with respect to any term or provision of any charter, by-law, mortgage, indenture, statute, rule or regulation applicable to it, or with respect to any order, writ, injunction, decree, rule or regulation of any court or administrative agency, which will preclude the performance of its obligations under this Agreement.
- 3.1.7. NO CONFLICT. Neither the execution nor delivery of this Agreement, nor the consummation of the transactions herein contemplated, nor the fulfillment of or compliance with the terms and provisions hereof will, to the best of BioClinical's knowledge, (1) violate any provisions of law, administrative regulation or court decree applicable to BioClinical; or (2) conflict with or result in a breach of any of the terms, conditions or provisions of or constitute a default under the certificate of incorporation or by-laws of

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BioClinical, or of any agreement or instrument to which BioClinical is a party or by which it is bound.

- 3.1.8. NO PRIOR DISCLOSURES. There have been no disclosures of BioClinical Magnetocluster Binding Assay Technology to any third parties whomsoever, and each employee of BioClinical having access to BioClinical Binding Assay Technology has executed and delivered to BioClinical an effective agreement whereby such employee will not disclose any such Technology except as directed by BioClinical.
- 3.2. BY CORNING. Corning represents and warrants to BioClinical, as follows:

- 3.2.1. CORPORATE STANDING. Corning is a corporation duly organized, validly existing, and in good standing under the laws of the State of New York.
- 3.2.2. CORPORATE POWER AND AUTHORIZATION. Corning has all necessary corporate power to enter into and perform its obligations under this Agreement and has taken all necessary corporate action under the laws of the State of New York and its certificate of incorporation and by-laws to authorize the execution and consummation of this Agreement.
- 3.2.3. NO DEFAULT. To the best of its knowledge, Corning is not in default with respect to any term or provision of any charter, by-law, mortgage, indenture, statute, rule or regulation

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applicable to it, or with respect to any order, writ, injunction, decree, rule or regulation of any court or administrative agency, which will preclude the performance of its obligations under this Agreement.

- 3.2.4. NO CONFLICT. Neither the execution nor the delivery of this Agreement, nor the consummation of the transactions herein contemplated, nor the fulfillment of or compliance with the terms and provisions hereof will, to the best of Corning's knowledge and belief, (1) violate any provision of law, administrative regulations or court decree applicable to Corning; or (2) conflict with or result in a breach of any of the terms, conditions or provisions of or constitute a default under the certificate of incorporation or by-laws of Corning, or any agreement or instrument to which Corning is a party or by which it is bound.
- 4. GRANT OF LICENSE. The following provisions relate to the licenses to be granted by BioClinical to Corning hereunder:
- 4.1 EXCLUSIVE LICENSE. Subject to the terms and conditions hereunder contained, BioClinical hereby grants to Corning the exclusive right and license throughout the world, with the right to grant sublicenses to others,

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(a) to produce, process or otherwise manufacture, to use, and to sell, Magnetocluster Binding Assay Products embodying or

made in accordance with any of the BioClinical Confidential Information and/or BioClinical Patent Rights;

- (b) to preclude the unauthorized disclosure of such BioClinical Confidential Information to any third parties; and
- (c) to enforce any issued patent or patents of such BioClinical Patent Rights against any third-party infringers who utilize such Patent Rights for the manufacture, use and/or sale of Magnetocluster Binding Assay Products.
- 4.2 EXCLUSIONS. Nothing contained in this Agreement shall be construed as granting Corning any right or license:
- (a) to produce, process or otherwise manufacture, to use, and to sell, any products other than Magnetocluster Binding Assay Products under the BioClinical Confidential Information and/or BioClinical Patent Rights;
- (b) to use the Excluded Technology and related confidential information and/or patent rights for any purpose whatsoever; and
- (c) to utilize BioClinical Magnetic Particle Technology to produce, process or otherwise

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manufacture, to use, and to sell, Uncoupled Magnetic Particles for any purpose other than for the manufacture, use and/or sale of Magnetocluster Binding Assay Products by Corning or any sublicensed Corning Affiliate in accordance with the provisions of Sections 4.1 and 4 hereof.

- 4.3 IRREVOCABILITY. After Corning has paid BioClinical all of the basic payments required pursuant to the provisions of Section 10 hereof, the exclusive license granted by BioClinical to Corning pursuant to the provisions of Section 4.1 and 4 hereof shall become irrevocable.
- 5. TECHNICAL DEMONSTRATIONS. The following provisions relate to technical demonstrations by BioClinical and Corning's acceptance of the feasibility of using the BioClinical Magnetocluster Binding Assay Technology:
- 5.1. CORNING'S SPECIFICATIONS. Corning has established performance specifications for the Designated Binding Assays listed in Schedule A, and Schedule B sets forth these performance specifications,

the dates for completion of the documentation and the format for the documentation, by which Corning shall require BioClinical to certify that it has met such performance specifications pursuant to the provisions of Section 5.2 hereof.

5.2. PERFORMANCE. As a condition precedent to the effectiveness of the license granted by BioClinical to Corning pursuant to the provisions of Section 4.1 hereof

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and as a condition concurrent to Corning's obligations to pay BioClinical pursuant to the provisions of Section 10 hereof, BioClinical shall demonstrate that it can meet the performance specifications for the Binding Assays listed in Schedule B within the time periods set forth in such schedule, using materials for such Binding Assays furnished to it by Corning. BioClinical shall document that is has met each performance specification for Binding Assays on Schedule B to Corning in accordance with the data format provided to it by Corning and shall certify to Corning that it has met the performance specifications for such Magnetocluster Binding Assay Product established by Corning pursuant to the provisions of Section 5.1 hereof.

5.3. ACCEPTANCE AND VALIDATION. Within twenty (20) days of receipt of BioClinical's certified documentation that it has met performance specifications for each particular Binding Assay in accordance with the provisions of Section 5.2 hereof, Corning shall notify BioClinical in writing either (a) that it has accepted the results set forth in such certified documentation as meeting its performance specifications for such Binding Assay; or (b) that it has rejected such results, particularly specifying the reasons for such rejection. In the event Corning rejects such results, BioClinical shall have sixty (60) days from the date of such notice of rejection to submit further documentation that it has

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complied with the Corning performance specification for such Magnetocluster Binding Assay Product to Corning's reasonable satisfaction.

5.4. DISCLOSURE OF EXISTING TECHNOLOGY. Upon the execution of this Agreement, BioClinical agrees to disclose promptly to Corning all existing BioClinical Magnetocluster Binding Assay Technology which BioClinical deems necessary or useful to enable Corning to produce, process or otherwise manufacture, to use, and to sell, Magnetocluster

5.5. CONSULTING SERVICES. Recognizing that Corning contemplates the continuing development of Magnetocluster Binding Assay Products during the Contract Period after Corning's acceptance of BioClinical's documentation pursuant to the provisions of Sections 5.2 and 5.3 hereof, during the period between January 1, 1984 and December 31, 1988 BioClincial shall make available to Corning the consulting services of a competent senior scientist and technologist employed by BioClinical, without charge to Corning, for an aggregate of one man-year time for each BioClinical employee. Corning agrees to reimburse BioClinical the reasonable travel costs and living expenses incurred by BioClinical in making such BioClinical employees available to Corning outside the area of Eastern Massachusetts.

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- 6. DISCLOSURE OF IMPROVEMENTS BY BIOCLINICAL. Throughout that part of the Contract Period commencing with the effective date of this Agreement and ending December 31, 1992, BioClinical agrees to disclose to Corning in writing all BioClinical Improvements.
- BIOCLINICAL'S RIGHT TO ACQUIRE SUBLICENSES. Whenever BioClinical or any BioClinical Affiliate hereafter successfully develops a new Magnetocluster Binding Assay Product for other than a Designated Binding Assay, BioClinical shall disclose to Corning in writing all data concerning such coupling. Within one hundred twenty (120) days following the date of such disclosure, Corning shall notify BioClinical in writing either (a) that it rejects the resultant product for inclusion in its product line of clinical immunoassays; or (b) that it desires to manufacture, to use, and to sell, such product or products under its licenses on enumerated terms and conditions (the "Corning Proposal") proposed by Corning, which proposal shall be either accepted or rejected by BioClinical within sixty (60) days after receipt. If Corning rejects such product or if BioClinical rejects the Corning Proposal, then Corning shall grant to BioClinical such royalty-free sub-licenses under BioClinical Confidential Information, BioClinical Improvements and BioClinical Patent Rights as may be necessary to enable BioClinical to make, use and sell such product throughout the world for the life of such rights.

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8. RESTRICTIONS ON DISCLOSURE AND USE OF CONFIDENTIAL INFORMATION. The following provisions relate to restrictions on the disclosure and the use of Confidential Information by the parties:

- 8.1. RESTRICTIONS BINDING ON BIOCLINICAL. BioClinical agrees as follows:
- 8.1.1. CONFIDENTIALITY. BioClinical agrees to treat as confidential and to use only in the conduct of its business (a) all BioClinical Confidential Information which BioClinical has disclosed to Corning under the Prior Agreement and this Agreement; and (b) all Corning Confidential Information disclosed to it by Corning, except insofar as this Agreement authorizes the use of such BioClinical Confidential Information for other purposes.
- 8.1.2. NON-DISCLOSURE AND NON-USE OF BIOCLINICAL CONFIDENTIAL INFORMATION. Unless this Agreement is terminated prior to December 31, 1992, BioClinical agrees until December 31, 2002 (a) not to disclose any of the BioClinical Confidential Information to any unauthorized third parties; and (b) not to use any of the BioClinical Confidential Information (1) except in its continuing program to create BioClinical Improvements to the BioClinical Magnetocluster Binding Assay Technology, and (2)

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except as otherwise permitted under the provisions of Sections 7 and 11.5 hereof.

- 8.1.3. NON-DISCLOSURE AND NON-USE OF CORNING CONFIDENTIAL INFORMATION. Until either (1) December 31, 1992, or (2) ten (10) years from the date of initial disclosure to BioClinical of Corning Confidential Information, whichever occurs later, BioClinical agrees (a) not to disclose any of the Corning Confidential Information to any unauthorized third parties; and (b) not to use any of the Corning Confidential Information for the manufacture, use and/or sale of any products or for any other purpose whatsoever absent an express license from Corning.
- 8.2. RESTRICTIONS BINDING UPON CORNING. To protect BioClinical's remainderman rights to the BioClinical Confidential Information in the event of termination of this Agreement in accordance with Section 19, and to protect BioClinical's confidential information on the Excluded Technology, Corning agrees as follows:
- 8.2.1. CONFIDENTIALITY. Until December 31, 1992, Corning agrees to treat as confidential and to use only in the conduct of its business all BioClinical Confidential Information disclosed to Corning under the Prior Agreement and this Agreement, except insofar as this Agreement authorizes its use for other purposes.

- 8.2.2. NON-DISCLOSURE AND NON-USE. In the event this Agreement is terminated prior to December 31, 1992, Corning covenants that it will cease and refrain from disclosing or using any BioClinical Confidential Information disclosed to it by BioClinical under the provisions of the Prior Agreement or this Agreement until December 31, 2002.
- 9. FURTHER PROVISIONS CONCERNING THE FILING, PROSECUTION, AND MAINTENANCE OF PATENT RIGHTS. The following further provisions relate to the filing, prosecution and maintenance of the licensed BioClinical Patent Rights:
- 9.1. DOMESTIC PATENTS. BioClinical shall at its sole expense diligently pursue (a) filing and prosecuting any United States patent applications covering the BioClinical Patent Rights based on inventions made on or before its completion of the performance specifications for the Designated Binding Assays listed on Schedule B and the filing and prosecution of all divisions, continuations, continuations—in—part, reissues or re—examinations thereof; (b) prosecuting and defending any interference involving such domestic applications or any United States Letters Patent granted thereon; and (c) upon and after the grant of any Letters Patent on any of such applications, maintaining such Letters Patent in force and paying all fees and filing all necessary papers required for such purposes, provided that if the invention covered by any Letters Patent of such

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Patent Rights has become obsolete or has for any other reason become commercially unimportant, then BioClinical, at its sole option but subject to Section 9.4 may discontinue all further expenditures in connection with maintaining such Letters Patent in force. Within thirty (30) days after the filing by BioClinical of each United States patent application relating to BioClinical's Patent Rights, BioClinical shall provide a copy of such application to Corning.

9.2. FOREIGN PATENTS. Subject to the provisions of Section 9.3 hereof, BioClinical shall at its sole expense diligently pursue (a) filing any foreign counterpart applications and all divisions, continuations, and continuations—in—part thereof in Canada, France, Federal German Republic, Japan and the United Kingdom; (b) prosecuting such foreign applications and defending against conflicts or oppositions filed by third parties against such foreign applications; and (c) upon and after the grant of any Letters Patent on any of such applications,

maintaining such Letters Patent in force and paying all taxes and filing all necessary papers required for such purposes by the patent laws of the particular country in which such Letters Patent were granted, provided that if the invention covered by any Letters Patent for such Patent Rights has become obsolete or has for any other reason become commercially unimportant, then BioClinical, at its

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sole option but subject to Section 9.4, may discontinue all further expenditures in connection with maintaining such Letters Patent in force.

- 9.3. FOREIGN PATENTS REQUESTED BY CORNING. Within one hundred eighty (180) days after the filing by BioClinical of each such United States patent application relating to BioClinical's Patent Rights, BioClinical shall inform Corning of the additional countries (over those referred to in Section 9.2), if any, in which BioClinical intends to file corresponding patent applications. Upon written request by Corning, BioClinical agrees to file, prosecute and maintain foreign counterpart patent rights in any country or countries not covered by the provisions of Section 9.2 hereof. Whenever Corning requests BioClinical to perform such services, Corning agrees to bear all reasonable costs incurred in the filing, prosecution and maintenance of such foreign Patent Rights.
- 9.4. TRANSFER TO CORNING. In the event BioClinical exercises its right to discontinue all further expenses in connection with maintaining any such domestic or foreign patent applications or Letters Patent in force in accordance with Sections 9.1 and 9.2 hereof, then BioClinical shall provide notice thereof to Corning at least 120 days prior to the lapse of such rights. Upon timely written request, BioClinical shall timely assign such Letters Patent to Corning or to its nominee at least 90 days prior to the lapse of any such rights.

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- 10. BASIC PAYMENTS. Subject to the terms and conditions herein contained, in consideration for the exclusive license granted by BioClinical pursuant to the provisions of Section 4.1 hereof, Corning agrees to pay BioClinical basic payments in the aggregate amount of Four Million Three Hundred Thousand (\$4,300,000.00) Dollars, as follows:
- 10.1. INITIAL BASIC PAYMENT. Upon the acceptance by Corning pursuant to the provisions of Section 5.3 hereof of, BioClinical's certified documentation that it has met the performance specifications

for free thyroxine (T(4)) as set forth in Schedule B, Corning shall pay BioClinical the sum of One Hundred Thousand (\$100,000.00) Dollars.

- 10.2. SECOND BASIC PAYMENT. Upon acceptance by Corning pursuant to the provisions of Section 5.3 hereof of BioClinical's certified documentation that it has met the performance specifications for thyroid stimulating hormone (TSH) as set forth in Schedule B, Corning shall pay BioClinical the sum of Two Hundred Thousand (\$200,000.00) Dollars.
- 10.3. ENSUING BASIC PAYMENTS. Following the First and Second Basic Payments to BioClinical, subject to the prepayment provisions of Section 10.4 hereof and the provisions of Section 16 hereof, Corning agrees to pay the remaining Four Million (\$4,000,000.00) Dollars to BioClinical at the rate of Eighty-Three Thousand Three

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Hundred Thirty-Three Dollars and Thirty-Three Cents (\$83,333.33) a month for forty-eight (48) consecutive months beginning the first month Corning receives and accepts certified documentation from BioClinical pursuant to the provisions of Section 5.3 relating to the remaining Binding Assays in accordance with the performance specifications set forth in Schedule B. All such monthly payments shall be made on the last day of each month on which such monthly payment is due.

- 10.4. PREPAYMENT. Upon giving ten (10) days' written notice to BioClinical, Corning may at any time prepay the remaining amount due under Section 10.3 hereof at the net present value of such amount computed by applying the prime rate established by Citibank, N.A., New York, New York, in effect on the first day of the month on which Corning gives BioClinical notice of its election to prepay such remainder.
- 11. EARNED AND MINIMUM ROYALTIES. In further consideration for the exclusive license granted by BioClinical pursuant to the provisions of Section 4.1 hereof, Corning agrees to pay BioClinical earned and minimum royalties as follows:
- 11.1. EARNED ROYALTIES. In addition to the basic payments due BioClinical pursuant to the provisions of Section 10 hereof, Corning Agrees to pay BioClinical earned royalties at the rate set forth in the following

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Royalty Schedule on all Net Sales of Magnetocluster Binding Assay

Products sold by Corning and by its sublicensed Affiliates which embody or are made in accordance with the BioClinical Confidential Information (including all BioClinical Improvements) and/or BioClinical Patent Rights:

#### ROYALTY SCHEDULE

- [A] With respect to the Magnetocluster Binding Assay Products based on Binding Assays listed in Schedule A, the royalty rates shall be as follows:
- [1] On the first [Confidential Treatment Requested] of Net Sales of such Magnetocluster Binding Assay Products, the royalty rate shall be [Confidential Treatment Requested];
- [2] On the next [Confidential Treatment Requested] of Net Sales of such Magnetocluster Binding Assay Products, the royalty rate shall be [Confidential Treatment Requested];
- [3] On the next [Confidential Treatment Requested] of Net Sales of such Magnetocluster Binding Assay Products, the royalty rate shall be [Confidential Treatment Requested]; and
- [4] On all Net Sales of such Magnetocluster Binding Assay Products in excess of [Confidential Treatment Requested], prior to [Confidential Treatment Requested] the royalty rate shall be [Confidential Treatment Requested].
- [B] With respect to the Magnetocluster Binding Assays other than those listed in Schedule A and which have been independently developed by Corning in accordance with the Corning Improvements, the royalty rate shall be either (1)

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three percent (3%) of the Net Sales of such Magnetocluster Binding Assay Products through December 31, 1992; or (2) the prevailing royalty rate set forth in subparagraph [A] above, whichever rate is higher.

- [C] With respect to Magnetocluster Binding Assays other than those listed in Schedule A and which have been independently developed by BioClinical in accordance with the BioClinical Improvements and accepted by Corning pursuant to the provisions of Paragraph 7 hereof, the royalty rate shall be that mutually agreeable to BioClinical and Corning based on BioClinical's acceptance of the Corning Proposal.
- 11.2. CONVERSION TO DOLLAR AMOUNTS. For the purposes of computing the applicable royalty payments in accordance with the provisions of Section 1.1 hereof, all Net Sales of Magnetocluster

Binding Assay Products which are invoiced in currencies other than United States funds shall be converted to dollar amounts by multiplying the unit sales represented by each such transaction times the average dollar-denominated value of such unit sales during the same period.

11.3. SUBLICENSES. In the event Corning grants any sublicenses to any non-affiliated third parties under the BioClinical Magnetocluster Binding Assay Technology (including any BioClinical Improvements), BioClinical Confidential Information and/or BioClinical Patent Rights

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at any time during the Contract period, then for each such sublicense Corning further agrees to pay BioClinical additional earned royalties at a rate equal to three-fourths (3/4) of the Net Royalties collected by Corning under such sublicense.

- 11.4. WHEN SALE MADE. For the purposes of this Agreement, Magnetocluster Binding Assay Products made by Corning shall be considered sold (a) when billed out to a customer other than to a Corning Affiliate; or (b) when transferred or sold by Corning to a Corning Affiliate, except that upon the termination of this Agreement in accordance with the provisions of Section 19 hereof, all Magnetocluster Binding Assay Products manufactured and placed in inventory on or prior to the date of such termination which shall not have been billed out prior thereto shall be considered sold and therefore subject to royalty. Royalties paid on Magnetocluster Binding Assay Products not accepted by the customer and returned to Corning or to the particular sublicensed Corning Affiliate shall be credited against and deducted from future royalties, PROVIDED, HOWEVER, that if such returned Magnetocluster Binding Assay Products are resold by Corning or by any sublicensed Corning Affiliate, royalties shall be paid thereon.
- 11.5. MINIMUM ROYALTIES. In the event that the earned royalties paid by Corning to BioClinical pursuant to

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the provisions of Section 11.1 hereof in any calendar year of the Contract Period do not equal or exceed the Minimum Royalty Schedule set forth in Schedule C, then Corning may elect either

(a) to continue its exclusive license under the provisions of Section 4.1 hereof by paying BioClinical the difference between the Earned Royalty paid BioClinical for such calendar year

and the amount for such calendar year set forth in Schedule C, such difference to be paid to BioClinical within sixty (60) days after the end of such calendar year; or

- (b) to grant BioClinical and its Affiliates an irrevocable, royalty-free right and license, with no right to grant sublicenses to others, to produce, process or otherwise manufacture, to use, and to sell, throughout the world, Magnetocluster Binding Assay Products embodying or made in accordance with the BioClinical Confidential Information (including BioClinical Improvements) and/or BioClinical Patent Rights.
- 11.6. CARRYOVER CREDIT. If for any calendar year the earned royalty paid or payable by Corning exceeds the minimum royalty for that year, such excess shall be available to Corning in later years as a credit against minimum royalties due BioClinical.

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- 12. RECORDS, REPORTS, AND ROYALTY PAYMENTS. The following provisions relate to records, reports, and royalty payments:
- 12.1. RECORDS. Corning agrees to keep adequate and complete records showing all Magnetocluster Binding Assay Products sold with respect to which royalty is due under this Agreement. Such records shall include all information necessary to verify the total amount and computation of royalties due hereunder, and shall be open to inspection by BioClinical during reasonable business hours to the extent necessary to verify the amount thereof. Such inspection shall be made not more often than once each calendar year at the expense of BioClinical by a Certified Public Accountant appointed by BioClinical and to whom Corning has no reasonable objection, PROVIDED, HOWEVER, that if such inspection reveals that BioClinical was entitled to receive more than ten percent (10%) in excess of the amount reported by Corning to be due and payable to BioClinical during the period covered by such inspection, then Corning shall pay the cost of such audit. Corning shall not be required to retain said records for more than three (3) years after the close of any Corning Quarter.
- 12.2. REPORTS. Within sixty (60) days from the close of any Corning Quarter throughout the Contract Period until December 31, 1992, Corning shall furnish BioClinical

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with a written report, signed by an authorized employee of Corning,

showing (a) the dollar value of each Magnetocluster Binding Assay Product sold by Corning and by each of its sublicensees (if any) during the preceding Corning Quarter; (b) the dollar value of all Magnetocluster Binding Assay Products sold by Corning and by its sublicensees (if any) during the preceding calendar quarter-year; and (c) the amount of earned royalties due on Magnetocluster Binding Assay Products sold by Corning and its sublicensees (if any) during the preceding Corning Quarter, computed pursuant to the provisions of Sections 11.1 and 11.2 hereof.

- 12.3. ROYALTY PAYMENTS. With each such quarterly report, Corning shall remit to BioClinical the total amount of earned royalties shown thereby to be due and payable. If such earned royalties are unpaid when due and payable, interest shall be payable on the unpaid royalties from the due date until paid at a rate per annum which shall be at all times be the lesser of either (a) one percent (1%) in excess of the prime rate of the Citibank, N.A., New York, New York, then in force for short-term borrowings; or (b) the maximum legal rate then permitted under the laws of the State of New York.
- 13. SUPPLY OF UNCOUPLED MAGNETIC PARTICLES. To enable Corning to manufacture Magnetocluster Binding Assay Products in accordance with the exclusive license granted by

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BioClinical to Corning pursuant to the provisions of Section 4.1 hereof, BioClinical agrees to supply Corning's requirements for such Uncoupled Magnetic Particles as follows:

- 13.1. INITIAL REQUIREMENTS. Throughout the calendar year 1983, BioClinical agrees to sell to Corning, and Corning agrees to purchase from BioClinical, all of Corning's requirements of Uncoupled Magnetic Particles at a price of [Confidential Treatment Requested] Dollars per gram, dry-weight basis, f.o.b. Cambridge, Massachusetts. All Uncoupled Magnetic Particles furnished by BioClinical to Corning pursuant to the provisions of this Section 13.1 shall meet mutually agreed specifications.
- 13.2. SUBSEQUENT SUPPLY ARRANGEMENTS. During each calendar year of the Contract Period commencing January 1, 1984, and ending December 31, 1992, BioClinical and Corning agree to negotiate an annual requirements contract, satisfactory in form and substance to each party, under which INTER ALIA, BioClinical would sell to Corning, all of Corning's requirements of Uncoupled Magnetic Particles for such calendar year at a price not to exceed BioClinical's direct manufacturing cost for the next preceding year plus [Confidential Treatment Requested] as determined in accordance with generally accepted accounting principles consistently applied by BioClinical. Corning shall have the right through

manufacturing cost from original records no more frequently than once annually. Corning shall bear the cost of such audit and shall reimburse BioClinical for out of pocket costs reasonably incurred thereby.

- give written notice to BioClinical (i) whenever control of the management of BioClinical shall change prior to January 1, 1993, by transfer of capital stock, merger, consolidation, amalgamation or otherwise, or (ii) at any time on or after December 1, 1991, that Corning elects to manufacture or have manufactured its requirements of Uncoupled Magnetic Particles and BioClinical agrees thereafter to disclose and license its Magnetic Particle Technology to Corning in accordance with the provisions of Section 13.4 hereof.
- 13.4. CONTINGENT DISCLOSURE AND LICENSE OF BIOCLINICAL MAGNETIC PARTICLE TECHNOLOGY. In the event either (1) that BioClinical is unable (for any reason, whether or not such inability may be a result of an event of force majeure) or unwilling to meet Corning's requirements for Uncoupled Magnetic Particles during any calendar year of the Contract Period commencing January 1, 1984, or (2) that Corning elects to manufacture or have manufactured its own requirements for Uncoupled Magnetic Particles pursuant to the provisions of Section 13.3 hereof, then BioClinical agrees

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- (a) to disclose to Corning within 30 days after Corning's written request therefore BioClinical Magnetic Particle Technology in sufficient detail to enable Corning to construct or to have constructed a turn-key plant to manufacture its requirements of Uncoupled Magnetic Particles; and
- (b) if the exclusive license granted pursuant to the provisions of Section 4.1 hereof has not been terminated, to grant Corning a non-exclusive, royalty-free right and license, with the right to grant sublicenses solely to the Corning Affiliates, to produce, process or otherwise manufacture, and to use, Uncoupled Magnetic Particles in accordance with BioClinical's Magnetic Particle Technology and/or any related confidential information and/or patent rights, solely for Corning's and for Corning's sublicensed Affiliate's manufacture of Magnetocluster Binding Assay Products and for no other purpose whatsoever.

- 14. EXTENSION OF SUBLICENSES. All sublicenses extended by Corning under any of the BioClinical Confidential Information and/or BioClinical Patent Rights shall include the following provisions:
- 14.1. RECORDS. The sublicensee shall (a) keep adequate and complete records showing the place of manufacture, and the net sales at each place, of all Magnetocluster Binding Assay Products sold by it pursuant

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to its sublicensee; (b) allow such records to be inspected at reasonable business hours by Corning; and (c) furnish Corning on or before the last day of each January, April, July and October with a signed written report, showing the places of manufacture and sale and the net sales at each place of all Magnetocluster Binding Assay Products sold or used by the sublicensee during the preceding calendar quarter-year.

- 14.2. CONFIDENTIALITY. The sublicensee shall agree to treat as confidential and to use only in the conduct of its business all BioClinical Confidential Information disclosed to it by Corning. The sublicensee shall further covenant that it will exercise every reasonable precaution to preclude the disclosure by any of its directors, officers, employees or agents to other parties of BioClinical Confidential Information disclosed to it by Corning.
- 14.3. NON-DISCLOSURE AND NON-USE. In the event that the sublicense agreement is terminated prior to December 31, 1992, the sublicensee shall agree that it will cease and refrain from disclosing or using any BioClinical Confidential Information disclosed to it by Corning until December 31, 2002.
- 15. INFRINGEMENT CHARGES AGAINST CORNING. The following provisions relate to infringement charges against Corning:

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15.1. CORNING'S OPTIONS. In the event any claim is made against Corning during the first five (5) calendar years of the Contract Period alleging that its manufacture of Magnetocluster Binding Assay Products in accordance with the BioClinical Confidential Information and/or BioClinical Patent Rights infringes any United States Letters Patent of a third party, Corning shall promptly notify BioClinical in writing and BioClinical shall grant Corning the option for a period of one hundred twenty (120) days from the date of such claim either

- (a) to negotiate directly with such third party for a license under the third party's patent, upon the election of which BioClinical will agree to reduce Corning's royalty payments pursuant to the provisions of Section 15.2 hereof; or
- (b) to have BioClinical, at BioClinical's own expense, undertake to settle such claim or to defend any legal proceedings based thereon, upon the election of which option BioClinical will agree (1) to undertake to settle such claim or defend such legal proceeding pursuant to the provisions set forth in Section 15.3 hereof; and (2) to reimburse Corning pursuant to the provisions set forth in Section 15.4 hereof.
- 15.2. CORNING'S RIGHT TO NEGOTIATE. In the event Corning elects to negotiate directly with such third

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party for a license under the third party's patent, BioClinical agrees to reduce Corning's royalty payments to BioClinical by the amount which Corning has to pay such third party for such patent license, provided that such reduction does not reduce the continuing royalties to be paid to BioClinical under this Agreement below seventy-five (75%) percent of the rates set forth in Section 11.1 of this Agreement and provided further that any royalty payments made by Corning to any such third parties shall be credited to Corning against Earned Royalties for the purpose of determining whether Corning has met the minimum royalty payment as provided in Schedule C.

15.3. BIOCLINICAL'S OBLIGATIONS TO DEFEND. In the event that Corning elects to have BioClinical undertake to settle such claim or to defend any legal proceedings based thereon, BioClinical agrees at its own expense to undertake to settle such claim or to defend any legal proceeding based thereon in the event settlement cannot be reached permitting Corning to manufacture Magnetocluster Binding Assay Products in accordance with the BioClinical Confidential Information and/or BioClinical Patent Rights, PROVIDED, HOWEVER, that if Corning declines to make any reasonable modifications (i.e., that do not materially and adversely affect the utility, marketability or value of the product) to the Magnetocluster Binding Assay Product(s) which BioClinical proposes be made to avoid the alleged

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infringement or to minimize the risk of liability therefor, BioClinical's obligations to settle such claim or to defend such legal

proceeding shall thereupon terminate. Throughout the pendency of such legal proceedings, Corning shall continue to pay royalties to BioClinical in accordance with the terms of this Agreement. Corning shall cooperate fully in any defense of such legal proceedings and shall, among other things, furnish information and evidence, including testimony by Corning, its agents and employees, as BioClinical may request with respect to the acts of Corning allegedly constituting infringement.

- 15.4. CORNING'S RIGHT IF INFRINGEMENT UPHELD. If any such legal proceedings are finally determined against Corning by a court of competent jurisdiction from which no appeal is taken within the time permitted for appeals, and if the adjudication is such that Corning cannot make, use or sell Magnetocluster Binding Assay Products in accordance with the BioClinical Confidential Information and/or BioClinical Patent Rights licensed hereunder without infringing the United States Letters Patent held infringed in such legal proceedings, then Corning may elect either
- (a) to terminate this Agreement forthwith by written notice to BioClinical, in which event BioClinical shall reimburse Corning for damages assessed against and paid by Corning in such legal

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proceedings to the extend of royalties theretofore paid under Section 11.1 of this Agreement; or

- (b) to continue this Agreement, in which event (1) BioClinical shall reimburse Corning for damages assessed against and paid by Corning in such legal proceedings to the extent of royalties theretofore paid under Section 11.1 of this Agreement; and (2) thereafter, Corning shall continue to pay royalties to BioClinical throughout the remainder of the Contract Period at fifty percent (50%) of the rates set forth in Section 11.1 of this Agreement.
- 16. CONTINGENT REDUCTION OF ROYALTIES. If no United States patent covering BioClinical Magnetocluster Binding Assay Technology issues on or before December 31, 1986 or if such patent issues but is declared invalid or unenforceable during the Contract Period, or if Corning is not using such patent, or if a substantial amount of the BioClinical Confidential Information licensed hereby to Corning shall become public information without breach of this Agreement, and a third party is using or selling Magnetocluster Binding Assay Products in the United States that compete with Magnetocluster Binding Assay Products sold by Corning resulting in gross revenues to such party in excess of (i) One Million Dollars (\$1,000,000) per year for all such Magnetocluster Binding Assay

Assay and as to which Products payments are being made by Corning to BioClinical under Sections 10 and 11 hereof, then future payments to be made under Sections 10 and 11 shall be reduced to one-half of the amounts therein provided.

- PRODUCT LIABILITY INDEMNIFICATIONS. Neither BioClinical nor any of its subsidiaries or other affiliates assume any responsibility for the manufacture or product specifications or end-use of any products which are manufactured by or for or sold by Corning or by any sublicensed Corning Affiliate under the BioClinical Magnetocluster Binding Assay Technology, BioClinical Confidential Information and/or BioClinical Patent Rights. All warranties in connection with such products shall be made by Corning (or by the particular Corning Affiliate involved) as manufacturer and/or seller and shall not directly or impliedly obligate BioClinical or any of its subsidiaries or other affiliates. Corning hereby indemnifies and hold harmless BioClinical, its subsidiaries and other affiliates rom any claim by third parties alleging that the manufacture, recommended use, deliver or operating performance of any Magnetocluster Binding Assay Products have failed to comply with any warranty or contract between Corning (or the Corning Affiliates) and such third party.
- 18. ARBITRATION. In the event any dispute shall arise between BioClinical and Corning with respect to any of the terms and conditions of this Agreement, then such dispute shall be submitted and finally settled by arbitration which

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shall be held in Boston, Massachusetts, pursuant to the prevailing Rules of the American Arbitration Association. The arbitrators shall include one nominee of BioClinical and nominee of Corning and a third person jointly selected by said nominees. In the vent the respective nominees of BioClinical and Corning are unable to jointly select such third person, then BioClinical and Corning shall request the American Arbitration Association at Philadelphia, Pennsylvania, to designate the third arbitrator.

19. TERM AND TERMINATION. The following provisions shall relate to the term and termination of this Agreement:

- 19.1. TERM. Unless sooner terminated in a manner herein provided, this Agreement shall continue in force until either (a) the last-to-expire of any patent included in BioClinical Patent Rights; or (b) December 31, 1997 if no patents are included in BioClinical Patent Rights.
- 19.2. TERMINATION. This Agreement may be terminated at any time prior to the term set forth in Paragraph 19.1 hereof, as follows:
- 19.2.1. BY CORNING. In the event either that BioClinical fails to meet performance specifications for each of the Binding Assays in Schedule B in accordance with the provisions of Section 5.2 or Section 5.3 hereof, then Corning may terminate this Agreement by giving BioClinical sixty

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- (60) days' written notice setting forth the effective date of such termination.
- 19.2.2. BY BREACH. In the event either party shall materially breach any of the terms, conditions and agreements contained herein to be kept, observed and performed by it, then the other party may terminate this Agreement, at its option and without prejudice to any of its other legal and equitable fights and remedies, by giving the party which committed the breach sixty (60) days' notice in writing, particularly specifying the breach, unless the notified party within such sixty (60) day period shall have cured the breach.
- 19.2.3. BY BANKRUPTCY. In the event (1) BioClinical shall become insolvent or shall suspend business, or shall file a voluntary petition or any answer admitting the jurisdiction of the Court and the material allegations of, or shall consent to an involuntary petition pursuant to or purporting to be pursuant to any reorganization or insolvency law of any jurisdiction, or shall make an assignment for the benefit of creditors, or shall apply for or consent to the appointment of a receiver or trustee of a substantial part of its property, and (2) no BioClinical Affiliate shall undertake to assume BioClinical's obligation under the provisions of this

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Agreement within ninety (90) days from the date on which BioClinical becomes so disabled, then to the extent permitted by law Corning may

thereafter immediately terminate this Agreement by giving written notice of termination to BioClinical.

- 20. MISCELLANEOUS PROVISIONS. The following miscellaneous provisions shall apply to this Agreement:
- 20.1. INDEPENDENT CONTRACTORS. No agency, partnership or joint venture is hereby established. Neither BioClinical nor Corning shall enter into, or incur, or hold itself out to third parties as having authority to enter into or incur on behalf of the other party any contractual obligations, expenses or liabilities whatsoever.
- 20.2. NOTICES. All notices and communications provided for hereunder shall be in writing and shall be mailed or delivered to the business address of the respective parties aforementioned, or to such other address as either party shall designate in writing to the other.
- 20.3. BENEFITS. All terms and provisions of this Agreement shall bind and inure to the benefit of the parties hereto and to their respective successors and assignees.
- 20.4. GOVERNING LAW. This Agreement shall be executed within, governed by and interpreted in accordance with the laws of the State of New York.
  - 20.5. COUNTERPARTS. This Agreement shall be

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executed simultaneously in multiple counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same agreement.

- 20.6. ENTIRE UNDERSTANDING. This Agreement constitutes the entire understanding between the parties hereto with respect to the subject matter hereof. No modifications, extensions, or waiver of any provisions hereof or any release of any right hereunder shall be valid, unless the same is in writing, contains reference to this Agreement and sets forth the plan or intention to modify same, and is consented to by all parties hereto.
- 20.7. HEADINGS. The headings of this Agreement are intended solely for convenience of reference and shall be given no effect in the construction or interpretation of this Agreement.

IN WITNESS WHEREOF, BioClinical and Corning have caused their respective corporate seals to be hereto affixed and duly witnessed and these presents to be signed by their respective corporate officers thereunto duly authorized.

BIOCLINICAL GROUP, INC.

	БУ
	Signed at Norwood, Mass. on the 21st day of January, 1983
ATTEST: [SEAL]	
	-46-
	CORNING GLASS WORKS
	BySigned at Norwood, Mass. on the 21st day of January, 1983
ATTEST: [SEAL]	
	-47-