

# CERUS CORP

## FORM 10-Q (Quarterly Report)

Filed 05/09/01 for the Period Ending 03/31/01

Address	2550 STANWELL DRIVE CONCORD, CA 94520
Telephone	9252886000
CIK	0001020214
Symbol	CERS
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

# CERUS CORP

## FORM 10-Q (Quarterly Report)

Filed 5/9/2001 For Period Ending 3/31/2001

Address	2411 STANWELL DR CONCORD, California 94520
Telephone	925-288-6000
CIK	0001020214
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10 - Q**

(Mark One)

- ☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**  
**For the quarterly period ended March 31, 2001**
- or**
- ☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**Commission File Number 0-21937**

**CERUS CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
Incorporation or organization)

**68-0262011**  
(I.R.S. Employer  
Identification Number)

**2411 Stanwell Dr.**  
**Concord, California 94520**  
(Address of principal executive offices, including zip code)

**(925) 288-6000**  
(Registrant's telephone number, including area code)

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

As of April 30, 2001 there were 14,119,982 shares of the Registrant's Common Stock outstanding.

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**CERUS CORPORATION**

**QUARTERLY REPORT ON FORM 10-Q  
THREE MONTHS ENDED MARCH 31, 2001**

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**PART I: FINANCIAL INFORMATION**

**ITEM I: FINANCIAL STATEMENTS**

**CERUS CORPORATION**

**CONDENSED BALANCE SHEETS**  
**UNAUDITED**  
(in thousands)

	March 31, 2001	December 31, 2000
Assets		
Current assets:		
Cash and cash equivalents	\$69,212	\$71,871
Short-term investments	10,902	18,389
Accounts receivable from a related party	177	267
Other current assets	1,161	512
Total current assets	81,452	91,039
Furniture and equipment, net of depreciation	2,906	2,994
Other assets	127	128
Total assets	\$84,485	\$94,161
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable to a related party	\$1,828	\$1,791
Accounts payable	3,457	4,279
Accrued expenses	6,458	6,055
Deferred revenue	964	-

Current portion of capital lease obligations	29	31
Total current liabilities	12,736	12,156
Capital lease obligations, less current portion	74	84
Redeemable convertible preferred stock	5,000	5,000
Total stockholders' equity	66,675	76,921
Total liabilities and stockholders' equity	\$84,485	\$94,161

See notes to condensed financial statements

**CERUS CORPORATION**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**UNAUDITED**  
(in thousands, except per share data)

	Three Months Ended March 31,	
	2001	2000
Revenue:		
Milestones and development funding	\$1,071	\$575
Government grants and cooperative agreements	373	52
Total revenue	1,444	627
Operating expenses:		
Research and development	11,318	7,071
General and administrative	2,379	1,739
Total operating expenses	13,697	8,810
Loss from operations	(12,253)	(8,183)
Interest income, net	1,188	665
Loss before provision for income taxes	(11,065)	(7,518)
Provision for income taxes	(100)	-
Net loss	\$(11,165)	\$(7,518)
Net loss per share - basic and diluted	\$(0.79)	\$(0.61)
Shares used in computing net loss per share - basic and diluted	14,097	12,282

See notes to condensed financial statements

**CERUS CORPORATION**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**UNAUDITED**  
(in thousands)

	Three Months Ended March 31,	
	2001	2000
Operating activities:		
Net loss	\$(11,165)	\$(7,518)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	280	141
Amortization of deferred compensation	-	7
Accrued cash dividend on preferred stock, payable to a related party	-	(166)

Changes in operating assets and liabilities:		
Accounts receivable from related a party	90	(292)
Other current assets	(649)	7
Other assets	1	-
Accounts payable to a related party	37	413
Accounts payable and accrued expenses	(419)	(268)
Accrued cash dividend on preferred stock, payable to a related party	-	166
Deferred revenue	964	-
Net cash used in operating activities	(10,861)	(7,510)
Investing activities:		
Purchases of furniture, equipment and leasehold improvements	(192)	(165)
Purchases of short-term investments	(988)	-
Maturities of short-term investments	8,475	17,969
Net cash provided by investing activities	7,295	17,804
Financing activities:		
Net proceeds from issuance of common stock	919	24,513
Repurchase of common stock	-	(1)
Payments on capital lease obligations	(12)	(8)
Net cash provided by financing activities	907	24,504
Net increase (decrease) in cash and cash equivalents	(2,659)	34,798
Cash and cash equivalents, beginning of period	71,871	3,537
Cash and cash equivalents, end of period	\$69,212	\$38,335

See notes to condensed financial statements

## CERUS CORPORATION

### NOTES TO CONDENSED FINANCIAL STATEMENTS UNAUDITED

#### Note 1 - Basis of Presentation

The accompanying unaudited condensed financial statements of Cerus Corporation have been prepared in accordance with generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accrual adjustments, considered necessary for a fair presentation have been included. Operating results for the three month period ended March 31, 2001 are not necessarily indicative of the results that may be expected for any future period.

These financial statements and notes should be read in conjunction with Cerus' audited financial statements and notes thereto for the year ended December 31, 2000 included in the company's 2000 Annual Report on Form 10-K.

#### Note 2 - Comprehensive Income (Loss)

Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income," requires that all items that are required to be recognized under accounting standards as comprehensive income (revenue, expenses, gains and losses) be reported in a financial statement that is displayed with the same prominence as other financial statements. Cerus does not have material components of other comprehensive income. Therefore, comprehensive loss is equal to net loss for all periods presented.

#### Note 3 - Net Loss per Share

Cerus' net loss per share has been calculated in accordance with Statement of Financial Accounting Standards No. 128, "Earnings per Share." Basic and diluted net loss per share has been computed using the weighted average number of common shares outstanding during the period. The effects of outstanding stock options and other convertible securities are excluded from the calculation of diluted net loss per share, as its inclusion would be antidilutive.

#### Note 4 - Revenue and Research and Development Expenses

Milestone and development funding revenue includes amounts recognized under development agreements with Baxter Healthcare Corporation, Kirin Brewery Company, Limited and the Consortium for Plasma Science. Baxter and the Consortium are related parties to Cerus. Revenue from related parties for the three months ended March 31, 2001 and 2000 was \$845,000 and \$575,000, respectively. Development funding revenue is recognized as the related project costs are incurred. Revenue related to milestones specified under development contracts is recognized as the milestones are achieved. Payments for achieved milestones are non-refundable and are not subject to future performance. Research and development expenses are recognized as incurred.

Revenue recognized under agreements with Baxter, Kirin and the Consortium for the three months ended March 31, 2001 and 2000 consisted of the following (in thousands):

	Three Months Ended March 31,	
	2001	2000
Milestones	\$36	\$-
Development funding	1,035	575
<b>Total milestones and development funding</b>	<b>\$1,071</b>	<b>\$575</b>

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

This discussion and analysis should be read in conjunction with Cerus' financial statements and accompanying notes included in this report and the company's 2000 audited financial statements and notes thereto included in its 2000 Annual Report on Form 10-K. Operating results for the periods presented are not necessarily indicative of results that may occur in future periods.

The following discussion includes forward-looking statements that involve risks and uncertainties. When used herein, the words "believe," "anticipate," "expect," "estimate" and similar expressions are intended to identify such forward-looking statements. There can be no assurance that these statements will prove to be correct. Certain important factors could cause actual results to differ materially from those discussed in such statements, including uncertainties associated with pre-clinical and clinical testing, market acceptance and other factors discussed below and under the caption "Risk Factors" elsewhere in this report. Cerus undertakes no obligation to update any of the forward-looking statements contained herein to reflect any future events or developments.

*Helinx* is a trademark of Cerus Corporation.

*INTERCEPT Blood System, INTERCEPT Platelet System, INTERCEPT Plasma System and INTERCEPT Red Blood Cell System* are trademarks of Baxter International, Inc.

### Overview

Cerus Corporation is developing medical systems and therapeutics that provide safer and more effective treatment options to patients. Cerus' product candidates are based on its proprietary Helinx™ technology for controlling biological replication. Cerus' most advanced programs are focused on systems to enhance the safety of the world's blood supply. These INTERCEPT Blood Systems, based on the Helinx technology, are designed to inactivate viruses, bacteria, other pathogens and harmful white blood cells. Cerus is also pursuing therapeutic applications of the Helinx technology to treat and prevent serious diseases.

Cerus is developing the INTERCEPT Platelet System, INTERCEPT Plasma System and the INTERCEPT Red Blood Cell System with its development and marketing partner, Baxter Healthcare Corporation. The INTERCEPT Blood Systems are intended to target and inactivate blood-borne pathogens, such as HIV and hepatitis B and C, as well as harmful white blood cells, while leaving the therapeutic properties of the blood components intact. The INTERCEPT Blood Systems inactivate a broad array of pathogens and have the potential to reduce the risk of transmission of pathogens for which testing is not completely effective or is not currently performed. Cerus believes that the INTERCEPT Blood Systems also have the potential to inactivate new pathogens before they are identified and before tests are developed to detect their presence in donated blood. An estimated four million units of platelets, seven million units of fresh frozen plasma (FFP) and 34 million units of red blood cells are transfused annually in the United States, Western Europe and Japan.

Cerus has completed its European Phase III (CE Mark) clinical trial, called euroSPRITE, of the INTERCEPT Platelet System with random donor platelets and submitted a CE Mark application for marketing approval of the INTERCEPT Platelet System in Europe in December 2000. Cerus is conducting a 20 patient ancillary clinical trial in Europe to qualify the system for its commercial configuration. Completion of this trial will be necessary before the system can receive marketing approval in Europe. Cerus is also conducting a 40 patient ancillary clinical trial in Europe to extend qualification of the system to platelets collected by Baxter's apheresis collection system. Cerus completed its Phase III clinical trial, called SPRINT, of the INTERCEPT Platelet System in the United States in March 2001. The INTERCEPT Plasma System is in

Phase III clinical trials in the United States, and the INTERCEPT Red Blood Cell System is in a Phase Ic clinical trial in the United States. Cerus' allogeneic cellular immune therapy (ACIT) program, designed to improve the outcome of bone marrow transplantation procedures through use of T-cells treated with the Helinx technology, is in Phase I clinical trials in the United States. Cerus' source plasma pathogen inactivation system and Epstein-Barr Virus (EBV) cellular vaccine program are in pre-clinical development.

Since its inception in 1991, Cerus has devoted substantially all of its efforts and resources to the research, development and clinical testing of medical systems based on its Helinx technology. Cerus has been unprofitable since inception and, as of March 31, 2001, had an accumulated deficit of approximately \$134.9 million. All of Cerus' product candidates are in the research and development stage, and Cerus has not received any revenue from product sales. Cerus must conduct significant research, development, pre-clinical and clinical evaluation and regulatory compliance activities on these product candidates that, together with anticipated general and administrative expenses, are expected to result in substantial losses at least until after commercialization. Cerus' ability to achieve a profitable level of operations in the future will depend on its ability to successfully complete development, obtain regulatory approvals and achieve market acceptance of the INTERCEPT Blood Systems. Cerus may never achieve a profitable level of operations. Further, under the agreements discussed below, a significant portion of development funding for the INTERCEPT Blood Systems is provided by Baxter based on an annual budgeting process. These agreements may be modified or terminated.

*Agreement with Baxter for development of the INTERCEPT Platelet System.* Cerus has a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Platelet System to inactivate viruses, bacteria and other infectious pathogens in platelets used for transfusion. This agreement provides for Baxter and Cerus generally to share system development costs equally, subject to mutually determined budgets established from time to time, and for Cerus to receive approximately 33.5% of revenue from sales of inactivation system disposables after each party is reimbursed for its cost of goods above a specified level. Baxter has an exclusive, worldwide distribution license and will be responsible for manufacturing and marketing the INTERCEPT Platelet System following regulatory approval. The agreement also provides for Baxter to make a \$5 million cash milestone payment to Cerus upon approval by the FDA of an application to market products developed under the platelet program, comparable approval in Europe or termination of the program.

*Agreement with Baxter for development of the INTERCEPT Red Blood Cell System and INTERCEPT Plasma System.* Cerus also has a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Red Blood Cell System and the INTERCEPT Plasma System to inactivate viruses, bacteria and other infectious pathogens in red blood cells and FFP for transfusion. This agreement provides for Baxter and Cerus generally to share INTERCEPT Red Blood Cell System development costs equally, subject to mutually determined budgets established from time to time. Cerus is solely responsible for funding the development costs of the INTERCEPT Plasma System. Baxter has an exclusive, worldwide distribution license and will be responsible for manufacturing and marketing the INTERCEPT Red Blood Cell System and INTERCEPT Plasma System following regulatory approvals. The agreement also provides for an equal sharing of revenue from sales of INTERCEPT Red Blood Cell System disposables, and for Cerus to receive 75% and Baxter to receive 25% of revenue from sales of INTERCEPT Plasma System disposables, after each party is reimbursed for its cost of goods and a specified percentage allocation, not to exceed 14% of revenue, is retained by Baxter for marketing and administrative expenses.

From inception through March 31, 2001, Cerus has received \$46.7 million in equity investments from Baxter and has recognized \$23.9 million in revenue from Baxter. Development funding is in the form of balancing payments made by Baxter to Cerus, if necessary, to reimburse Cerus for development spending in excess of the levels determined by Baxter and Cerus. Development funding revenue is recognized as the related project costs are incurred.

*Agreement with Kirin.* In January 2001, Cerus entered into a collaborative agreement with the Pharmaceutical Division of Kirin to develop and market products for stem cell transplantation based on Cerus' Helinx technology. Under the terms of the agreement, Cerus and Kirin will jointly develop the products. Cerus has received an initial license fee of \$1 million, and may receive additional payments upon achievement of development milestones. In addition, Kirin will fund all development expenses for the Asia-Pacific region and a portion of Cerus' development activities aimed at obtaining product approval in the United States. Upon product approval, Kirin will market the products in the Asia-Pacific region, including Japan, China, Korea and Australia, and Cerus will receive a specified share of product revenue, including a royalty and reimbursement of its cost of goods. Cerus retains all marketing rights for the rest of the world, including the United States and Europe.

*Agreement with the Consortium for Plasma Science.* In December 1998, Cerus and the Consortium for Plasma Science entered into an agreement for the development of a pathogen inactivation system for source plasma used for fractionation. The Consortium is co-funded by four plasma fractionation companies: Alpha Therapeutics Corporation, Aventis Behring, Bayer Corporation and Baxter. The Consortium, which is a separate entity from its members, provides research and development funding worldwide for technologies to improve the safety of source plasma. Under the agreement, the Consortium is funding development of Cerus' proprietary technology for use with source plasma, subject to a periodic review process. Subject to the Consortium meeting certain funding requirements, Cerus will pay the Consortium a royalty based on a percentage of product sales, if any. Development activities are ongoing under this agreement, which may be extended periodically upon mutual approval of a development plan and budget. There is no guarantee that the agreement will be extended.

## **Results of Operations**

### ***Three Month Period Ended March 31, 2001 and 2000***

*Revenue.* Milestone and development revenue from Baxter, Kirin and the Consortium increased 86% to \$1.1 million for the three months ended March 31, 2001 from \$0.6 million for the comparable period in 2000. The increase was principally from increased development revenue from Baxter for the INTERCEPT Red Blood Cell System, primarily as a result of increased expenses incurred by Cerus relative to Baxter in 2001.



Revenue earned under the agreements with Baxter is dependent on the relative spending by Cerus and Baxter on the programs for which development costs are shared. Cerus recognized milestone and development funding revenue from Kirin in 2001, which also contributed to the increase. Cerus recognized milestone revenue of \$36,000 in the three months ended March 31, 2001. There was no milestone revenue recognized in 2000.

Revenue from government grants and cooperative agreements increased 617% to \$0.4 million for the three months ended March 31, 2001 from \$0.1 million for the comparable period in 2000. The increase was primarily due to revenue recognized from a cooperative agreement with the Armed Forces of the United States entered into in February 2001. Cerus also has a grant from the National Institutes of Health which expires in September 2002. There can be no assurance that Cerus will receive additional government grants in the future.

Cerus anticipates that its sources of revenue until product sales occur will be limited to payments under collaboration agreements, including Cerus' development agreements with Baxter, Kirin and the Consortium, and payments from the United States government under cooperative agreement and research grant programs.

*Research and Development Expenses.* Research and development expenses increased 60% to \$11.3 million for the three months ended March 31, 2001 from \$7.1 million for the comparable period in 2000. The increase was due principally to the addition of scientific personnel and consultants and increased costs for clinical trials, pre-clinical safety studies and chemical manufacturing. Cerus anticipates that its research and development expenses will continue to increase as a Premarket Approval (PMA) application is prepared for the INTERCEPT Platelet System, Phase III clinical trials of the INTERCEPT Plasma System continue, additional clinical trials of the INTERCEPT Red Blood Cell System are initiated and research and development activity relating to its other programs increases.

*General and Administrative Expenses.* General and administrative expenses increased 37% to \$2.4 million for the three months ended March 31, 2001 from \$1.7 million for the comparable period in 2000. The increase was primarily attributable to the addition of administrative personnel and increased facilities expenses associated with expansion of Cerus' operations. Cerus expects its general and administrative expenses to continue to increase as development activities expand.

*Net Interest Income.* Net interest income increased 79% to \$1.2 million for the three months ended March 31, 2001 from \$0.7 million for the comparable period in 2000. The increase was attributable primarily to increased average cash and investments balances related to proceeds from the private placement of common stock to an institutional investor in August 2000. Cerus typically maintains substantial balances of cash equivalents and short-term investments to fund future research and development activities. Cerus expects to earn interest at market rates in proportion to the balances it maintains.

## **Liquidity and Capital Resources**

Cerus' sources of capital to date have consisted of public offerings and private placements of equity securities, payments received under its agreements with Baxter, Kirin and the Consortium, United States government grants and interest income. To date, Cerus has not received any revenue from product sales, and it will not derive revenue from product sales unless and until one or more products under development receives regulatory approval and achieves market acceptance.

At March 31, 2001, Cerus had cash, cash equivalents and short-term investments of \$80.1 million. Net cash used in operating activities was \$10.9 million for the three months ended March 31, 2001, compared to \$7.5 million for the same period in 2000, resulting primarily from the net loss of \$11.2 million during the period, offset by changes in other operating balances. Net cash provided by investing activities during the three months ended March 31, 2001 of \$7.3 million resulted principally from the maturities of \$8.5 million of short-term investments, offset by the purchases of \$1.0 million of short-term investments. Working capital decreased to \$68.7 million at March 31, 2001 from \$78.9 million at December 31, 2000, primarily due to decreased cash, cash equivalent and short-term investment balances.

Cerus believes that its available cash balances, together with anticipated cash flows from existing development and grant arrangements, will be sufficient to meet its capital requirements for at least the next 12 months. These near-term capital requirements are dependent on various factors, including the development progress of the INTERCEPT Blood Systems and other programs; payments by Baxter, Kirin, the Consortium and the federal government; and costs related to creating, maintaining and defending Cerus' intellectual property position. Cerus' long-term capital requirements will be dependent on these factors and on Cerus' ability to raise capital through public or private equity or debt financings or through additional collaborative arrangements or government grants, the achievement of milestones, regulatory approval and successful commercialization of the INTERCEPT Blood Systems and other products under development, competitive developments and regulatory factors. Future capital funding transactions may result in dilution to investors in Cerus. Capital may not be available on favorable terms, or at all. Cerus does not guarantee that it will be able to meet its capital requirements for this or any other period.

## **Financial Instruments**

Cerus maintains an investment portfolio of various issuers, types and maturities. These securities are generally classified as available for sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of stockholders' equity, if material. Unrealized gains and losses at March 31, 2001 and December 31, 2000 were not material. Cerus' investments primarily consist of short-term money market mutual funds, United States government obligations and commercial paper. Of Cerus' investments balance of \$80.1 million at March 31, 2001, approximately 86% have original maturity dates of less than 90 days and approximately 5% of this balance have original maturities of 90 days to one year. Cerus does not believe its exposure to interest rate risk to be material given the short-term nature of its investment portfolio.

## **Risk Factors**

Cerus' business faces significant risks. These risks include those described below and may include additional risks of which Cerus is not currently aware or which Cerus currently does not believe are material. If any of the events or circumstances described in the following risks actually occurs, Cerus' business, financial condition or results of operations could be harmed. These risks should be read in conjunction with the other information set forth in this report.

### ***Our products are in development, and there is a high risk of failure.***

We have no products that have received regulatory approval for commercial sale. Our product candidates are in various stages of development, and we face the risks of failure inherent in developing medical devices and biotechnology products based on new technologies. Our products must satisfy rigorous standards of safety and efficacy before the United States Food and Drug Administration and international regulatory authorities can approve them for commercial use. Our platelet, fresh frozen plasma, red blood cell and stem cell transplantation programs are undergoing clinical testing. Our other programs are still in the early stages of research and development. We will have to conduct significant additional research and pre-clinical (animal) and clinical (human) testing before we can file applications for product approval with the FDA and foreign regulatory agencies. Clinical trials in particular are expensive and have a high risk of failure. In addition, to compete effectively, our products must be easy to use, cost-effective and economical to manufacture on a commercial scale. Any of our product candidates may fail in the testing phase or may not attain market acceptance, which could prevent us from achieving profitability.

### ***If our pre-clinical and clinical trials are not successful, we will be unable to commercialize our products and generate revenue.***

We must provide the FDA and foreign regulatory authorities with pre-clinical and clinical data that demonstrate our products are safe and effective before they can be approved for commercial sale. It may take us several years to complete our testing, and failure can occur at any stage of testing. We cannot rely on interim results of trials to necessarily predict their final results, and acceptable results in early trials might not be repeated in later trials. Any trial may fail to produce results satisfactory to the FDA or foreign regulatory authorities. Pre-clinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to a program are successful.

### ***We may fail to complete our clinical trials on time or be unable to complete them at all.***

We typically rely on third-party clinical investigators to conduct our clinical trials and on other third-party organizations to perform data collection and analysis. As a result, we have less control over certain aspects that may delay:

- obtaining approvals from a study site's review board;
- training and qualifying personnel at the study site; and
- enrolling qualified subjects.

In addition, some of our clinical trials involve patient groups with rare medical conditions, which may make it difficult to identify and enroll a sufficient number of patients to complete the trials on time. Our product development costs will increase if we have delays in testing or approvals. Significant clinical trial delays could allow competitors to bring products to market before we do and impair our ability to commercialize our products.

### ***Because our product candidates have not been manufactured on a commercial scale, we face manufacturing uncertainties that could limit their commercialization.***

Our product candidates, and many of their components, have never been manufactured on a commercial scale. We intend to use third-party manufacturers to produce commercial quantities of the inactivation compounds to be used in our products. These compounds have never been produced in commercial quantities. The manufacturers will need to develop new methods and processes to manufacture these compounds on a commercial scale and demonstrate to us, the FDA and foreign regulatory authorities that their commercial scale manufacturing processes comply with government regulations. It may be difficult or impossible to economically manufacture our products on a commercial scale.

Baxter is responsible for manufacturing and assembling our pathogen inactivation systems. Baxter intends to rely on third parties to manufacture and assemble system components, many of which are customized and have not been manufactured on a commercial scale. Baxter has not produced the pathogen inactivation systems in commercial quantities and may not be able to manufacture and assemble them on an economical basis.

### ***We depend on a limited number of suppliers to manufacture our product candidates and their components.***

A limited number of suppliers manufacture our inactivation compounds for our use in product development, including clinical trials. We have contracted with one manufacturer to provide enough S-59, the inactivation compound we use in our platelet and fresh frozen plasma systems,

to meet our anticipated clinical trial and product development requirements. We have contracted with one manufacturer to produce an intermediate compound, S-301, which is used by another manufacturer which is producing S-303, the inactivation compound we use in our red blood cell systems. If any of these manufacturers cannot produce our compounds in the required quantities or to the required standards, we may face delays and shortfalls before we are able to identify alternate or additional manufacturers to meet these requirements. Also, any new manufacturer will have to prove both to us and to the FDA and foreign regulatory authorities that its manufacturing process complies with government regulations.

Baxter intends to purchase certain key components of the pathogen inactivation systems from a limited number of suppliers. While we believe there are alternative suppliers for these components, it would be expensive and time-consuming to establish additional or replacement suppliers for these components. If Baxter were unable to find adequate suppliers for these components, we may be required to redesign the systems, which could lead to additional testing and clinical trials. If we were required to redesign the products, our development costs would increase, and our programs could be delayed significantly.

***Our products may not achieve acceptance in the health care community.***

Even if our product candidates receive regulatory approval for commercial sale, physicians, patients and healthcare payors may not believe that the benefits of using our systems justify their additional cost, because the blood supply has become safer. We believe that our ability to successfully commercialize products will depend in part on the availability of adequate reimbursement for product costs and related treatment of blood components from governmental authorities and private health care insurers (including health maintenance organizations), which are increasingly attempting to contain health care costs by limiting both the extent of coverage and the reimbursement rate for new tests and treatments. In addition, our products may not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens may inhibit their acceptance. In addition, for logistical and financial reasons, the transfusion industry has not always integrated new technologies into their processes, even those with the potential to improve the safety of the blood supply. If our products fail to achieve market acceptance, we may never become profitable.

***We will need to develop and test additional configurations of our platelet pathogen inactivation system to address the entire market.***

We are developing our platelet pathogen inactivation system in the United States to treat apheresis platelets collected on Baxter's automated collection platform. Apheresis platelets are collected from a single donor using an automated collection machine. Currently, we estimate that the majority of platelets used in the United States are collected by apheresis, with the remainder prepared from pooled random donor platelets using a manual process. Blood centers in the United States preparing random donor platelets may be reluctant to switch to apheresis collection, and the FDA may require us to make our systems compatible with random donor platelets. If we are required to develop a platelet pathogen inactivation system compatible with random donor platelets, or if we decide to address the random donor platelet market in the United States, we will need to perform additional product development and testing, including clinical trials. These development activities would increase our costs significantly, and may not be successful. In addition, FDA regulations limit the time from pooling to transfusion to four hours to minimize the proliferation of bacterial contamination in the pooled product. As a result, most pooling occurs in hospitals. Our platelet system is designed for use in blood centers, not at hospitals, and is intended to permit storage of platelets for five days after treatment and pooling. The FDA's time limit between pooling and transfusion currently precludes the use of our system with pooled random donor platelets. Although our system is designed to reduce the risk of bacterial contamination, we cannot predict whether the FDA would remove this process time constraint to allow our system to be used with pooled random donor platelets.

Baxter is one of three primary manufacturers of equipment for the collection of apheresis platelets. The equipment, design and materials used to collect the platelets vary from manufacturer to manufacturer. We are conducting our pre-clinical and clinical studies in the United States for apheresis platelets collected using only Baxter's equipment and materials. As a result, market acceptance of our platelet system for apheresis platelets will depend on market acceptance of Baxter's collection equipment. Blood centers using other equipment may be reluctant to replace their existing equipment, and the regulatory agencies may require us to make our systems compatible with other equipment. If we are required to develop platelet pathogen inactivation systems compatible with other manufacturers' equipment, or if we decide to address this broader market, we will need to perform additional product development and testing, including clinical trials. These development activities would increase our costs significantly, and may not be successful.

We are conducting our pre-clinical and clinical studies for buffy coat platelets collected using only Baxter's platelet collection and pooling materials. As a result, market acceptance in Europe of our platelet system for buffy coat platelets will depend on market acceptance of Baxter's platelet collection and pooling sets. We are conducting a clinical trial of our pathogen inactivation system for apheresis platelets in Europe using only Baxter's equipment and materials. As a result, market acceptance of our platelet system for apheresis platelets in Europe will depend on market acceptance of Baxter's collection equipment.

***A small number of customers will determine market acceptance of our products.***

The market for our pathogen inactivation systems is dominated by a small number of blood collection centers. In the United States, the American Red Cross collects and distributes approximately 50% of the nation's supply of blood and blood components. Other major United States blood centers include the New York Blood Center and United Blood Services, each of which distributes approximately 6% of the nation's supply of blood and blood components. In Western Europe and Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. Failure to properly market, price or sell our products to any of these large customers could significantly diminish potential product revenues.

***We rely heavily on Baxter for development funding, manufacturing, marketing and sales.***

We have development and commercialization agreements with Baxter for our platelet, fresh frozen plasma and red blood cell pathogen inactivation systems, and we rely on Baxter for significant financial and technical contributions to these programs. Our ability to develop, manufacture and market these products successfully depends significantly on Baxter's performance under these agreements.

- *Baxter can terminate our agreements or fail to perform* . Baxter can terminate the agreements without cause under certain circumstances. A development program under the agreements may be terminated by either party on 90 days' notice in the case of the platelet program, or 270 days' written notice in the case of the FFP or red blood cell program. If Baxter terminates the agreements or fails to provide adequate funding to support the product development efforts, we will need to obtain additional funding from other sources and will be required to devote additional resources to the development of our products. We cannot assure you that we would be able to find a suitable substitute partner in a timely manner, on reasonable terms or at all. If we fail to find a suitable partner, our research, development or commercialization of certain planned products would be delayed significantly which would cause us to incur additional expenditures.
- *We rely on Baxter for manufacturing and supplying components of our pathogen inactivation systems*. Under the terms of our agreements, Baxter is responsible for manufacturing or supplying the disposable units, such as blood storage containers and related tubing, as well as any device associated with the inactivation processes. If these agreements were terminated or if Baxter otherwise failed to deliver an adequate supply of components, we would be required to identify other third-party component manufacturers. We cannot assure you that we would be able to identify such manufacturers on a timely basis or enter into contracts with such manufacturers on reasonable terms, if at all. Any delay in the availability of devices or disposables from Baxter could adversely affect the timely submission of INTERCEPT Blood Systems for regulatory approval or the market introduction and subsequent sales of such systems. Moreover, the inclusion of components manufactured by others could require us to seek new approvals from government regulatory authorities, which could result in delays in product delivery. There can be no assurance that we would receive any such required regulatory approvals.
- *We rely on Baxter for the marketing, sales and distribution of our pathogen inactivation systems* . We do not have and currently do not plan to develop our own marketing and sales organization. Instead, we plan to rely on Baxter to market and sell the pathogen inactivation systems. If our joint development agreements with Baxter are terminated or if Baxter is unable to market the products successfully, we will be required to find another marketing, sales and distribution partner or develop these capabilities ourselves. We may not be able to find a suitable partner on favorable terms or on a timely basis, if at all. Developing marketing, sales and distribution capabilities ourselves would delay commercialization of our pathogen inactivation systems and increase our costs.
- *We share control over management decisions* . Baxter and we share responsibility for managing the development programs for the pathogen inactivation systems. Management decisions are made by a management board that has equal representation from both Baxter and us. Our interests and Baxter's may not always be aligned. Disagreements with Baxter may be time-consuming to resolve, and cause significant delays in the development of our products. If we disagree with Baxter on program direction, a neutral party will make the decision. The neutral party may not decide in our best interest. Under the agreements, Baxter may independently develop a pathogen inactivation system for fresh frozen plasma using their pre-existing methylene blue technology. Such an effort by Baxter could create conflicts in our joint program for the development of a pathogen inactivation system for fresh frozen plasma.

***Our products are subject to extensive regulation by domestic and foreign governments.***

Our products under development and anticipated future products are subject to extensive and rigorous regulation by United States local, state and federal regulatory authorities and by foreign regulatory bodies. These regulations are wide-ranging and govern, among other things:

- product development;
- product testing;
- product manufacturing;
- product labeling;
- product storage;
- product premarket clearance or approval;
- product sales and distribution;
- product use standards and documentation; and
- product advertising and promotion.

The FDA and other agencies in the United States and in foreign countries impose substantial requirements upon the manufacturing and

marketing of products such as those we are developing. The process of obtaining FDA and other required regulatory approvals is long, expensive and uncertain. The time required for regulatory approvals is uncertain and the process typically takes a number of years, depending on the type, complexity and novelty of the product. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses, or we may not be successful at all.

Even if our product candidates receive approval for commercial sale, their marketing and manufacturing will be subject to continuing FDA and other regulatory requirements, such as requirements to comply with good manufacturing practices. The failure to comply with these requirements could result in enforcement action, which could harm our business. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the product or manufacturer, including withdrawal of the product from the market. Regulatory authorities may also require post-marketing testing, which can involve significant expense. The government may impose new regulations which could further delay or preclude regulatory approval of our potential products. We cannot predict the impact of adverse governmental regulation which might arise from future legislative or administrative action.

Distribution of our products outside the United States also is subject to extensive government regulation. These regulations, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations, vary by country. Failure to obtain necessary regulatory approvals or any other failure to comply with regulatory requirements could result in reduced revenue and earnings.

To support our requests for regulatory approval to market our product candidates, we intend to conduct various types of studies including:

- toxicology studies to evaluate product safety;
- laboratory and animal studies to evaluate product effectiveness; and
- human clinical trials to evaluate the safety, tolerability and effectiveness of treated blood components.

We have conducted many toxicology studies to demonstrate our product candidates' safety, and we plan to conduct additional toxicology studies throughout the product development process. At any time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products' safety, which could delay commercialization. We believe the FDA and other regulatory authorities are likely to weigh the potential risks of using our pathogen inactivation products against the incremental benefits, which may be less compelling in light of improved safety in the blood supply. In addition, our clinical development plan assumes that we will not be required to perform human clinical studies to demonstrate our systems' ability to inactivate pathogens. Although we have discussed this plan with the FDA and other regulatory authorities, they may find it unacceptable at any time and may require human clinical trials to demonstrate efficacy in inactivating pathogens. Trials of this type may be too large and expensive to be practical.

Regulatory agencies may limit the uses, or indications, for which any of our products is approved. For example, we believe that we will be able to claim the inactivation of particular pathogens only to the extent we have laboratory or animal data to support such claims. After regulatory approval for the initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications.

In addition to the regulatory requirements applicable to us and our products, there are regulatory requirements applicable to our prospective customers, the blood centers that process and distribute blood and blood products. Blood centers and others will likely be required to obtain approved license supplements from the FDA before using products processed with our pathogen inactivation systems. This requirement or FDA delays in approving these supplements may deter some blood centers from using our products. Blood centers that do submit supplements may face disapproval or delays in approval that could provide further delay or deter them from using our products. The regulatory impact on potential customers could slow or limit the potential sales of our products.

***We are using prototype components in our clinical trials and have not completed their commercial design.***

The system disposables and ultraviolet light sources we use in our clinical trials are prototypes. As a result, we plan to perform studies, both pre-clinical and clinical, to demonstrate the equivalence of the prototype and the commercial design. However, regulatory agencies may require us to perform additional studies, both pre-clinical and clinical, using the commercial versions of the systems, which may increase our expenses and delay the commercialization of our products. If we fail to develop commercial versions of the systems on schedule, our competitors may be able to bring products to market before we do, which would delay or diminish our potential revenues.

***We have only a limited operating history and we expect to continue to generate losses.***

We may never achieve a profitable level of operations. To date, we have engaged primarily in research and development. Our development and general and administrative expenses have resulted in substantial losses. As of March 31, 2001, we had an accumulated deficit of approximately \$134.9 million. All of our products are in the research and development stage, and we have not received any revenue from product sales. We have received all of our revenue from our agreements with Baxter, Kirin and the Consortium for Plasma Science and from federal research grants. We will be required to conduct significant research, development, clinical testing and regulatory compliance activities for each of these products. We expect our losses to continue at least until our product candidates are commercialized and achieve significant market acceptance. Our ability to become profitable will depend on our ability to, among other things:

- complete our product development;
- obtain product regulatory approvals;
- achieve market acceptance for our products; and
- establish adequate protection of our intellectual property rights.

***We will need additional funds.***

Our product development programs are capital-intensive. We expect to continue to spend substantial funds for our operations for the foreseeable future. We believe that our existing capital resources, together with anticipated payments from Baxter, the Consortium, Kirin and federal research grants and projected interest income, will support our current and planned operations for at least the next 12 months. Our cash, liquidity and capital requirements will depend on many factors, including additional research and development needs, product testing results, regulatory requirements, competitive pressures and technological advances and setbacks.

We may require substantial additional funds for our long-term product development, marketing programs and operating expenses. We do not know if we will be able to raise additional funds on acceptable terms. If we raise additional funds by issuing equity securities, our existing stockholders may experience substantial dilution.

***We operate in a competitive industry with rapidly changing technology.***

We expect our products to encounter significant competition. Our products may compete with other approaches to blood safety and improving the outcome of stem cell transplantation currently in use, as well as with future products developed by biotechnology and pharmaceutical companies, hospital supply companies, national and regional blood centers and governmental organizations and agencies. Our success will depend in part on our ability to respond quickly to medical and technological changes through the development and introduction of new products. Product development is risky and uncertain, and we cannot assure you that we will develop our products successfully. Competitors' products or technologies may make our products obsolete or non-competitive before we are able to generate any significant revenue. Many of our competitors or potential competitors have substantially greater financial and other resources than we have. They may also have greater experience in pre-clinical testing, human clinical trials and other regulatory approval procedures. Our ability to compete successfully will depend, in part, on our ability to:

- attract and retain skilled scientific personnel;
- develop technologically superior products;
- develop lower cost products;
- obtain patent or other proprietary protection for our products and technologies;
- obtain required regulatory approvals for our products;
- be early entrants to the market; and
- manufacture, market and sell our products, independently or through collaborations.

Several companies are developing technologies which are, or in the future may be, the basis for products that will directly compete with or reduce the market for our pathogen inactivation systems. A number of companies are specifically focusing on alternative strategies for pathogen inactivation in various blood components. In May 1998, the FDA approved solvent-detergent for use in treating FFP in the United States. If the treatment of FFP by solvent-detergent becomes a widespread practice, which has not happened to date, it could impair our ability to market our FFP pathogen inactivation system in the United States. At least one other company is currently marketing solvent-detergent based pathogen inactivation systems for FFP in Europe.

Other groups are developing synthetic blood product substitutes and products to stimulate the growth of platelets. Development of any of these technologies could impair the potential market for our products.

***Failure to attract and retain key employees will impair our business.***

Because of the scientific nature of our business, we depend on the principal members of our management and scientific staff. Our success will depend largely on our ability to attract and retain highly skilled scientific and managerial personnel. Competition for scientific and managerial personnel is particularly intense in the San Francisco Bay Area where we, together with numerous other life sciences companies, universities and research institutions, maintain our operations. The failure to maintain our management and scientific staff and to attract additional key

personnel could significantly impede achievement of our research and development and commercialization objectives. Although we intend to provide incentive compensation to attract and retain our key personnel, we cannot guarantee these efforts will be successful.

***We may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others.***

Our technology will be protected from unauthorized use by others only to the extent that it is covered by valid and enforceable patents or effectively maintained as trade secrets. As a result, our success depends in part on our ability to:

- obtain patents;
- protect trade secrets;
- operate without infringing upon the proprietary rights of others; and
- prevent others from infringing on our proprietary rights.

We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Others may independently develop technologies similar to ours or independently duplicate our technologies. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

We cannot be certain that we were the first to make the inventions covered by each of our issued or pending patent applications or that we were the first to file patent applications for such inventions. We may need to license the right to use third-party patents and intellectual property to continue development and commercialization of our products. We may not be able to acquire such required licenses on acceptable terms, if at all. If we do not obtain such licenses, we may need to design around other parties' patents or we may not be able to proceed with the development, manufacture or sale of our products.

We may face litigation to defend against claims of infringement, assert claims of infringement, enforce our patents, protect our trade secrets or know-how, or determine the scope and validity of others' proprietary rights. Patent litigation is costly. In addition, we may require interference proceedings declared by the United States Patent and Trademark Office to determine the priority of inventions relating to our patent applications. Litigation or interference proceedings could be expensive and time consuming, and we could be unsuccessful in our efforts to enforce our intellectual property rights.

We may rely, in certain circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We protect our proprietary technology and processes, in part, by confidentiality agreements with employees and certain contractors. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others, disputes may also arise as to the rights in related or resulting know-how and inventions.

***We may be liable if our products harm people.***

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and products. We may be liable if any of our products causes injury, illness or death. We intend to obtain product liability insurance before the commercial introduction of any product, but do not know whether we will be able to obtain and maintain such insurance on acceptable terms. Any insurance we obtain may not provide adequate coverage against potential liabilities. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products.

***We use hazardous substances that are subject to environmental regulation.***

Our research and development involves the controlled use of hazardous materials, including certain hazardous chemicals, radioactive materials and pathogens. Accordingly, we are subject to federal, state and local laws governing the use, handling and disposal of these materials. We may incur significant costs to comply with additional environmental and health and safety regulations in the future. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with regulatory requirements, we cannot eliminate the risk of accidental contamination or injury. If an accident occurs, we could be held liable for any damages that result.

***The market price of our stock may be highly volatile.***

The market prices for our securities and those of other emerging medical device and biotechnology companies have been, and may continue to be, volatile. Announcements may have a significant impact on the market price of our common stock. Such announcements may include:

- biological or medical discoveries;

- technological innovations or new commercial services by us or our competitors;
- developments concerning proprietary rights, including patents and litigation matters;
- regulatory developments in both the United States and foreign countries;
- public concern as to the safety of new technologies;
- general market conditions;
- comments made by analysts, including changes in analysts' estimates of our financial performance; and
- quarterly fluctuations in our revenue and financial results.

The stock market has from time to time experienced extreme price and volume fluctuations, which have particularly affected the market prices for emerging biotechnology and medical device companies, and which have often been unrelated to the operating performance of such companies. These broad market fluctuations may adversely affect the market price of our common stock. In the past, following periods of volatility in the market price of a company's stock, securities class action litigation has occurred against the issuing company. Such litigation could result in substantial costs and a diversion of management's attention and resources, which could have a material adverse effect on our revenue and earnings. Any adverse determination in such litigation could also subject us to significant liabilities.

***Anti-takeover provisions in our charter documents and under Delaware law may make it more difficult to acquire us, even though an acquisition may be beneficial to our stockholders.***

Provisions of our certificate of incorporation and bylaws could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions:

- establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least two-thirds of our capital stock;
- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- limit who may call a special meeting of stockholders;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In November 1999, our board of directors adopted a stockholder rights plan, commonly known as a "poison pill." The provisions described above, our poison pill and provisions of the Delaware General Corporation Law relating to business combinations with interested stockholders may discourage, delay or prevent a third party from acquiring us, even if our stockholders might receive a premium for their shares in the acquisition over then current market prices.

### **ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The information called for by this item is provided under the caption "Financial Instruments" under Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations.

## **PART II OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

Not Applicable.

### **ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS**

Not Applicable.



**ITEM 3.        DEFAULTS UPON SENIOR SECURITIES**

Not Applicable.

**ITEM 4.        SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

Not Applicable.

**ITEM 5.        OTHER INFORMATION**

Not Applicable.

**ITEM 6.        EXHIBITS AND REPORTS ON FORM 8-K**

(a)       Exhibits

10.37\* Collaborative License Agreement between Cerus and Kirin Brewery Company, Limited.

(b)       Reports on Form 8-K

No reports on Form 8-K were filed during the three month period ended March 31, 2001.

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\*       Confidential treatment has been requested for certain portions of this exhibit.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date:       May 7, 2001       /s/ Gregory W. Schafer

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CERUS CORPORATION

Gregory W. Schafer  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

**Exhibit 10.37**

**COLLABORATIVE LICENSE AGREEMENT**

**Between**

**Cerus Corporation**

**And**

**Kirin Brewery Co mpany, L imited**

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[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to 24-B2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT A CERUS PATENTS  
EXHIBIT B KIRIN TERRITORY  
EXHIBIT C SUMMARY OF TERMS OF MANUFACTURING AND SUPPLY

## COLLABORATIVE LICENSE AGREEMENT

This **Collaborative** License Agreement (the "Agreement") is made and entered into effective as of December 31, 2000 (the "Effective Date") by and between **Cerus Corporation**, a Delaware corporation having its principal place of business at 2411 Stanwell Drive, Concord, California, U.S.A. ("Cerus"), and **Kirin Brewery Company, Limited** a corporation organized and existing under the laws of Japan having its principal place of business at 10-1, Shinkawa 2-chome, Chuo-ku, Tokyo, Japan ("Kirin"). Cerus and Kirin may be referred to herein collectively as the "Parties" or individually as a "Party."

### RECITALS

- A. Cerus has developed and owns certain proprietary ACIT Technology (as defined below), and Kirin possesses research, development and marketing capabilities for pharmaceutical and other medical products.
- B. Kirin desires to obtain from Cerus a license to develop and commercialize, in Japan and certain other Asian and Oceanic countries, Products based on such technology.
- C. Cerus and Kirin will enter into a Manufacturing Agreement consistent with the Summary of Supply Terms, which will establish the terms and conditions for the Parties' purchase and supply of Kits and Illumination Devices.

NOW, THEREFORE, the Parties agree as follows:

### ARTICLE 1

#### DEFINITIONS

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

**1.1 "ACIT Technology"** means technology to treat leukocytes to inhibit proliferation but preserve leukocyte function, leukocytes so treated and methods of use of such leukocytes, including Illumination Devices and Compounds used in such treatment, and including the Cerus Know-How, the Cerus Improvements and the Cerus Patents, either collectively or any part thereof. For the purpose of such definition, the term "preserve leukocyte function" means that the leukocytes continue both to [ \* ] and [ \* ]. For the purpose of clarity, it is understood that Cerus is separately pursuing programs for inactivation of pathogens; any inactivation or modulation of the activity of leukocytes incidental to such pathogen inactivation shall be considered outside the definition of ACIT Technology.

**1.2 "Affiliate"** means, with respect to a particular Party, a person, corporation or other entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For the purposes of this definition, "control" means the direct or indirect ownership by a Party of at least fifty percent (50%) of the outstanding voting securities of the controlled entity; provided, that in any country where the law does not permit foreign equity ownership of at least fifty percent (50%), then with respect to corporations organized under such country's laws, "control" shall mean the direct or indirect ownership by a Party of outstanding voting securities of such corporation at the maximum amount permitted by the law of such country.

**1.3 "Controlled"** means, with respect to a particular item, material, or intellectual property right, that a Party owns or has a license under such item, material or intellectual property right and has the ability to grant to the other Party access to and/or a license or sublicense under such item, material or intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with, or the rights of, any Third Party.

**1.4 "Cerus Improvement"** means any improvement to ACIT Technology in the Field, including new applications of the ACIT Technology, that is made and Controlled by Cerus during the term of the Development Program.

**1.5 "Cerus Know-How"** means all Information Controlled by Cerus during the term of the Development Program that relates to ACIT Technology in the Field.

**1.6 "Cerus Patents"** means the Patents and Patent applications Controlled by Cerus during the term of the Agreement, that claim an invention in the Cerus Know-How or Cerus Improvements. Such Patents existing as of the Effective Date are listed on Exhibit A, and Cerus will use reasonable efforts to amend such Exhibit A from time to time to reflect any changes. Cerus warrants and represents to Kirin that Exhibit A is a complete and accurate list of all Cerus Patents as of the Effective Date and that Cerus has the full right and authority to grant to Kirin the licenses and/or sublicenses granted herein under all such Cerus Patents.

**1.7 "Cerus Territory"** means all countries of the world and all territories and possessions thereof, excluding all countries, territories and possessions within the Kirin Territory.

**1.8 "Compound"** means, with respect to a particular Product, any proprietary compound of Cerus, including without limitation S-59, that is required for commercial manufacture and/or use of such Product.

**1.9 "Core ACIT Research and Development"** is non-clinical research and development and clinical development intended to support a Drug Approval Application with the U.S. Food and Drug Administration ("FDA").

**1.10 "Development Committee"** shall have the meaning set forth in Section 3.1.

**1.11 "Development Program"** means, collectively, all of the projects to develop Products to be carried out pursuant to this Agreement.

**1.12 "Drug Approval Application"** means an application for Regulatory Approval required before commercial sale or use of a Product for human therapy or prophylaxis in a regulatory jurisdiction.

**1.13 "Field"** means leukocytes for human therapeutic or prophylactic use.

**1.14 "Illumination Devices"** means devices to emit light of a wavelength appropriate to activate a Compound to cross-link with nucleic acid of leukocytes.

**1.15 "Information"** means any and all information and data of any kind, including without limitation techniques, inventions, practices, methods, knowledge, know-how, skill, experience, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, manufacturing data and descriptions, compositions, assays, and information about marketing, costs and sales.

**1.16 "Kirin Improvement Patents"** means all Patents and Patent applications Controlled by Kirin during the term of this Agreement that claim an invention in the Kirin Improvements.

**1.17 "Kirin Improvements"** means any improvement to ACIT Technology in the Field, including new applications of the ACIT Technology, that is made and Controlled by Kirin or its Affiliates during the term of the Development Program.

**1.18 "Kirin Know-How"** means all Information Controlled by or on behalf of Kirin or its Affiliates during the term of the Development Program that relates to ACIT Technology in the Field.

**1.19 "Kirin Technology"** means the Kirin Improvements, Kirin Know-How and Kirin Improvement Patents, either collectively or any part thereof.

**1.20 "Kirin Territory"** means the countries listed in Exhibit B and their possessions and dependencies.

**1.21 "Kits"** means Compounds and a set of disposable (expected to consist of blood bags and tubing) which permit storage of Compound, mixture of Compound with leukocytes and treatment of the leukocytes in connection with the ACIT Technology.

**1.22 "Manufacturing Agreement"** A manufacturing and supply agreement to be entered into between Kirin and Cerus consistent with the Summary of Terms of Manufacturing and Supply set forth on Exhibit C to this Agreement , provided, however, that until a separate Manufacturing Agreement is executed, the terms of Exhibit C will be binding upon the Parties .

**1.23 "Net Revenue"** means the total revenue received by Kirin, and any Affiliate or Sublicensee of Kirin, for sale or other disposition of a Product to a Third Party, less the following to the extent actually incurred or allowed by Kirin or such Affiliate or Sublicensee with respect to such sale or disposition: (i) discounts, including cash discounts, or rebates, price reductions or allowances actually allowed or granted at the time of invoice from the billed amount; (ii) credits or allowances actually granted upon claims, rejections or returns of Products, including recalls; (iii) freight, postage, shipping and insurance charges paid for delivery of Product, to the extent billed separately and (iv) taxes, duties or other governmental charges levied on or measured by the billing amount when separately included in billing, as adjusted for rebates and refunds. In the event that in any country in the Kirin Territory, the [ \* ] or [ \* ] companies, as the case may be, establish a [ \* ] to Kirin, its Affiliates or Sublicensees, for a [ \* ] that includes [ \* ] , but does not establish a [ \* ] itself, the Net Revenue allocable to the Product will be a [ \* ] . Such [ \* ] shall be [ \* ] and shall take into account the [ \* ] of the Product and the [ \* ] of the Product in [ \* ] where the Product is [ \* ] . In addition, if Kirin charges a customer a [ \* ] which includes the [ \* ] and also of [ \* ] , the Net Revenue allocable to the Product will be computed on the [ \* ] if the Product had been [ \* ] , according to principles stated in the preceding sentence. If Kirin sells any Product or Illumination Devices and Kits through a distributor or sales agent, Net Revenue will be calculated based on the price charged to the end user for such Product (rather than solely the revenue received by Kirin), subject to the deductions in clauses (i) through (iv) above. Kirin will require the distributor or sales agent to provide such information to Kirin.

**1.24 "Patent"** means (i) a valid and enforceable patent, including any extension, registration, confirmation, reissue, re-examination or renewal thereof; and (ii) to the extent valid and enforceable rights are granted by a governmental authority thereunder, a patent application.

**1.25 "Patent Costs"** means the fees and expenses paid to outside legal counsel and other Third Parties, and filing and maintenance expenses, incurred in connection with the establishment and maintenance of rights under Patents applicable to the ACIT Technology including the costs of patent interference proceedings.

**1.26 "Pivotal Study"** means that portion of a clinical development program that provides assessment of safety and efficacy of a product in patients, which is intended to gather the pivotal information to support the marketing approval such product in a particular country. Any such clinical development program shall be performed in accordance with the U.S.A. Federal Food, Drug and Cosmetic Act and applicable regulations promulgated thereunder (including without limitation 21 CFR Part 312), as amended from time to time, or the comparable foreign laws and regulations in the applicable country.

**1.27 "Product"** means: (a) any product comprising leukocytes that embody, use or are made, treated or modified through use of the ACIT Technology; and/or (b) any service to a patient that involves use of the ACIT Technology. Further, the Parties may agree in writing to amend and extend the definition of Product as provided in Section [ \* ] .

**1.28 "Reasonable Efforts"** shall mean efforts and resources commonly used in the research-based pharmaceutical industry for the research, development and commercialization of a product at a similar stage in its product life taking into account the establishment of the product in the marketplace, the competitiveness of the marketplace, the proprietary position of the product, the regulatory structure involved, the profitability of the product and other relevant factors.

**1.29 "Regulatory Approval"** means any approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other government entity, necessary for the manufacture, use, storage, import, transport or sale of Products in a regulatory jurisdiction.

**1.30 "Sublicensee"** shall mean any Third Party expressly licensed by Kirin to develop, make and sell one or more Products. Sublicensees shall not include distributors or sales agents that do no more than purchase and resell finished Products on behalf of Kirin.

**1.31 "Summary of Supply Terms"** means that certain Summary of Terms of Manufacturing and Supply attached as Exhibit C to this Agreement.

**1.32 "S-59"** means the compound whose chemical structure is shown in a letter dated January 18, 2001 from Howard G. Ervin of Cerus to Dr. Kinya Ohgami of Kirin.

**1.33 "Third Party Royalties"** means royalties payable to a Third Party in respect of the sale of Products other than royalties payable with respect to licenses entered into prior to the Effective Date.

**1.34 "Third Party"** means any entity other than Cerus or Kirin or an Affiliate of Cerus or Kirin.

## ARTICLE 2

## LICENSES AND RELATED RIGHTS

### 2.1 Licenses Granted to Kirin .

(a) Subject to the terms of this Agreement, Cerus hereby grants to Kirin an exclusive license to practice the ACIT Technology to develop, use, make, have made, sell and offer for sale Products for any indications in the Field in the Kirin Territory; provided that the Products are prepared or made using Kits supplied by Cerus pursuant to the Manufacturing Agreement or are manufactured by or for Kirin pursuant to the manufacturing license provided for in Section 2.1(e) of this Agreement.

(b) Kirin may grant sublicenses to its Affiliates under the foregoing license for any permitted purpose without Cerus' prior written approval. Kirin may grant sublicenses under such rights to Third Parties solely for making, use or sale of Products in the Kirin Territory with Cerus' prior written approval, which shall not be unreasonably withheld or delayed . Kirin may grant sublicenses to Third Parties for development of Products in the Kirin Territory only upon the prior approval of the Development Committee, which is acknowledged in writing by Cerus. Any such development will be in accordance with plans approved by the Development Committee. As a condition to such sublicense, Cerus may require that the Sublicensee enter into an agreement in form and substance satisfactory to Cerus to protect Cerus confidential information and provide for rights in intellectual property consistent with this agreement. Any sublicense with a Third Party entered into in the absence of Cerus' consent will be null and void. Kirin will provide to Cerus a copy of any proposed sublicense agreement not later than ten (10) business days prior to execution of such agreement, and will provide to Cerus a copy of the final executed agreement promptly upon execution. Kirin will provide such proposed sublicense agreement, and the final executed agreement, in English translation, if the sublicense is not already in English. Prior to providing copies to Cerus of the proposed sublicense agreement and final sublicense agreement, Kirin may, if it chooses, delete information specifying the split of Product revenues between Kirin and the Sublicensee, it being understood that royalties to Cerus will be computed on Net Revenues received collectively by the Sublicensee and Kirin, irrespective of such split. Kirin will remain responsible for the payment of royalties on the Net Revenues of any Sublicensee.

(c)

Additionally, Kirin and its Affiliates may conduct clinical development in the Cerus Territory, of particular Products, so long as Kirin obtains Cerus' prior written approval of the location and clinical study protocol of any such clinical work or study of each such Product, such approval not to be unreasonably withheld or delayed , and so long as such work is intended to generate data to be used in obtaining Regulatory Approval of such Product.

(d) Subject to the terms of Section [ \* ] , and except as otherwise provided in the Manufacturing Agreement, the license rights granted in subsection (a) of this section are subject to the following express limitation (and to all other obligations and limitations in the Agreement):

(i) Kirin obtains no license or rights to practice any of the ACIT Technology to sell Illumination Devices, Compounds or Kits or any other devices or products for use in the treatment of leukocytes, except as set forth in Section [ \* ] in which Kirin [ \* ] . In case Kirin [ \* ] , Kirin's license in Section 2.1 (a) will be [ \* ] . Otherwise, Kirin may use Illumination Devices and Kits only as part of preparing a Product or performing a service comprising a Product.

(ii) Kirin's license to develop is a license to develop in accordance with plans previously approved by the Development Committee; provided that if there are regional issues requiring testing or trials that concern only countries in the Kirin Territory, and which do not have a potential effect outside the Kirin Territory, Kirin may undertake such testing or trials without the plans being first approved by the Development Committee.

(iii) In the event that Kirin elects not to participate in funding Cerus Core ACIT Research and Development costs for a particular indication, as provided in Section 4.5 of this Agreement, Kirin will not practice the license rights for such particular indication until the Parties have renegotiated rights to that indication, as provided in such Section 4.5.

(e) Kirin may obtain Kits and Illumination Devices only under the terms of the Manufacturing Agreement. Kirin obtains no license or other rights to make or have made Illumination Devices, Compounds or Kits , or any other devices for use in the treatment of leukocytes, unless (i) Cerus is unable to supply such item to Kirin, or (ii) Cerus, pursuant to Section 10.2 of this Agreement, elects to license Kirin to manufacture such items. In such case Kirin's license in Section 2.1 (a) will be expanded to include a license to make or have made the Illumination Device s , Kit s or Compound s that Cerus is unable to supply. The license to Cerus Patent PCT/US94/07185, referenced on Exhibit A, is limited to a license to make or have made Compounds in the event it is not supplied by Cerus.

### 2.2 Licenses Granted to Cerus .

(a) Subject to the terms of this Agreement, Kirin hereby grants to Cerus a perpetual exclusive royalty-free license in the Cerus Territory, with the right to sublicense, under Kirin Improvements, the Kirin Know-How and the Kirin Improvement Patents to develop, make, have made, use, import and sell products in the Field.

(b) Kirin may from time to time disclose to Cerus , in Kirin's sole discretion, other technologies Controlled by Kirin in the area of immune therapy or prophylaxis that may be complementary to the ACIT technology, and in which Cerus may have interest. Kirin agrees that,

at Cerus' request, Kirin will discuss with Cerus possible licenses to use such other technology in the Cerus Territory, and the royalties and other terms of any such license agreement will be negotiated in good faith.

**2.3 Notice of Development for New Indications .** Upon reasonable request by Cerus, Kirin will provide Cerus with Information regarding Kirin pre-clinical studies of the ACIT Technology and the Products that are in Kirin clinical trials for new indications. . Upon reasonable request by Kirin, Cerus will provide Kirin with Information regarding Cerus pre-clinical studies of the ACIT Technology and the Products that are in Cerus clinical trials for new indications .

**2.4 Cerus License to Third Parties .** If Cerus licenses the ACIT Technology in the Field to a Third Party (outside the Kirin Territory), Cerus will use its best efforts to negotiate a license that permits Kirin to share and use pre-clinical and clinical development data of such Third Party.

**2.5 Trade mark Rights .**

(a) **License Grants.** Subject to the limitations set forth below, Cerus grants to Kirin a non-exclusive, royalty-free license, with the right to sublicense, to use any and all marks Cerus adopts for use with the Products (the " Licensed Marks"), solely in connection with the promotion and sale of Products in the Field in the Kirin Territory. Kirin shall not use Licensed Marks in connection with any other products or activities without prior written approval of Cerus. The mark "Cerus," however, is excluded from this license.

(b) **Form of Use.** Kirin, its Affiliates and Sublicensees shall use the Licensed Marks only in the form(s) approved in writing by Cerus and shall include where appropriate the designations (R) and (TM) and a statement that Licensed Marks are the trademarks of Cerus Corporation, and other proprietary notices as reasonably required by Cerus from time-to-time. Kirin agrees to comply with all applicable laws and regulations pertaining to the proper use and designation of trademarks.

(c) **Ownership of Licensed Marks**

(i). **Ownership.** Kirin acknowledges that it has no interest in the other Licensed Marks other than the license granted under this Agreement and that Cerus is, and will continue to be, the sole and exclusive owner of all right, title and interest in the Licensed Marks.

(ii). **No Contest.** Kirin will not contest, oppose or challenge Cerus' ownership of its Licensed Marks. Kirin agrees that it will do nothing to impair Cerus' ownership or rights in its Licensed Marks. In particular, Kirin will not register or attempt to register Cerus' Licensed Marks in any jurisdiction nor oppose Cerus' registration of its Licensed Marks, alone or with other words or designs, in any jurisdiction. If Kirin uses, registers or applies to register a licensed mark that violates its obligations under this section, Kirin agrees, at Cerus' request, to abandon the use of such mark and any application or registration for such mark.

(iii). **Adverse Use.** Kirin shall notify Cerus of any adverse use by a Third Party of the Licensed Marks or of a mark or name confusingly similar to the Licensed Marks of which Kirin becomes aware, and agrees to take no action with respect thereto except with Cerus' written authorization. Cerus may thereupon take such action as it in its sole discretion deems advisable for the protection of its rights in and to its Licensed Marks, including allowing Kirin to bring and prosecute a claim against such Third Party at Kirin's expense and for Kirin's sole benefit. Kirin further agrees to provide full cooperation (at Cerus' expense) with any legal or equitable action by Cerus to protect Cerus' title and interest in the Licensed Marks.

(d) **Quality Control.** The nature and quality of all goods sold by Kirin, its Affiliates and Sublicensees in connection with Licensed Marks and all advertising and promotional uses and all other related uses of Licensed Marks by Kirin, its Affiliates and Sublicensees shall conform to Cerus' standards. Kirin further agrees to provide samples of advertising and other promotional material bearing the Licensed Marks to Cerus for approval at least thirty (30) days before such materials are to be distributed, displayed or otherwise used. Kirin, its Affiliates and Sublicensees will not distribute, display or otherwise use such materials without Cerus' prior written approval, which approval shall not be unreasonably withheld or delayed .

(e) **Confusingly Similar and/or Combination Marks.** Kirin agrees that Kirin, its Affiliates and Sublicensees will not adopt or use any other trademarks, words, symbols, letters, designs or marks (i) in combination with Licensed Marks in a manner that would create combination marks or (ii) that would be confusingly similar to Licensed Marks, provided, however, that Kirin, its Affiliates and Sublicensees may use Licensed Marks with other marks or names if such other marks or names are sufficiently separated from Licensed Marks and sufficiently distinctive to avoid the consumer impression that such other marks or their owners are associated with Cerus.

## **ARTICLE 3**

### **MANAGEMENT**

**3.1 The Development Committee .** Cerus and Kirin agree to form , as of the Effective Date , a committee to facilitate the research and development of Products ("the Development Committee"). The Development Committee shall comprise four (4) individuals, two (2) being Cerus employees, appointed and replaced by Cerus at its discretion, and two (2) being Kirin employees, appointed and replaced by Kirin at its discretion. The size and composition of the Development Committee may be changed by mutual agreement of the Parties. The Parties shall



form the Development Committee within forty-five ( 45 ) days after the Effective Date. The Development Committee shall have the following authority and obligations:

- (a) To encourage and facilitate the ongoing cooperation of the Parties in conducting the research and development of Products;
- (b) To establish and implement specific plans to obtain Regulatory Approval of Products and commercialize Products as soon as possible, and otherwise accomplish the tasks and goals of the Parties as set forth in the Agreement;
- (c) To coordinate the communication, information exchange and efforts of the Parties with respect to all matters under this Agreement;
- (d) To discuss and resolve, if possible, any issues or disputes that arise under the Agreement; and
- (e) To review new indications to be addressed by the ACIT Technology and budgets for such projects within the Development Program.

**3.2 Development Committee Meetings .** The Development Committee shall act at meetings held regularly with all members present, according to the following procedures:

- (a) The Development Committee meetings shall take place at such times and places as shall be determined by the Development Committee but no less frequently than once per six (6) months; it is expected that the meetings will alternate between appropriate offices of each Party, or will be held at such other convenient locations as agreed;
- (b) If requested by a Party, the Development Committee may conduct a particular meeting by telephone or video conference or other acceptable electronic means, provided that all Development Committee members attend such meeting and can hear and communicate with all other members, and any decisions made during such meeting are recorded in writing and confirmed by signature of at least one of the Development Committee members from each of the Parties;
- (c) A Party may bring a reasonable number of additional representatives, in a non-voting capacity, to attend appropriate Development Committee meetings, provided that such attendance is helpful to the Development Committee carrying out its tasks and obligations;
- (d) Prior to each meeting, the designated chair of the Development Committee (which may vary during the term) shall circulate an agenda for the meeting, and the Development Committee shall keep minutes reflecting matters discussed and the actions taken at the meeting, a copy of which shall be provided to each Party; and
- (e) The Development Committee may act on a specific issue or matter without a meeting if the Development Committee members all agree as to such action and such agreement is set forth in a written consent signed by all the members of the Development Committee.

**3.3 Decision-Making and Issue Resolution .** All decisions of or actions taken by the Development Committee shall be by unanimous approval of all the members of the Development Committee or such subcommittee, and voting on any matters shall be reflected in the minutes of the meeting at which the vote was taken. If the Development Committee fails to reach unanimous agreement on an issue or matter needing resolution, the matter shall be referred for good faith discussion and resolution by the appropriate senior executive officer of each Party.

**3.4 Other Research .** Kirin acknowledges and agrees that nothing in this Agreement shall prevent or otherwise hinder Cerus from conducting, and Cerus shall retain full rights to conduct, its own independent research and development work with respect to ACIT Technology or any aspect thereof for any use or purpose outside the Kirin Territory or any use or purpose outside the Field in the Kirin Territory, and including conducting such research and development work with or on behalf of Third Party partners.

## **ARTICLE 4**

### **RESEARCH AND DEVELOPMENT FUNDING**

**4.1 Funding for Initial Indications .** Subject to the other provisions of this Article, Kirin will fund [ \* ] % of Cerus' Core ACIT Research and Development costs, commencing January 1, 2001, for Cerus' ongoing and planned haploidentical and unrelated donor stem cell transplant indications, provided that Kirin's responsibility for such funding shall be limited to a maximum of U.S. \$ [ \* ] over [ \* ] years. It is understood that Kirin's contributions under this Section 4.1 and under Section 4.2 are in addition to, and not reduced by, the milestone development payments under Article 6 of this Agreement.

**4.2 Funding for New Indications .** The Development Committee will review new indications for the ACIT Technology program and the corresponding pre-clinical and clinical expenses required to pursue those indications. Assuming that the Development Committee agrees to include a new clinical indication in the Development Program, Kirin will fund [ \* ] % of Cerus' Core ACIT Research and Development costs (subject to reasonable caps for Kirin and for Cerus to be agreed upon before such costs are incurred) for such new indication. If the caps for

Kirin and Cerus are reached before completion of the Core ACIT Research and Development for such new indication, the parties will discuss how to proceed for completion of such development.

**4.3 Funding for Kirin Territory .** Kirin will fund 100% of the research and development costs in the Kirin Territory required for Reasonable Efforts to obtain Regulatory Approval of Products. These expenses are independent of Kirin's contributions to the Core ACIT Research and Development activities and not subject to the limitations on expenditure obligations set forth in Section 4.1, above.

**4.4 Cerus Funding .** Cerus will fund 100% of its costs in the Cerus Territory, except for the Core ACIT Research and Development cost.

**4.5 Kirin Decision Not to Participate .** If Kirin decides not to participate in funding Cerus' Core ACIT Research and Development for a particular indication, but wishes to retain commercialization rights to such indication, Kirin will so notify Cerus in writing promptly following Kirin's decision not to fund such indication, and the parties will renegotiate rights to that indication in the Kirin Territory. If Kirin does wish to retain rights to commercialize Products in the Kirin Territory for such indication, Kirin will use Reasonable Efforts to obtain Regulatory Approval and to market and sell the Products for such indication in the Kirin Territory. If Kirin does not wish to retain rights to commercialize Products for such indication in the Kirin Territory, Kirin will execute and deliver such documentation as Cerus may reasonably request, releasing Kirin's rights to the ACIT Technology for such indication.

**4.6 Core ACIT Research and Development Costs .** Cerus' Core ACIT Research and Development costs will be considered to include, in addition to any such costs funded directly by Cerus, any costs funded by other Cerus collaborators in the ACIT program, including without limitation the [ \* ], and any funding for research and development of the ACIT Technology from governmental or other organizations. All such costs will be subject to the recordkeeping and disclosure requirements set forth in Section 4.9 below.

**4.7 Development Efforts and Expenses .** Each of the Parties will maintain scientific staff, laboratories, offices and other facilities necessary to carry out the tasks and obligations assigned to it pursuant to this Agreement. Each party shall use Reasonable Efforts to conduct and complete such tasks and obligations.

**4.8 Advance Payments .** Prior to, or promptly following, the Effective Date and each January 1 and July 1 during the term of the Development Program, Cerus will submit to Kirin a projected estimate of Core ACIT Research and Development costs to be incurred by Cerus during the six month period commencing on such date. Kirin will pay to Cerus an amount equal to [ \* ] % of such costs reasonably projected by Cerus to be incurred in such period within thirty (30) days after Kirin receives invoice of Cerus' projected estimate .

**4.9 Expenditures .** Cerus shall maintain detailed records which accurately identify Core ACIT Research and Development Costs incurred and paid in connection with the Development Program. Such records shall be open during reasonable business hours, for a period of three (3) years from the creation of individual records, for examination at Kirin's expense, and not more often than once each year and upon not less than thirty (30) days advance notice, by a certified public accountant selected by Kirin and acceptable to Cerus for the sole purpose of verifying the correctness of calculations or payments made under this Agreement. Cerus shall submit this information to Kirin following the end of each semi-annual period of the Agreement (ending June 30 and December 31). Expenses internally generated because tasks are performed by Cerus' own staff will be accounted for based upon a single average hourly rate agreed upon annually by the Parties; provided, however, that such expenses will only be included among those shared by Kirin if they are attributable to individual Cerus employees who each devote their working hours to Core ACIT Research and Development.

**4.10 Reconciliation of Expenditures .** Unless otherwise agreed, the Parties shall reconcile actual cash outlays and expenses for Core ACIT Research and Development on a semi-annual basis within sixty (60) days after each January 1 and July 1, such that costs have been incurred in the proportion specified in Sections 4.1 and 4.2 of this Agreement. If they are not in such proportion, Cerus will make a cash payment to Kirin, or Kirin will make a cash payment to Cerus, in order to achieve such proportion. The payment shall be made in cash within thirty (30) days after its receipt of an invoice based on the determination of the amount to be reconciled.

## ARTICLE 5

### DEVELOPMENT AND MARKETING IN THE KIRIN TERRITORY

**5.1 Kirin Efforts .** Kirin shall use Reasonable Efforts to develop and obtain Regulatory Approval in the Kirin Territory for the Products and to obtain the maximum reimbursement prices for the Products. Kirin shall pay all the development and registration costs for all Products in the Kirin Territory. Kirin shall use Reasonable Efforts to market and sell in the Kirin Territory all Products for which Regulatory Approval in the Kirin Territory has been obtained.

**5.2 Meetings Concerning Marketing .** The Parties shall meet from time-to-time to discuss and exchange marketing information and strategies in order to optimize customer acceptance and effective promotion of the Product for each approved indication in the Kirin Territory. Kirin will be responsible to make marketing and sales decisions using reasonable business judgment, and to use its best efforts to maximize Net Revenues in the interest of both parties.

## ARTICLE 6

## MILESTONE DEVELOPMENT PAYMENTS

**6.1 Milestone Development Payments .** Kirin shall pay Cerus milestone development payments (which will be non-refundable) payable in accordance with the following schedule:

- (a) On January 31, 2001 : One Million Dollars (U.S. \$1,000,000);
- (b) Upon [ \* ]: [ \* ] Dollars (U.S. \$ [ \* ] )
- (c) Upon [ \* ]: [ \* ] Dollars (U.S. \$ [ \* ] )
- (d) Upon [ \* ]: [ \* ] Dollars (U.S. \$ [ \* ] )
- (e) Upon [ \* ]: [ \* ] Dollars (U.S. \$ [ \* ] )
- (f) Upon [ \* ]: [ \* ] Dollars (U.S. \$ [ \* ] ) (payment to be made only upon the first occurrence of this condition)

**6.2 Withholding Taxes .** The foregoing milestone development payments are inclusive of such withholding taxes as are finally and reasonably ascertained to be due and payable by Kirin on account of Cerus. Kirin will provide Cerus with evidence of payment of such withholding tax so that Cerus may seek to claim foreign tax credit in the United States. If Kirin receives a refund or rebate for taxes it has paid on behalf of Cerus, Kirin shall promptly remit it to Cerus.

**6.3 Method of Payment .** Payment of the milestone development payments shall be made by wire transfer to an account designated by Cerus for such purpose within thirty (30) days after each milestone event described Section 6.1 has occurred .

**6.4 Application of Milestone Development Payments .** Without limiting Kirin's responsibility under Article 4 to pay [ \* ] % of Core ACIT Research and Development Costs, Cerus will apply the milestone development payments to pay or reimburse Cerus' expenditures in developing the ACIT Technology.

## ARTICLE 7

### ROYALTIES

**7.1 Royalties on Sales of Products .**

(a) Subject to subsection (b) and Section 7.5 below, Kirin shall pay Cerus royalties on sales of Products by or on behalf of Kirin or its Affiliates or Sublicensees, as follows:

- [ \* ] percent ( [ \* ] %) on the first \$ [ \* ] million of annual Net Revenue (aggregate of all countries in Kirin Territory); and
- [ \* ] percent ( [ \* ] %) royalty on annual Net Revenue over \$ [ \* ] million (aggregate of all countries in Kirin Territory) .

The calendar year shall be used for the purpose of determining annual Net Revenues. The increase of royalty rate to [ \* ] percent ( [ \* ] %) shall not apply to China to the extent China continues to impose an upper limit on royalties or other regulations (as referenced in Section 7.1(c)) that make such royalty rate uneconomical.

(b) For each particular Product, Kirin shall pay the royalties specified above, on a country by country basis, during the Term of this Agreement .

(c) For China or any other country in the Kirin Territory which imposes an upper limit on royalty rate or other regulations , Cerus and Kirin will discuss the royalty rate and the other terms and conditions to reach an arrangement that is equitable to both parties .

**7.2 Payment of Royalties .** Royalty obligations hereunder shall accrue at the time of sale of the applicable Product, and all such royalties that have accrued during a particular calendar quarter shall be paid quarterly within sixty ( 60 ) days after the end of such calendar quarter. Such royalties shall be calculated on the basis of Net Revenue in the local currency of each country, and converted into U.S. Dollars and paid in U.S. Dollars by using the average currency exchange rate at each end of the month for the applicable calendar quarter for purchase quoted by the Bank of Tokyo-Mitsubishi (or its successor). Each royalty payment shall be accompanied by a statement of such royalties showing the Net Revenue for the applicable royalty-bearing Products, on a country-by-country and product-by-product basis and, in addition, a statement indicating the total revenues and line item deductions from which the Net Revenue was derived. Royalty payments shall be made by wire transfer to an account designated by Cerus for such purpose.

**7.3 Royalty Structure and Marketing Strategy .** The terms of this Agreement permit Kirin to market and sell Products to hospitals and other similar health-care provider organizations as services or as products. Kirin shall not sell Illumination Devices or Kits to Third Parties , provided, however, that in the event that (i) Kirin [ \* ] as provided in Section 1.27 in any country in the Kirin Territory by certain [ \* ] and/or (ii) the [ \* ] , Kirin [ \* ] in accordance with [ \* ] to be agreed by the Parties . In such event , the Parties also shall agree on any needed [ \* ] to the [ \* ] established for [ \* ] , including appropriate amendments to the definitions of such terms under Article 1. Any change to the

current marketing strategy, and any adjustment to the royalty calculation mechanism related thereto, must be set forth in writing and signed by an authorized representative of each Party.

**7.4. Withholding Taxes.** The foregoing royalty payments are inclusive of such withholding taxes as are finally and reasonably ascertained to be due and payable by Kirin on account of Cerus. Kirin will provide Cerus evidence of payment of such withholding tax so that Cerus may seek to claim foreign tax credit in the United States. If Kirin receives a refund or rebate for taxes it has paid on behalf of Cerus, Kirin shall promptly remit it to Cerus.

**7.5. Third Party Royalties.** In the event that Kirin is required to obtain a license under a Third Party patent that covers or claims the manufacture, use or sale of a Product in order to practice a Cerus Patent in the field of allogeneic stem cell transplantation in any country in the Kirin Territory, as permitted under the licenses in Article 2, Kirin shall be entitled to deduct from amounts owing to Cerus [ \* ] of any royalties owing to such Third Party based on the sale of Products in such country under such license, subject to a maximum royalty reduction of [ \* ] of the amounts that otherwise would be owed by Kirin under Article 7 hereof. Royalty reduction, if any, in a field other than allogeneic stem cell transplantation will be negotiated in good faith by both parties. Kirin shall disclose the relevant portions of such license under such Third Party patent to Cerus in English and the extent of any alleged infringement.

## ARTICLE 8

### CONFIDENTIALITY

**8.1 Confidentiality; Exceptions .** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, for the term of this Agreement and for ten (10) years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose to a Third Party or use for any purpose other than as provided for in this Agreement any Information and materials furnished to it by the other Party pursuant to this Agreement (collectively, "Confidential Information"), except to the extent that it can be established by the receiving Party by competent proof that such Confidential Information:

- (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure, other than through any act or omission of the receiving Party in breach of this Agreement;
- (d) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others ; or
- (e) was independently developed by the receiving Party without reference to or reliance upon any information or materials disclosed by the disclosing Party .

**8.2 Authorized Disclosure .** Each Party may disclose the other's Confidential Information to the extent such disclosure is reasonably necessary in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations or conducting preclinical or clinical trials, provided that if a Party is required by law or regulation to make any such disclosure of the other Party's Confidential Information it will, except where impracticable for necessary disclosures, for example in the event of medical emergency, give reasonable advance notice to the other Party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such Confidential Information required to be disclosed. Cerus may provide information contained in royalty reports to its auditors and may report payments received in accordance with normal practices.

**8.3 Survival .** This Article 8 shall survive the termination or expiration of this Agreement for a period of ten (10) years.

## ARTICLE 9

### INTELLECTUAL PROPERTY

**9.1 Ownership .** Each Party shall solely own Patents for any inventions made solely by that Party's employees or consultants in the course of performing any work under this Agreement. The law of inventorship of the United States shall apply to any inventions, whether made inside or outside the United States by either of the Parties.

**9.2 Prosecution and Maintenance of Patents by Cerus; Abandonment.** Cerus shall have the responsibility to file, prosecute and maintain the Cerus Patents and joint Patents relating to the ACIT Technology in the world and shall bear all expenses associated therewith. All decisions regarding prosecution of the Cerus Patents in the world will be at Cerus' sole discretion and responsibility. Cerus agrees to keep Kirin informed of the course of patent prosecution or other proceedings relating to the Cerus Patents in the Kirin Territory in the Field. In the

event Cerus elects not to prosecute such Patent application filed or to abandon such issued Patent in the Kirin Territory in the Field, Cerus shall notify Kirin not less than two (2) months before any relevant deadline, and thereafter Kirin shall have the right to pursue, at its expense and sole discretion, prosecution of such Patent application or maintenance of such issued Patent and in the event that Kirin pursue prosecution of such Patent application or maintenance of such issued Patent, Cerus shall promptly assign its rights therein to Kirin. **9.3 Prosecution and Maintenance of Kirin Improvement Patents by Kirin ; Abandonment.** Kirin shall have the responsibility to file, prosecute and maintain the Kirin Improvement Patents in the world and shall bear all expenses associated therewith. All decisions regarding prosecution of the Kirin Improvement Patents in the world will be at Kirin's sole discretion and responsibility. Kirin agrees to keep Cerus informed of the course of patent prosecution or other proceedings relating to the Kirin Improvement Patents in the Cerus Territory in the Field. In the event Kirin elects not to prosecute such Patent application filed or to abandon such issued Patent in the Cerus Territory in the Field, Kirin shall notify Cerus not less than two (2) months before any relevant deadline, and thereafter Cerus shall have the right to pursue, at its expense and sole discretion, prosecution of such Patent application or maintenance of such issued Patent. In such event, Kirin shall promptly assign its rights therein to Cerus .

**9.4 Defense and Settlement of Third Party Claims.** If a Third Party files a claim, suit or action against a Party claiming that a Patent or other intellectual property right owned by such Third Party is infringed by the development, use, marketing, distribution or sale of a Product, and such claim, suit or action (a "Claim") arises out of such Party's operation in the Field pursuant to this Agreement, the Party against whom the Third Party has filed such Claim ("Defending Party") will have the right to defend against any such Claim. The other Party will assist in the defense of any such Claim as reasonably requested by the Defending Party and at the Defending Party's expense and may retain separate counsel at its own expense. The Defending Party shall not settle any such Claim without the prior express written consent of the other Party, which consent shall not be unreasonably withheld or delayed, if such settlement would impose on such other Party the obligation to pay any damages or would adversely affect such Party's rights.

## **9.5 Enforcement of Patent Rights**

(a) If any Cerus Patent , Kirin Improvement Patent or joint patent relating to ACIT Technology in the Field is infringed by a Third Party, the Party to this Agreement first having knowledge of such infringement shall promptly notify the other in writing. The notice shall set forth the facts of such infringement in reasonable detail.

(b) Cerus shall have the right, but not the obligation, to institute, prosecute and control any action or proceeding with respect to infringement in the Cerus Territory of Cerus Patents, Kirin Improvement Patents and joint patents relating to the ACIT Technology.

(c) Kirin shall have the right, but not the obligation, to institute, prosecute and control any action or proceeding with respect to infringement in the Kirin Territory of Cerus Patents , Kirin Improvement Patents and joint patents relating to ACIT Technology and patents abandoned by Cerus pursuant to Section 9.2.

(d) If a Party given the right to enforce a Cerus Patent or Kirin Improvement Patent pursuant to Section 9. 5 (b) or Section 9. 5 (c) fails to bring an action or proceeding against a suspected infringer within a period of ninety (90) days after having knowledge of such infringement in the Field, the other Party shall have the right to bring and control an action against such infringer by counsel of its own choice, and the non-enforcing Party shall have the right to be represented in any such action by counsel of its own choice at its own expense.

(e) The Party controlling an action involving any infringement in the Field shall consider in good faith the interests of the other Party in so doing, and shall not settle or consent to an adverse judgment in any such action which would have a material adverse effect on the rights or interests of the other Party without the prior express written consent of such other Party, which shall not be unreasonably withheld. If one Party brings any such action or proceeding, the other Party agrees to be joined as a Party plaintiff if necessary to prosecute the action and to give the first Party reasonable assistance and authority to file and prosecute the suit. In each case relating to infringement within the Field, each Party shall bear the costs of its enforcement of the Patent rights discussed in this section and any amounts received from Third Parties shall be equitably shared between the Parties in a manner to be negotiated.

(f) The Parties shall consult regarding the institution, prosecution and control of any action or proceeding with respect to infringement outside the Field of any of the Kirin Improvement Patents. In the absence of Agreement with respect to infringement outside the Field, Kirin may proceed in such manner as the law permits.

## **ARTICLE 10**

### **REPRESENTATIONS AND WARRANTIES; UNDERTAKINGS CONCERNING SUPPLY**

**10.1 Representations and Warranties.** Each of the Parties hereby represents and warrants as follows:

(a) This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

(b) Such Party has not, and during the term of the Agreement will not, grant any right to any Third Party relating to its respective technology in the Field licensed to the other Party hereunder that would conflict with such rights granted to the other Party.

**10.2 Cerus Warranties and Undertakings .** Cerus represents and warrants to Kirin that Cerus owns the rights to manufacture Compounds, Kits and the Illumination Devices, and undertakes to provide Kirin with (i) the Kits and the Illumination Devices as Kirin, its Affiliate and permitted Sublicensees require to conduct clinical development of the Product at cost of goods plus reasonable handling charge and (ii) Kirin's, its Affiliate and/or permitted Sublicensees' commercial requirements of Compounds, Kits and Illumination Devices in response to and in accordance with the terms set forth on Exhibit C to this Agreement, which will be included in the Manufacturing Agreement. It is agreed, however, that with respect to Kirin's commercial requirements, Cerus may elect to permit Kirin to manufacture Compounds, Kits and/or Illumination Devices, instead of supplying them to Kirin. If Cerus intends not to supply Compounds, Kits or Illumination Devices, it will give Kirin notice of such decision reasonably in advance of the time when Kirin will need such Compounds, Kits or Illumination Devices, to permit Kirin to make arrangements in timely manner for manufacturing. In such event, Cerus will continue to be obligated to provide Compounds to Kirin, but will be relieved of its obligations to provide Kits (except for Compounds) or Illumination Devices, according to Cerus' election.

## **ARTICLE 11**

### **REPORTS, RECORDS AND MATERIAL**

**11.1 Sharing of Information .** Commencing on the Effective Date and continuing during the term of this Agreement, each Party will make available and disclose to the other Party the Information Controlled by such Party that reasonably relates to such other Party's activities under this Agreement in the Field. In particular, Cerus will disclose to Kirin on a regular basis the ACIT Technology and results of Core ACIT Research and Development, and provide reasonable assistance to Kirin (at Kirin's request and expense) in transferring such ACIT Technology for use in and commercializing Products in the Field in the Kirin Territory. Cerus shall deliver to Kirin within thirty (30) working days of the Effective Date a copy of documents relating to the ACIT technology, including, but without limitation, IND, clinical protocols and pre-clinical or clinical results. Similarly, Kirin will disclose to Cerus on a regular basis the Kirin Technology and results of Kirin research and development relating to ACIT Technology, and provide reasonable assistance to Cerus (at Cerus' request and expense) in transferring such Kirin Technology for use in and commercializing Products in the Field in the Cerus Territory. In addition, both Parties will disclose to each other any non-clinical and clinical regulatory information which relates to such other Party's activities under this Agreement in the Field.

**11.2 Records of Net Revenue .** Kirin will maintain, and will require each sublicensee to maintain, complete and accurate records of Net Revenue which are relevant to payments to be made under this Agreement. Such records shall be open during reasonable business hours, for a period of three (3) years from creation of individual records, for examination at Cerus' expense, and not more often than once each year and upon not less than thirty (30) days advance notice, by a certified public accountant selected by and acceptable to Kirin for the sole purpose of verifying for Cerus the correctness of calculations or payments made under this Agreement.

**11.3 Materials; Technical Support .** The Parties intend to maintain an open and extensive exchange of biological, chemical and other tangible materials during the course of the Agreement. Information obtained by the other Party in the testing of such materials will be promptly disclosed to the Party providing the sample, and all such Information will be considered Confidential Information of the party supplying the proprietary materials, to be protected under the restrictions of Article 8. The Party supplying any such materials will be entitled to recover its cost of goods from the party receiving the materials. Any such materials supplied will be used solely for the uses authorized under this Agreement. Upon termination of this Agreement, any unused materials will be returned to the Party who supplied them. If Kirin requests technical support from Cerus for development or commercialization of the Products in the Kirin Territory (beyond the activities Cerus is conducting for its own development and commercialization in the Cerus Territory), Cerus will be entitled to receive reimbursement from Kirin for Cerus' costs of such technical support on a time and materials basis.

**11.4 Publicity Review .** If either Party is required by law or regulation to make a public disclosure or announcement concerning this Agreement or the subject matter thereof, such Party shall, to the extent practicable, give reasonable prior advance notice of the proposed text of such disclosure or announcement to the other Party for its review and comment. The terms of this Agreement may also be disclosed to Third Parties with the consent of the other Party, which consent shall not be unreasonably withheld so long as such disclosure is made under a binder of confidentiality.

**11.5 Publications.** Each Party agrees that it shall not publish or present the results of studies carried out pursuant to this Agreement without the opportunity for prior review by the other Party . Each Party shall provide to the other Party the opportunity to review any proposed abstracts, manuscripts or presentations (including information to be presented verbally) which relate to the Field at least thirty (30) days prior to their intended submission for publication, and each Party agrees, upon written request from the other Party , not to submit such abstract or manuscript for publication or to make such presentation until the other Party is given a reasonable period of time to secure patent protection for any material in such publication or presentation which it believes is patentable.

**11.6 Adverse Event Reporting.** In the event that either Party, its Affiliates or Sublicensees obtains, directly or indirectly, information and data on the side effects or toxicity of a Product during the development, marketing and distribution of any of the Products hereunder, such Party shall disclose, as soon as reasonably practicable, such information and data to the other Party. Either Party, its Affiliates and Sublicensees shall notify the other Party as soon as reasonably practicable of any complaints or reports of adverse events associated with the Products which are serious, new or unexpected events, or events with increased frequency. All other adverse events associated with Products shall be reported by either Party to the other Party in summary format at least quarterly. At the request of either Party, the other Party shall cooperate in the

investigation and respond to any Product complaints which may relate to the role of the informed Party in the development or manufacture of the Products. Each Party shall be responsible for all reporting of adverse events to regulatory authorities in its respective territory.

## ARTICLE 12

### TERM AND TERMINATION

**12.1 Term .** This Agreement shall commence on the Effective Date and, unless sooner terminated as provided herein, shall continue in effect for each Product and on a country by country basis until the later of the expiration of ten (10) years from the first commercial launch of such Product in such country or the expiration of all Patents with claims covering such Product or its manufacture, sale or use in such country.

**12.2 Termination for Breach .** If either Party materially breaches this Agreement at any time, which breach is not cured within thirty (30) days of written notice thereof if such breach is caused by the failure of a Party to meet its financial obligations under this Agreement, or within ninety (90) days of written notice thereof for any other material breach of this Agreement, from the non-breaching Party specifying in detail the nature of the breach, the breaching Party's licenses granted in this Agreement shall terminate and the non-breaching Party shall continue to have whatever licenses it had at the time of such termination and on the terms of this Agreement for such licenses, under the breaching Party's technology, Patents and (if applicable) Licensed Marks to make, have made, use and sell Products it already had developed or sold, in those countries in which it already had developed or sold such Products. The breaching Party will assist the non-breaching Party in every proper way to effect the license granted above. The breaching Party shall further deliver to the non-breaching Party such relevant tangible materials embodying such technology, Patents and Licensed Marks as may be necessary or useful to the exercise of the non-breaching Party of the license hereunder.

**12.3 Surviving Rights .** The obligations and rights of the Parties under Section 2.2, Section 2.5(b)–(e), Article 8, Section 9.1, Section 11.4 , Section 11.5, Section 12.4 , Sections 13.1-13.3, and Article 14 of this Agreement will survive termination.

**12.4 Non-exclusive License s after Expiration.** Upon the expiration of the Agreement under Section 12.1, Kirin shall retain a non-exclusive, royalty-free license to use the ACIT Technology and Licensed Marks to make, have made, use offer for sale and sell in the Field in the Kirin Territory the Products that Kirin was selling as of the date of such expiration.

**12.5 Termination by Kirin Without Cause.** On or after January 1, 2002, Kirin may terminate this Agreement and all of its rights and obligations hereunder except as otherwise provided herein without cause upon on hundred eighty (180) days prior written notice to Cerus. At such time, all licenses granted to Kirin under this Agreement shall terminate, and Kirin shall covenant not to use any Information or materials of any kind related to, made or derived from the ACIT Technology or Licensed Marks after such termination. Kirin also shall return to Cerus all Information and materials of any kind related to, made or derived from the ACIT Technology or Licensed Marks upon such termination. Kirin's licenses to Cerus under this Agreement shall survive any such termination.

**12.6 Termination by Cerus of Funding.** On or after January 1, 2002, Cerus may discontinue funding of Core ACIT Research and Development in its entirety or for particular indications on hundred eighty (180) days prior written notice to Kirin if Cerus determines that the ACIT Technology or such particular indications, as the case may be, are not likely to be technically or clinically viable or financially successful in the United States. In the event that Cerus ceases such funding in its entirety , Kirin may nevertheless proceed with development of Products and will retain its license rights thereto , provided that Kirin's obligations of milestone development payment set forth in Section 6.1(b), (c) and (e), and research and development funding obligation set forth in Section 4.1 and 4.2 will be terminated, except for any research and development funding obligation incurred, but not paid, prior to the date of termination . In the event that Cerus discontinues funding for any indication, but continues funding for other indications, Kirin's obligations of milestone development payment set forth in Section 6.1(b), (c) and (e), and the research and development funding obligation set forth in Section 4.1 and 4.2 will be terminated solely for such discontinued indication, except for any research and development funding obligation incurred, but not paid, prior to the date of termination. In the event that Kirin obtains Regulatory Approval of a Product in the Kirin Territory for any indication as to which Cerus has previously ceased funding of Core ACIT Research and Development, the Parties will renegotiate the milestone development payments other than mentioned in the preceding sentence and royalty obligations of Kirin with respect to Products for such indication in light of such circumstances.

## ARTICLE 13

### INDEMNIFICATION AND INSURANCE

**13.1 Indemnification in Kirin Territory .** Kirin shall indemnify, defend and hold harmless Cerus [ \* ] from and against any and all liability, damage, loss, cost (including reasonable attorneys' fees) and expense from any infringement, claim of bodily injury or property damage arising in the Kirin Territory to the extent (a) relating to the development, manufacture, use, distribution or sale of any Product by Kirin, its Affiliates, Sublicensees, employees or agents or (b) due to the negligence or willful misconduct of Kirin or its Affiliates, Sublicensees, employees or agents.

**13.2 Indemnification in Cerus Territory .** Cerus shall indemnify and hold Kirin harmless from and against any and all liability, damage, loss, cost (including reasonable attorneys' fees) and expense from any infringement, claim of bodily injury or property damage arising in the

Cerus Territory to the extent (a) relating to the development, manufacture, use, distribution or sale of any Product by Cerus, its Affiliates, Sublicensees, employees or agents or (b) due to the negligence or willful misconduct of Cerus or its Affiliates, Sublicensees, employees or agents.

**13.3 Indemnification Procedure.** Each Party's obligations under Sections 13.1 and 13.2 are conditioned on the Indemnified Party's (a) providing written notice to Indemnifying Party of any claim, demand or action arising out of the indemnified activities within thirty (30) days after Indemnified Party has knowledge of such claim, demand or action; (b) permitting Indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such claim or demand; (c) assisting Indemnifying Party, at Indemnified Party's reasonable expense, in the investigation of, preparation for and defense of any such claim or demand; and (d) not compromising or settling such claim or demand without Indemnifying Party's written consent, which shall not be unreasonably withheld.

**13.4 Insurance .** Kirin will maintain product liability insurance or self-insurance covering the clinical trials and sale of Products in the Kirin Territory in amounts customary for medical products in the Kirin Territory. Kirin will provide Cerus [ \* ] with a certificate of insurance evidencing such coverage.

## ARTICLE 14

### MISCELLANEOUS

**14.1 Assignment.** Neither Party shall assign any of its rights and obligations hereunder except (i) as incident to the merger, consolidation, reorganization or acquisition of stock affecting actual voting control or transfer of substantially all of the assets of the assigning Party or (ii) to an Affiliate; provided, however, that in no event shall either Party's rights and obligations hereunder be assigned without prior written notice to the other Party. In any case, neither Party may make an assignment of its assets which renders it unable to perform its material obligations hereunder. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their permitted successors and assigns.

**14.2 Retained Rights .** Nothing in this Agreement shall limit in any respect the right of either Party to conduct research and development with respect to, and market products outside of, the Field using such Party's Technology, but no license to use the other Party's technology to do so is granted herein expressly or by implication.

**14.3 Force Majeure .** Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance (other than the payment of monies) by the defaulting Party if the failure is occasioned by government action, war, fire, explosion, flood, strike, lockout, embargo, act of God, or any other similar cause beyond the control of the defaulting Party, provided that the Party claiming *force majeure* has exerted all reasonable efforts to avoid or remedy such *force majeure* ; provided, however, in no event shall a Party be required to settle any labor dispute or disturbance.

**14.4 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**14.5 No Trademark Rights .** Except as otherwise provided herein, no right, express or implied, is granted by the Agreement to use in any manner the name "Cerus" or "Kirin" or any other trade name or trademark of the other Party in connection with the performance of the Agreement.

**14.6 Notices.** All notices and other communications hereunder shall be in writing and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):

If to Cerus, addressed to:

Cerus Corporation  
2411 Stanwell Drive  
Concord, CA 94520  
Attention: Vice President, Legal Affairs  
Telephone: +1 (925) 288-6116  
Telecopy: +1 (925) 288-0194

With copy to:

Cooley Godward LLP  
Five Palo Alto Square, 4th Floor

Palo Alto, CA 94306  
Attention: Bob Jones



Telephone: +1 (650) 843-5000  
Telecopy: +1 (650) 849-7400

If to Kirin, addressed to:

Kirin Brewery Co mpany, L imited  
26-1, Jingumae 6-chome  
Shibuya-ku  
Tokyo 150-8011, Japan  
Attention: General Manager of Licensing  
Pharmaceutical Division  
Telephone: +81 (3) 5485-6 206  
Telecopy: +81 (3) 3499-6152

**14.7 Dispute Resolution .** If any dispute, controversy or claim arises out of or in connection with this Agreement, the Parties shall use reasonable efforts to settle it by friendly negotiation within sixty (60) days of notice from one Party to the other of such dispute, controversy or claim, before pursuing any other remedies available to them. If either Party fails or refuses to participate in such negotiations, or if, in any event, the dispute, controversy or claim is not resolved to the satisfaction of both Parties within the sixty (60) day period, any such dispute, controversy or claim shall be settled by arbitration. Any such arbitration shall be conducted in accordance with the Japan-American Trade Arbitration Agreement of September 16, 1952. The Parties agree that any such arbitration shall be conducted in the English language in a location within the United States selected by the Party that did not initiate such arbitration, and the Agreement shall be governed by and construed in accordance with the laws of the State of California and the United States of America. The arbitrators shall include one independent, un-affiliated nominee selected by each Party and a third neutral arbitrator selected by such nominees. The Parties agree that any arbitration panel shall include members knowledgeable as to the evaluation of biopharmaceutical technology. Judgment upon the award rendered may be entered in the highest state or federal court or forum, state or federal, having jurisdiction; provided, however, that the provisions of this Section 14.7 shall not apply to any dispute or controversy as to which any treaty or law prohibits such arbitration. The prevailing Party shall be entitled to reasonable attorney's fees and costs to be fixed by the arbitrators.

**14.8 Waiver.** Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

**14.9 Severability .** If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance shall, to any extent, be held to be invalid or unenforceable, then the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition of this Agreement shall be valid and be enforced to the fullest extent permitted by law.

**14.10 Ambiguities .** Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

**14.11 Entire Agreement .** This Agreement sets forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with regard to the subject matter discussed herein and supersedes and terminates all prior agreements and understanding between the Parties with regard to the subject matter discussed herein. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with regard to the subject matter discussed herein other than as set forth in this Agreement; provided that the services of manufacturing and supply of products will be set forth in a Manufacturing Agreement to be negotiated and executed by the Parties consistent with the Summary of Supply Terms. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

**14.12 Headings .** The Section and Paragraph headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of the Section or Paragraphs to which they apply.

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their proper officers as of the date and year first above written.

**CERUS CORPORATION**

**KIRIN BREWERY CO MPANY, L IMITED**

By: /s/ Stephen Israel

By /s/ Koichiro Aramaki :

Printed Name: Stephen Israel

Printed Name: Koichiro Aramaki

Title: President & CEO

Title: President, Pharm. Div.

## **EXHIBIT A**

### **CERUS PATENTS**

Cerus' initial U.S. filing was 09/119,707 (PCT/US98/15067) , which was also filed in the PCT and is now pending in Australia, Japan and China, among other countries. Cerus filed a continuation-in-part (CIP) in the U.S., 09/238,355, and has intentionally abandoned the initial filing in the U.S. in favor of this CIP case. The CIP includes all of the [ \* ] , plus a [ \* ] . Cerus did not file this CIP in the PCT, as Cerus [ \* ] . Cerus is continuing to [ \* ] .

Cerus has licensed from [ \* ] U.S. Patent [ \* ] issued [ \* ] , which license rights include U.S. Patent Application [ \* ] . The license rights in Article 2 of the Agreement include a sublicense of rights to foreign counterparts of this patent and application in the Kirin Territory. Regarding [ \* ] , a patent has been issued in [ \* ] . This case is in the national phase in [ \* ] , among other countries.

PCT/US94/07185 for S-59 composition of matter.

## **EXHIBIT B**

### **KIRIN TERRITORY**

Afghanistan  
Australia  
Bangladesh  
Brunei  
Cambodia  
Indonesia  
Japan  
Laos  
Malaysia  
Mongolia  
Myanmar  
Nepal  
New Zealand  
North Korea  
Pakistan  
Peoples Republic of China (including Hong Kong and Macao)  
Philippines  
Singapore  
South Korea  
Sri Lanka  
Taiwan  
Thailand  
Vietnam

## **EXHIBIT C**

### **SUMMARY OF TERMS OF MANUFACTURING AND SUPPLY**

- Cerus owns rights of manufacturing Compounds, Kits and Illumination Devices, and is responsible for supplying to Kirin Compounds, Kits and Illumination Devices for treatment of leukocytes , in cases that (i) Kirin markets and sells Products to hospitals and other similar health-care provider organizations and (ii) that Kirin sells [ \* ] pursuant to Section [ \* ] .
- The transfer price of the Kits is [ \* ] (such [ \* ] not to exceed \$ [ \* ] per Kit) plus a Kit [ \* ] (computed on a country-by-country basis) per unit of Product to end users received by Kirin, its Affiliates, Sublicensees, distributors and sales agents . The transfer price of the Illumination Devices is [ \* ] % of Cerus' [ \* ] . In case that Kirin sells [ \* ] , the transfer price

calculation mechanism will be [ \* ], as provided in Section [ \* ] of the Collaborative License Agreement.

- Kirin will remit the transfer price of the Illumination Devices within thirty ( 30 ) days after invoice on shipment of the Illumination Devices to Kirin or its Affiliate or Sublicensee. Kirin will remit the transfer price of the Kits not later than one hundred and fifty (150) days after shipment of the Kits to Kirin or its Affiliate or Sublicensee.
- The Manufacturing Agreement will provide for rolling forecasts of Kirin's needs for Illumination Devices and Kits.
- The Manufacturing Agreement will not require Cerus to supply Kits to Kirin at a loss.
- In the event Cerus is unable to supply Illumination Devices, Kits or Compounds to Kirin, or Cerus elects to license Kirin to manufacture such items, Cerus grants Kirin a license to manufacture such items, in accordance with Sections 2.1(e) and 10.2 of the Collaborative License Agreement and the compensation to Cerus will be appropriately reduced.

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**End of Filing**

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