## FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED DECEMBER 31, 1998, OR . . . . . . . . . . . [\_] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_ Commission file number 0-22025 -----AASTROM BIOSCIENCES, INC. ..... (Exact name of registrant as specified in its charter) Michigan 94-3096597 ~ ----------(State or other jurisdiction of (I.R.S. employer incorporation or organization) identification no.) 24 Frank Lloyd Wright Dr. P.O. Box 376 Ann Arbor, Michigan 48106 (Address of principal executive offices) (Zip code) (734) 930-5555 - ----------(Registrant's telephone number, including area code) -----(Former name, former address and former fiscal year, if changed since last report) Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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. [\_] - No [X] - Yes

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

COMMON STOCK, NO PAR VALUE (Class)

16,486,635 Outstanding at February 1, 1999

(Mark One)

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## Item 1. Financial Statements

# AASTROM BIOSCIENCES, INC. (a development stage company)

# CONDENSED BALANCE SHEETS

	June 30, 1998	December 31, 1998
ASSETS		(Unaudited)
CURRENT ASSETS: Cash and cash equivalents Short-term investments Receivables Prepaid expenses	\$ 2,078,000 9,134,000 167,000 270,000	175,000
Total current assets		11,128,000
PROPERTY, NET	725,000	
Total assets	\$12,374,000 ======	\$11,740,000
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES: Accounts payable and accrued expenses Accrued employee expenses Current portion of capital lease obligations Total current liabilities	\$ 1,313,000 150,000 65,000 1,528,000	30,000
<pre>SHAREHOLDERS' EQUITY: Preferred stock, no par value; shares authorized 5,000,000; shares issued and outstanding 2,200,000 and 4,000, respectively Common stock, no par value; shares authorized - 40,000,000; shares issued and outstanding - 13,639,817</pre>		3,742,000
and 16,473,258, respectively Deficit accumulated during the development stage Stock purchase warrants Unrealized gains on investments	59,474,000 (58,897,000) 335,000 4,000	70,677,000 (64,818,000) 335,000 -
Total shareholders' equity	10,846,000	9,936,000
Total liabilities and shareholders' equity	\$12,374,000 ======	\$11,740,000 ======

The accompanying notes are an integral part of these financial statements.

## AASTROM BIOSCIENCES, INC. (a development stage company)

# CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

	Three months ended December 31,		Six months ended December 31,				March 24, 1989 (Inception) to		
	-	1997			.997			1998	
REVENUES :									
Grants Research and development agreements		49,000	207,000		62,000 3,000		370,000	\$   2,390,0 2,389,0	900
Total revenues		49,000	207,000		65,000		370,000	4,779,0	900
COSTS AND EXPENSES: Research and development General and administrative		3,788,000 883,000 4,671,000	 3,165,000 696,000		7,031,000 1,496,000 8,527,000		6,258,000 1,347,000	13,247,0	900
Total costs and expenses		4,671,000	 3,861,000		8,527,000		7,605,000	73,435,0	
LOSS FROM OPERATIONS		(4,622,000)	3,654,000)		(8,462,000)		7,235,000		
OTHER INCOME (EXPENSE): Other income Interest income Interest expense Other income		216,000 (2,000) 214,000	 1,237,000 142,000 (1,000) 1,378,000		436,000 (7,000) 			3,501,0 (266,0 4,472,0	900 900) 
NET LOSS		(4,408,000)	2,276,000) ======		(8,033,000)		5,638,000	) \$(64,184,0 =======	
COMPUTATION OF NET LOSS APPLICABLE TO COMMON SHARES: Net loss Dividends and yields on preferred stock Charge related to issuance of preferred stock		(4,408,000) (47,000) (3,439,000)	2,276,000) (63,000) -		(8,033,000) (47,000) (3,439,000)				
Net loss applicable to Common Shares		(7,894,000)	2,339,000)		11,519,000)		5,921,000	)	
NET LOSS PER COMMON SHARE (Basic and Diluted)	\$	(.59)	\$ (.16)	\$	(.87)	\$	(.42	)	
Weighted average number of common and common equivalent shares outstanding	==:	13,268,000 ======							

The accompanying notes are an integral part of these financial statements.

## AASTROM BIOSCIENCES, INC. (a development stage company)

# CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	Six months ended December 31,		March 24, 1989 (Inception) to December 31,
	1001	1998	1998
OPERATING ACTIVITIES: Net loss Adjustments to reconcile net loss to net cash used for operating activities:	\$(8,033,000)	\$(5,638,000)	\$(64,184,000)
Depreciation and amortization Loss on property held for resale Amortization of discounts and	303,000 -	175,000 -	2,563,000 110,000
premiums on investments Stock compensation expense Changes in assets and liabilities:	(82,000) 320,000	(70,000) 4,000	(453,000) 1,632,000
Receivables Prepaid expenses Accounts payable and accrued expenses	(39,000) 73,000 391,000	(8,000) 169,000 316,000 (5,000)	(199,000) (101,000) 1,629,000
Accrued employee expenses Net cash used for operating activities	(32,000)  (7.099.000)	(5,000)  (5,057,000)	145,000  (58,858,000)
INVESTING ACTIVITIES: Organizational costs Purchase of short-term investments Maturities of short-term investments Capital purchases Proceeds from sale of property held for resale	(10,353,000) 7,000,000 (89,000)	(1,000,000) 9,200,000 (62,000)	(73,000) (44,464,000) 43,917,000 (2,438,000) 400,000
Net cash provided by (used for) investing activities	(3,442,000)	8,138,000	(2,658,000)
FINANCING ACTIVITIES: Issuance of preferred stock Issuance of common stock Payments received for stock purchase rights Payments received under shareholder notes Principal payments under capital lease obligations	-	39,000	3,500,000
Net cash provided by financing activities	9,868,000	(35,000) 4,693,000	71,368,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		7,774,000	
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	1,943,000	2,078,000	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 1,270,000	\$ 9,852,000 ======	\$ 9,852,000
SUPPLEMENTAL CASH FLOW INFORMATION: Interest paid Additions to capital lease obligations	\$     7,000 - 	\$     3,000 	\$ 266,000 1,174,000 ========

The accompanying notes are an integral part of these financial statements.

#### AASTROM BIOSCIENCES, INC. (A development stage company) NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

#### 1. ORGANIZATION

Aastrom Biosciences, Inc. (the "Company") was incorporated in March 1989 ("Inception") under the name Ann Arbor Stromal, Inc. The Company changed its name in 1991 concurrent with the commencement of employee-based operations. The Company is in the development stage with its principal business activities being research and product development, conducted both on its own behalf and in connection with various collaborative research and development agreements with others, involving the development of processes and products for the ex vivo production of human cells for use in cell and ex vivo gene therapy.

#### 2. BASIS OF PRESENTATION

The condensed financial statements included herein have been prepared by the Company without audit according to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to such rules and regulations. The financial statements reflect, in the opinion of management, all adjustments (which consist solely of normal recurring adjustments) necessary to present fairly the financial position and results of operations as of and for the periods indicated. The results of operations for the three and six months ended December 31, 1998, are not necessarily indicative of the results to be expected for the full year or for any other period.

These financial statements should be read in conjunction with the audited financial statements and the notes thereto included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission.

#### 3. NET LOSS PER COMMON SHARE

Net loss per common share is computed using the weighted average number of common and common equivalent shares outstanding during the period. Common equivalent shares are not included in the per share calculation where the effect of their inclusion would be anti-dilutive. Upon the completion of the Company's initial public offering, all outstanding shares of preferred stock at that time were automatically converted into common stock. Accordingly, such shares of preferred stock are assumed to have been converted into common stock at the time of issuance.

The computation of net loss per common share reflects dividends, yields and other adjustments relating to Company's preferred stock which affect only the computation of net loss per common share and are not included in the computation of net loss for the period.

#### 4. COMPREHENSIVE INCOME

In June 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" ("SFAS 130"), which sets forth additional requirements for companies to report in the financial statements Comprehensive Income in addition to Net Income. The Company adopted SFAS 130 as of July 1, 1998 which did not have a material effect on the accompanying financial statements.

## 5. PREFERRED STOCK

In December 1998, all 2,200,000 shares of the Company's 5.5% Convertible Preferred Stock were converted into 2,240,326 shares of common stock. Additionally, during November and December 1998, a total of 1,000 shares of the Company's Series I Convertible Preferred Stock were converted into 458,043 shares of common stock.

#### 6. DISTRIBUTION AGREEMENT

In 1993 the Company entered into a product Distribution Agreement (the "Distribution Agreement") with Cobe BCT, Inc. ("Cobe"). The Distribution Agreement provided Cobe with worldwide marketing and distribution rights for the AastromReplicell/TM/ Cell Production System ("System") and related therapy kits for use in the field of stem cell therapy. The Company is implementing the initial European market introduction of the AastromReplicell/TM/ System and related therapy kits for the production of either bone marrow derived cells or the expansion of umbilical cord blood cells used in stem cell therapy. The Company believes that upon completion of AastromReplicell/TM/ System and European market introduction for stem cell therapy, development of additional therapy kits can be pursued for a number of emerging cell therapies being developed by others. Such other cell therapy applications were outside of the scope of the Distribution Agreement and outside of Cobe's area of focus. Accordingly, the Company and Cobe terminated the Distribution Agreement, effective November 16, 1998. In connection with the termination, Cobe paid \$1,237,000 to the Company which has been recorded as Other Income in the accompanying Statements of Operations for the periods ended December 31, 1998. Cobe currently owns approximately 2.4 million shares of the Company's common stock, and as part of the termination agreement, Cobe has agreed not to sell any such shares until at least January 1, 2001. The Company believes that this action, which brings rights to all fields of use to the Company, will better allow for a consolidated marketing plan to be implemented for the AastromReplicell/TM/ System product line.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

#### OVERVIEW

Since its inception, the Company has been in the development stage and engaged in research and product development, conducted principally on its own behalf, but also in connection with various collaborative research and development agreements with other entities. The Company does not expect to generate positive cash flows from operations for at least the next several years and until product sales commence. Until product sales commence, the Company expects that its revenue sources will continue to be limited to grant revenue, research funding and milestone payments and licensing fees from potential future corporate collaborators. The timing and amount of such future cash payments and revenues, if any, will be subject to significant fluctuations, based in part on the success of the Company's research activities, the receipt of necessary regulatory approvals, the timing of the achievement of certain other milestones and the extent to which associated costs are reimbursed under grant or other arrangements. A substantial portion of all of the Company's revenues from product sales, if any, will be subject to the Company's obligation to make aggregate royalty payments of up to 2% to certain licensors of its technology. Research and development expenses may fluctuate due to the timing of expenditures for the varying stages of the Company's research, product development and clinical development programs. Generally, product development expenses for the AastromReplicell/TM/ System are expected to decrease as the product progresses through market launch and clinical development costs are expected to increase as the Company begins its U.S. pivotal clinical trials. Additionally, marketing and general and administrative expenses are expected to increase in support of European marketing activities. In November 1998, the Company implemented a reduction in work force, affecting 19 staff positions and certain other contract positions, reducing overall operating expenses by approximately 15%. The reduction in headcount generally affected staff and operations that were not required for product manufacturing and support or to support the Company's clinical development programs. Under the Company's license agreement with Immunex, annual renewal fees of \$1,000,000 are payable in March 1999 and March 2000. As a result of these and other factors, the Company's results of operations have fluctuated and are expected to continue to fluctuate significantly from year to year and from quarter to quarter and therefore may not be comparable to or indicative of the result of operations for any future periods.

Over the past several years, the Company's net loss has primarily increased, consistent with the growth in the Company's scope and size of operations. Although the Company reduced its workforce in November 1998, a future growth in employee headcount may become necessary to address increasing requirements in the areas of product and customer support, research, clinical and regulatory affairs, quality systems and administration. Assuming capital is available to finance such growth, the Company's operating expenses will increase as a result. At least until such time as the Company enters into arrangements providing research and development funding or initiates product sales, the Company will continue to incur net operating losses. The Company has never been profitable and does not anticipate having net income unless and until product sales commence. Through December 31, 1998, the Company has accumulated losses of

\$64,184,000. There can be no assurance that the Company will be able to achieve profitability on a sustained basis, if at all.

RESULTS OF OPERATIONS

Three and six months ended December 31, 1998 and 1997

Revenues for the quarter and six-month periods ended December 31, 1998, consisted of grant funding and increased to \$207,000 and \$370,000, respectively, from \$49,000 and \$65,000, respectively in 1997. The increases in revenues during 1998 are the result of an in increase in research activities under research grants received by the Company.

Costs and expenses decreased to \$3,861,000 for the quarter ended December 31, 1998 from \$4,671,000 for the same period in 1997, and decreased to \$7,605,000 for the six-month period ended December 31, 1998 compared to \$8,527,000 in 1997. The decreases in costs and expenses were principally the result of decreases in research and development expense to \$3,165,000 and \$6,258,000 for the quarter and six months ended December 31, 1998, respectively, from \$3,788,000 and \$7,031,000 for the same periods in 1997. General and administrative expenses also decreased to \$696,000 and \$1,347,000 for the quarter and six months ended December 31, 1998, for the quarter and six months ended periods and \$1,496,000, for the same periods in 1997, primarily as a result of certain non-cash charges incurred in 1997.

Interest income was \$142,000 for the quarter ended December 31, 1998, compared to \$216,000 for the same period in 1997, and was \$363,000 for the six months ended December 31, 1998, compared to \$436,000 for the same period ending in 1997. These changes primarily reflect an overall decrease in the levels of cash, cash equivalents and short-term investments during the periods.

Net loss for the quarter ended December 31, 1998 was \$2,276,000, or \$.16 per common share, compared to a net loss of \$4,408,000, or \$.59 per common share for the same period in 1997. Net loss for the six months ended December 31, 1998 was \$5,638,000, or \$.42 per common share compared to \$8,033,000, or \$.87 per common share in 1997. The net loss for the periods ended December 31, 1998 include other income of \$1,237,000 representing a one-time payment received from Cobe in connection with the termination of the Company's marketing and distribution agreement with Cobe in November 1998. The computations of net loss per common share for the periods ended December 31, 1997, reflect a one-time charge of \$3,439,000 related to the sale of preferred stock by the Company in December 1997. This one-time charge and dividends and yields on the Company's preferred stock affect only the computation of net loss per common share and are not included in the net loss for the periods.

Liquidity and capital resources

The Company has financed its operations since Inception primarily through public and private sales of its equity securities, which from Inception through December 31, 1998, have totaled approximately \$74,419,000, and, to a lesser degree, through grant funding, payments received under research agreements and collaborations, interest earned on cash, cash equivalents, and

short-term investments, and funding under equipment leasing agreements. These financing sources have historically allowed the Company to maintain adequate levels of cash and other liquid investments.

The Company's combined cash, cash equivalents and short-term investments totaled \$10,852,000 at December 31, 1998, a decrease of \$360,000 from June 30, 1998. The primary uses of cash, cash equivalents and short-term investments during the six months ended December 31, 1998, included \$4,987,000 to finance the Company's operations and working capital requirements, \$62,000 in capital equipment additions and \$35,000 in scheduled debt payments. The Company plans to continue its policy of investing excess funds in short-term, investment-grade, interest-bearing instruments.

The Company's future cash requirements will depend on many factors, including continued scientific progress in its research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, the cost of product commercialization and the degree of market acceptance of the Company's products. The Company does not expect to generate a positive cash flow from operations for at least the next several years due to continuing expenses for its research and development programs and the expected cost of commercializing its product The Company intends to seek additional funding through research and candidates. development agreements with suitable corporate collaborators, grants, public or private financing transactions and other means that may be available to the Company. The Company anticipates that its available cash resources and expected interest income thereon, will be sufficient to finance the development and manufacture of the AastromReplicell/TM/ System for use in clinical trials, expand its clinical trials, and to fund other research and development and working capital and other corporate requirements through mid-1999. This estimate is a forward-looking statement based on certain assumptions which could be negatively impacted by the matters discussed under this heading and under the caption "Business Risks" in the Company's Annual Report on Form 10-K. The Company expects that its primary sources of capital for the foreseeable future will be through collaborative arrangements and through the public or private sale of its debt or equity securities. There can be no assurance that such collaborative arrangements, or any public or private financing, will be available on acceptable terms, if at all, or can be sustained. Several factors will affect the Company's ability to raise additional funding, including, but not limited to, market volatility of the Company's common stock and economic conditions affecting the public markets generally or some portion or all of the technology sector. If adequate funds are not available, the Company will be required to further delay, reduce the scope of, or eliminate one or more of its research and development programs, or curtail some or all or its operations, which would have a material adverse effect on the Company's business. See "Business Risks Future Capital Needs; Uncertainty of Additional Funding" in the Company's 1998 Annual Report on Form 10-K and Notes to Financial Statements included therein.

## RECENT ACCOUNTING PRONOUNCEMENTS

In June 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" ("SFAS 130"), which sets

forth additional requirements for companies to report in the financial statements Comprehensive Income in addition to Net Income. The Company adopted SFAS 130 as of July 1, 1998 which did not have a material effect on the accompanying financial statements.

CERTAIN BUSINESS CONSIDERATIONS

#### Product Development Uncertainties

Commercialization of the Company's technology and product candidates, including its lead product candidate, the AastromReplicell/TM/ Cell Production System ("System"), will require substantial additional research and development by the Company as well as substantial clinical trials. There can be no assurance that the Company will successfully complete development of the AastromReplicell/TM/ System or its other product candidates, or successfully market its technologies or product candidates, which lack of success would have a material adverse effect on the Company's business, financial condition and results of operations. The Company or its collaborators may encounter problems or delays relating to research and development, market development, clinical trials, regulatory approval and intellectual property rights of the Company's technologies and product candidates. The Company's initial product development efforts are primarily directed toward obtaining regulatory approval to market the AastromReplicell/TM/ System as an alternative, or improvement, to currently used stem cell collection methods. These existing stem cell collection methods have been widely practiced for a number of years, and there can be no assurance that any of the Company's technologies or product candidates will be accepted by the marketplace as readily as these or other competing processes and methodologies, or at all. The Company also plans to pursue through strategic relationships, clinical applications of the AastromReplicell/TM/ System into emerging cell therapies being developed by others. There can be no assurance that such strategic relationships, if established, will successfully lead to commercial applications of the AastromReplicell/TM/ System.

#### Termination of Cobe Distribution Agreement

In 1993 the Company entered into a product Distribution Agreement (the "Distribution Agreement") with Cobe BCT, Inc. ("Cobe"). The Distribution Agreement provided Cobe with worldwide marketing and distribution rights for the AastromReplicell/TM/ Cell Production System ("System") and related therapy kits for use in the field of stem cell therapy. The Company is implementing the initial European market introduction of the AastromReplicell/TM/ System and related therapy kits for the production of either bone marrow derived cells or the expansion of umbilical cord blood cells used in stem cell therapy. The Company believes that upon completion of AastromReplicell/TM/ System and European market introduction for stem cell therapy, development of additional therapy kits can be pursued for a number of emerging cell therapies being developed by others. Such other cell therapy applications were outside of the scope of the Distribution Agreement and outside of Cobe's area of focus. Accordingly, the Company and Cobe terminated the Distribution Agreement, effective November 16, 1998. In connection with the termination, Cobe paid \$1,237,000 to the Company which has been recorded as Other Income in the accompanying Statements of Operations for the periods ended December 31, 1998. Cobe currently owns approximately 2.4 million shares of the Company's common stock, and as part of the termination agreement, Cobe has agreed not to sell any such shares until

at least January 1, 2001. Thereafter, sale of the shares into the market could effect the price of the Company's common stock. The Company believes that termination of the Distribution Agreement, which brings rights to all fields of use to the Company, will better allow for a consolidated marketing plan to be implemented for the AastromReplicell/TM/ System product line. The AastromReplicell/TM/ System consists of an automated clinical system designed to enable hospitals to produce patient-specific cells for use in the treatment of a broad range of diseases. The Company believes that with diverse fields of use, the overall market development and customer interface plans will benefit from the consolidation of the product line under disease-specific programs. There can be no assurance that the Company will be able to enter into a new marketing and distribution relationship on acceptable terms with another partner, if at all, or that if such a marketing and distribution partnership is achieved, it will result in the successful commercialization and distribution of the Company's technologies and product candidates. Failure to enter into such a new relationship, and any delay in the planning or implementation of distribution or marketing activities while a new partnership is sought, will have a material adverse effect on the Company's business, financial condition and results of operations.

## Uncertainties of Clinical Trials

The approval of the United States Food and Drug Administration (the "FDA") will be required before any commercial sales of the Company's product candidates may commence in the United States. The Company is currently conducting clinical trials to demonstrate the safety and biological activity of cells produced in the AastromReplicell/TM/ System in a limited number of patients. If the results from these trials are successful, the Company intends to use these results to support a limited market introduction of the AastromReplicell/TM/ System in Europe and to seek clearance from the FDA to commence additional pivotal clinical trials in the U.S., the first of which began in December 1998. patients enrolled in these trials and future trials will have undergone The extensive chemotherapy or radiation therapy treatments prior to infusion of cells produced in the AastromReplicell/TM/ System. Such treatments will have substantially weakened these patients and may have irreparably damaged their hematopoietic systems. Due to these and other factors, it is possible that these patients may die or suffer severe complications during the course of the current trials or future trials. For example, in the trials to date, some of the patients who have been in the transplant recovery process have died from complications related to the patient's clinical condition that, according to the physicians involved, were unrelated to the AastromReplicell/TM/ System procedure. The Company may experience delays in patient accruals in its current clinical trials or in future clinical trials, which could result in increased costs associated with the clinical trials or delays in receiving regulatory approvals and commercialization, if any. The results of preclinical studies and early clinical trials of the Company's product candidates may not necessarily be indicative of results that will be obtained from subsequent or more extensive clinical trials. Further, there can be no assurance that pre-pivotal or pivotal clinical trials of any of the Company's product candidates will demonstrate the safety, reliability and efficacy of such products, or of the cells produced in such products, to the extent necessary to obtain required regulatory approvals or market acceptance. There can be no assurance that, even after the expenditures of substantial time and financial resources, regulatory approval will be obtained for any products developed by the Company.

#### European Regulatory Matters

The AastromReplicell/TM/ System components, are currently being regulated in Europe as Class I Sterile or Class IIb medical devices, under the authority of the new Medical Device Directives ("MDD") being implemented by European Union ("EU") member countries. In order for the Company to market its products in Europe, it must obtain permission from a Notified Body to affix the CE Mark which certifies that the Company and its operations comply with certain minimum quality standards and compliance procedures, or, alternatively, that its manufactured products meet a more limited set of requirements. Additionally, the Company may be required to comply with certain country-specific regulations in order to market its products. The Company has received approval to affix the CE Mark to the AastromReplicell/TM/ System instrumentation platform and the various components of its SC-I Therapy Kit for the production of bone marrow derived cells and CB-I Therapy Kit used for expansion of umbilical cord blood cells. While initial approvals have been obtained, there can be no assurance that the Company and its suppliers will be able to meet the minimum requirements necessary to maintain such compliance. Upon the completion of production-level manufacturing and the Company's product release procedures, the CE Mark will permit market introduction of the AastromReplicell/TM/ System in the EU. inability to complete the transition to production-level manufacturing of the AastromReplicell/TM/ System or non-compliance with the ongoing regulatory requirements to permit commercialization would have a material adverse effect on the Company's business, financial condition and results of operations. Further, there can be no assurance that the AastromReplicell/TM/ System will continue to be regulated in Europe under its current status. If the AastromReplicell/TM/ System is not so regulated, the Company could be forced to obtain additional regulatory approvals and could be subject to additional regulatory requirements and uncertainty, which would have a material adverse effect on the Company's business, financial condition and results of operations.

## Dependence on Third Parties for Materials

The Company currently arranges for the manufacture of its product candidates and their components, including certain cytokines, serum and media, with third parties, and expects to continue to do so for the foreseeable future. There can be no assurance that the Company's supply of such key cytokines, components, product candidates and other materials will not become limited, be interrupted or become restricted to certain geographic regions. There can also be no assurance that the Company will be able to obtain alternative components and materials from other manufacturers of acceptable quality, or on terms or in quantities acceptable to the Company, if at all. Additionally, there can be no assurance that the Company will not require additional cytokines, components and other materials to manufacture, use or market its product candidates, or that necessary key components will be available for use by the Company in the markets where it intends to sell its products. In the event that any of the Company's key manufacturers or suppliers fail to perform their respective obligations or the Company's supply of such cytokines, components or other materials becomes limited or interrupted, the Company would not be able to market its product candidates on a timely and cost-competitive basis, if at all, which would have a material adverse effect on the Company's business, financial condition and results of operations. Certain of the compounds used by the Company in its current stem cell

expansion process involve the use of animal-derived products. The availability of these compounds for clinical and commercial use may become limited by suppliers or restricted by regulatory authorities, which may impose a potential competitive disadvantage for the Company's products compared to competing products and procedures. There can be no assurance that the Company will not experience delays or disadvantages related to the future availability of such materials which would have a material adverse effect on the Company's business, financial condition and results of operations.

## History of Operating Losses

The Company is a development stage company and there can be no assurance that its product candidates for cell therapy will be successful. The Company yet completed the development and clinical trials of any of its product The Company has not candidates and, accordingly, has not yet begun to generate revenues from the commercialization of any of its product candidates. The Company expects to incur significant operating losses until commercialization of its product candidates, primarily owing to its research and development programs, including pre-clinical studies and clinical trials. The development of the Company's products will require the Company to raise substantial additional funds or to seek collaborative partners, or both, to finance related research and development activities. Because of the Company's potential long-term funding requirements, it may attempt to access the public or private equity markets if and whenever conditions are favorable, even if it does not have an immediate need for additional capital at that time. There can be no assurance that any such additional funding will be available to the Company on reasonable terms, or at all. Several factors will affect the Company's ability to raise necessary additional funding, including market volatility of the Company's stock and economic conditions affecting the public markets generally or some portion or all of the technology sector. If adequate funds are not available, the Company will be required to delay or terminate research and development programs, curtail capital expenditures, and reduce or terminate business development and other operating activities.

## Year 2000 Issues

Many currently installed computer systems and software products are not capable of distinguishing 20th century dates from 21st century dates. As a result, in less than one year, computer systems and/or software used by many companies in a wide variety of applications will experience operating difficulties unless they are modified or upgraded to adequately process information involving, related to, or dependent upon the century change. Significant uncertainty exists in the software and information services industries concerning the scope and magnitude of problems associated with the century change. In light of the potentially broad effects of the year 2000 on a wide range of business systems, the Company may be affected. The Company utilizes and is dependent upon data processing computer hardware and software to conduct its business. The Company has completed its assessment of its own computer systems and based upon this assessment, the Company believes its computer systems are substantially "Year 2000 compliant;" that is, its computer systems are capable of adequately distinguishing 21st century dates from 20th century dates. However, there can be no assurance that the Company has timely identified or will timely identify and remediate all significant Year 2000 problems in its own computer systems, that remedial efforts subsequently made will not involve significant time and expense,

or that such problems will not have a material adverse effect on the Company's business, operating results and financial condition. The Company has yet to determine the extent, or completed activities to minimize the risk, that the computer systems of the Company's suppliers and manufactures are not Year 2000 compliant, or will not become compliant on a timely basis. The Company expects that the process of making inquiries with these suppliers will be ongoing through the end of 1999. If Year 2000 problems prevent any of the Company' suppliers from timely delivery of products or services required by the Company, the Company's operating results could be materially adversely affected. The Company currently estimates that its costs to address the Year 2000 issue relating to its suppliers will not be material, and that these costs will be funded from its operating cash flows. To the extent practical, the Company intends to identify alternative suppliers and manufactures in the event its preferred suppliers become incapable of delivering products or services required by the Company on a timely basis. The Company's estimates of Year 2000 costs relating to its suppliers and manufactures are management's best estimates, which were derived from numerous assumptions of future events, including the continued availability of certain resources, third party remediation plans with regard to Year 2000 issues, and other factors. There can be no assurance that these estimates are correct and actual results could differ materially from these estimates.

## Private Equity Financing

In July 1998 the Registrant sold 5,000 shares of its newly created 1998 Series I Convertible Preferred Stock (the "Series I Preferred") to one investor for an aggregate purchase price of \$5 million. The shares of Series I Preferred are convertible, at the option of the holder, into shares of the Company's common stock at the lower of (i) \$4.81, or (ii) a price based on the market price of the Company's common stock prior to conversion. With limited exceptions, the shares of Series I Preferred are not convertible into common stock until April 1999 and, subject to extension under certain circumstances, will automatically convert into common stock on July 2, 2001, unless sooner converted. As of December 31, 1998, 4,000 shares of Series I Preferred remain outstanding. In general, the Company may require the holders to convert the Series I Preferred if the average closing bid price of the Company's common stock exceeds \$9.62 for specified periods beginning in July 1999. In connection with the sales of Series I Preferred, the investor agreed to purchase an additional \$3 million of a new series of Preferred Stock (to be designated 1998 Series II Convertible Preferred Stock) if the common stock of the Company trades at a price greater than \$6.00 for a specified duration during the period ending in August, 1999.

These business considerations, and others, are discussed in more detail and should be read in conjunction with the Business Risks discussed in the Company's Annual Report of Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 1. Legal Proceedings

None.

- Item 2. Changes in Securities and Use of Proceeds
  - (c) In December 1997, the Company issued 2,200,000 shares of its 5.5% Convertible Preferred Stock ("5.5% Preferred Stock") in a registered direct placement at a price of \$5.00 per share. In December 1998, all 2,200,000 shares of the 5.5% Preferred Stock were converted into 2,240,326 shares of common stock. The shares of common stock issued upon conversion were issued in a transaction exempt from the registration requirements of the Securities Act of 1933 by reason of Section 3(a)(9) thereof. These shares were issued to existing security holders upon conversion of outstanding securities of the Company in a transaction where no commission or other remuneration was paid directly or indirectly in connection with such exchange.

In July 1998 the Registrant sold 5,000 shares of Series I Preferred. The shares of Series I Preferred are convertible, at the option of the holder, into shares of the Registrant's common stock at the lower of (i) 4.81, or (ii) a price based on the market price of the Registrant's common stock prior to conversion. The Company has issued 458,043 shares of common stock, upon the conversion of 1,000 shares of Series I Preferred. The shares of common stock issued upon conversion were issued in a transaction exempt from the registration requirements of the Securities Act of 1933 by reason of Section 3(a)(9) thereof. These shares were issued to existing security holders upon conversion of outstanding securities of the Company in a transaction where no commission or other remuneration was paid directly or indirectly in connection with such exchange.

Item 3. Defaults Upon Senior Securities

None.

## Item 4. Submission of Matters to a Vote of Security Holders

- (a) The Annual Meeting of Shareholders of Aastrom Biosciences, Inc. was held on November 11, 1998.
- (b) At the 1998 Annual Meeting of Shareholders, votes were cast on matters submitted to the shareholders, as follows:

The election of two directors.

NOMINEE	IN FAVOR	WITHHELD
Robert J. Kunze	11,983,515	23,215
Steven G. Emerson, Ph.D.	11,982,715	24,015

Approval of the issuance of the Company's common stock upon the conversion of up to 5,000 and 3,000 shares of the Series I Preferred Stock and Series II Preferred Stock, respectively.

FOR	AGAINST	ABSTAIN	NON-VOTES
8,706,114	83,633	38,623	3,178,360

Approval of the selection of PricewaterhouseCoopers LLP as the Company's independent public accountants for the year ending June 30, 1999.

FOR	AGAINST	ABSTAIN	NON-VOTES
11,986,025	7,100	13,605	Θ

Item 5. Other Information

In November 1998, Horst R. Witzel, Dr. Ing., retired from Aastrom's board of directors and Joseph A. Taylor was appointed to the board. In February 1999, and following the termination of Aastrom's distribution agreement with Cobe, Edward C. Wood, Jr. (President of Cobe BCT) resigned from the board.

## Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

See Exhibit Index.

(b) Reports on Form 8-K

No reports on Form 8-K were filed during the period.

## 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.

# AASTROM BIOSCIENCES, INC.

Date: February 9, 1999	/s/ R. Douglas Armstrong
	R. Douglas Armstrong, Ph.D. President, Chief Executive Officer (Principal Executive Officer)
Date: February 9, 1999	/s/ Todd E. Simpson
	Todd E. Simpson Vice President, Finance and Administration, Chief Financial Officer (Principal Financial and Accounting Officer)
	18

## EXHIBIT INDEX

Exhibit	
Number	Description

- 3.1 \* Restated Articles of Incorporation of the Company.
- 3.2 \*\* Bylaws of the Company. Certificate of Designations Preferences and Rights of 1998 Series I 4.1 \*\*\* Preferred Stock.
- 4.2 Certificate of Designation of 5 1/2% Convertible Preferred Stock.
- 10.1 Cobe Termination and Transition Agreement.
- 10.2 Supplemental Agreement to Cobe Termination and Transition Agreement.
- 27.1 Financial Data Schedule.

\* Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 1996, as filed on March 7, 1997. Incorporated by reference to the Company's Registration Statement on \* \*

- Form S-1 (No. 333-15415), declared effective on February 3, 1997.
- \* \* \* Incorporated by reference to the Company's Form 8-K filed on July 15, 1998.

AASTROM BIOSCIENCES, INC.

CERTIFICATE OF DESIGNATION

Pursuant to Section 302 of the Michigan Business Corporation Act

This Certificate of Designation of Aastrom Biosciences, Inc., a Michigan corporation (the "Corporation"), eliminates the Corporation's 5 1/2% Convertible Preferred Stock, designated by that Certificate of Designation filed with the State of Michigan by the Corporation on November 26, 1997 ("5 1/2% Stock"). The Corporation hereby certifies that there are no outstanding shares of the Corporation's 5 1/2% Stock and that there are no outstanding shares or bonds convertible into shares of the series and no other rights, options or warrants issued by the Corporation that could require issuing shares of the series. The Corporation hereby additionally certifies that the following resolution has been duly adopted by the Board of Directors of the Corporation:

RESOLVED, that pursuant to Section 450.1302(5) of the Michigan Business Corporation Act, the Corporation shall amend its Articles of Incorporation by filing the Certificate of Designation as set forth in the attachment hereto to eliminate the 5 1/2% Stock.

IN WITNESS WHEREOF, the Corporation has cause this Certificate of Designation to be signed by its President, and attested by its Secretary this 28th day of January, 1999.

AASTROM BIOSCIENCES, INC.

By: /s/ R. Douglas Armstrong

Its: President/CE0

This Agreement is entered into as of November 16, 1998 by and among Aastrom Biosciences, Inc., a Michigan corporation ("Aastrom") or ("Supplier"), Cobe BCT, Inc., a Colorado corporation ("Cobe"), and Cobe Laboratories, Inc., a Colorado corporation ("Cobe Laboratories") with respect to the following facts:

A. Aastrom and Cobe entered into that certain Restated Distribution Agreement, dated as of October 22, 1993 (the "Distribution Agreement"), wherein Aastrom is the "Supplier" and Cobe is the "Distributor."

B. The principal product which is being developed and manufactured by Aastrom at the current time for Cobe to market and distribute pursuant to the Distribution Agreement is the Aastrom Replicell Cell Production System (the "Product"). The Product is getting ready for European market launch in late 1998 and early 1999.

C. For a variety of business reasons, Aastrom and Cobe have decided to terminate the Distribution Agreement, effective as of November 16, 1998, with a termination and transition to be accomplished in accordance with the terms of this Agreement.

D. The parties intend to work together cooperatively for a smooth transition of the distribution responsibilities from Cobe to Aastrom (or Aastrom's designee). The parties have developed a Term Sheet (the "Term Sheet") attached hereto as Exhibit A, which identifies the principle tasks which will need to be performed as part of the transition of distribution responsibilities from Cobe to Aastrom.

E. The parties recognize that the Term Sheet is not exhaustive and that there will be a need for cooperative efforts between Cobe and Aastrom to work through various implementation details for accomplishing the intended smooth transition.

F. Aastrom and Cobe Laboratories entered into that certain Stock Purchase Agreement dated as of October 22, 1993, pursuant to which Cobe purchased stock in Aastrom. Cobe has also purchased additional stock in Aastrom beyond the stock specified in the Stock Purchase Agreement. Pursuant to the terms of the Stock Purchase Agreement, Cobe Laboratories has various rights and restrictions with respect to the Aastrom stock held by Cobe Laboratories.

WHEREFORE, the parties hereto mutually agree as follows.

1. Termination of Distribution Agreement. Parties hereby mutually

agree to a termination of the Distribution Agreement effective as of November 16, 1998.

2. Term Sheet. The parties hereby agree to implement and carry out

a transition of the distribution responsibilities from Cobe to Aastrom for the market launch for the Product in Europe as set forth in the Term Sheet.

3. Transition Support. In consideration of the early termination

of the Distribution Agreement and of Aastrom assuming responsibilities to perform various distribution activities as set forth in the Term Sheet, Cobe and Cobe Laboratories hereby agree that Cobe Laboratories shall assign and transfer to Aastrom 825,000 shares of Aastrom common stock owned by Cobe Laboratories for Aastrom to cancel (the "Transfer Shares").

4. Compensation For Cobe Services as Agent. With respect to the

technical services to be provided after December 31, 1998, by Cobe as an agent of Aastrom as set forth in Section IV J 2 of the Term Sheet, Aastrom will pay Cobe's prevailing service rates for its then existing customers, on a country by country basis.

5. Effect of Termination of Distribution Agreement. The effect of the termination of the Distribution Agreement shall be that:

(a) All rights for marketing and distribution of the Product and all other Aastrom products shall revert to Aastrom, with Cobe having no further distribution rights, license rights, or other rights to market or sell Aastrom's products for stem cell therapy applications or for any other applications, and with Cobe having no right to share in any of the proceeds from the sale of any Aastrom product.

(b) Aastrom is entitled to arrange for a new distributor to replace Cobe and to enter into whatever distribution agreement, agency agreement, joint venture agreement, or any other relationship which Aastrom may deem appropriate with a new replacement distributor party. In the event that Aastrom is able to locate a replacement distributor on an early expedited basis, so that Cobe does not need to perform all of the post-termination services as specified for Cobe to perform pursuant to the Term Sheet, then Cobe, Aastrom the replacement distributor store to coperate for an earlier termination of appropriate specified services otherwise to be performed by Cobe pursuant to the Term Sheet.

(c) By at least December 20, 1998, Cobe shall deliver to Aastrom copies or originals any and all files, work product, studies, plans, marketing materials, customer leads, and other such information, data and papers as Cobe may have developed or acquired with respect to its performance or anticipated performance of Cobe's responsibilities under than the Distribution Agreement, so as to assist Aastrom (or its designee) in continuing to perform the distribution functions which were contemplated to be performed by Cobe pursuant to the Distribution Agreement.

(d) With respect to any governmental regulations for the approval of the Product or the marketing of the Product, to the extent that Cobe has obtained such governmental approvals in Cobe's name or has applied for such approvals in Cobe's name, Cobe shall use diligent efforts to accomplish a transfer of the same to Aastrom (or Aastrom's designee).

(e) All of the rights and obligations of the parties under the Distribution Agreement shall cease upon the termination of the Distribution Agreement, excepting only that the following terms and provisions shall remain in full force and effect:

- (S)7.08 Attorneys Fees and Costs
- (S)8.01 Confidentiality
- (S)8.02 Survival of Covenants to Keep Secret
- (S)10.02 Notice
- (S)10.03 Arbitration
- (S)10.04 Governing Law

(f) Cobe shall have no license or other right to use any of Aastrom's intellectual property, including without limitation, patents, trademarks, trade secrets, confidential information.

(g) Aastrom shall no license or other right to use any of Cobe's intellectual property, including without limitation, patents, trademarks, trade secrets and confidential information; provided however, not withstanding the foregoing, Aastrom shall be entitled to use any and all information which Cobe has previously disclosed to Aastrom or which Cobe hereafter discloses to Aastrom which may be helpful for the development, marketing and/or distribution of the Product.

6. No Disparaging Comments. The parties have mutually approved a

message platform and a press release describing the reasons for this Agreement and the termination of the Distribution Agreement. Each party shall use reasonable and diligent efforts to inform its employees and agents as to said reasons and to restrict its employees and agents from making any statements contrary to the substances expressed in the mutually approved message platform and press release.

7. Stock Purchase Agreement. Pursuant to Section 6.01 of the Stock

Purchase Agreement, all of the rights of the parties as set forth in the Stock Purchase Agreement automatically terminate upon the termination of the Distribution Agreement.

8. Stock Resale Restrictions. In order to avoid a disruption of

the public market for the stock of Aastrom, Cobe Laboratories hereby agrees to not offer for sale on the public market any of the Aastrom stock held by Cobe Laboratories until after January 1, 2001, and thereafter only through coordination with the broker/investment banker who is at that time Aastrom's principal market maker. If the stock market conditions change such that Aastrom determines it would not be a disruption in the market for Cobe Laboratories to offer for sale Aastrom shares on an earlier basis, then Aastrom shall so inform Cobe Laboratories, and if Cobe Laboratories so desires, then Cobe Laboratories may sell on an earlier basis a number of Aastrom shares, as is mutually approved by Aastrom.

## 9. Stock Registration Rights. Not withstanding the automatic

termination of the Stock Purchase Agreement and the stock registration rights set forth in Section 5.02 of the Stock Purchase Agreement, Aastrom hereby agrees that Cobe Laboratories shall continue to have the following stock registration rights for the Aastrom common stock held by Cobe Laboratories, in accordance with the terms set forth in Section 5.02 of the Stock Purchase Agreement, as modified as set forth below.

(a) From and after January 1, 2001, Cobe Laboratories shall have the "piggy back" registration rights as set forth in Section 5.02 of the Stock Purchase Agreement; and

(b) From and after six (6) months following the first public stock offering following January 1, 2001, for which "piggy back" registration rights were applicable for Cobe Laboratories, Cobe Laboratories shall have one "demand" registration right as set forth in Section 5.02 of the Stock Purchase Agreement.

10. Bring Along Rights. With respect to the Aastrom common stock

which Cobe Laboratories continues to own, if a majority in interest of Aastrom's shareholders (excluding the Aastrom shares owned by Cobe Laboratories or Cobe's Affiliates) approves a particular sale or merger of Aastrom, then Cobe Laboratories hereby agrees to approve and participate in the same sale or merger, on the same basis and economic terms as all other holders of Aastrom's common stock.

11. General Provisions.

(a) The parties shall cooperate and use good faith efforts to take such other actions and to execute such other documents as may be necessary or appropriate to carry out the purposes and intentions of this Agreement and the Term Sheet.

(b) This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, and all of which taken together shall constitute one and the same Agreement. The parties may sign and deliver this Agreement via facsimile.

IN WITNESS WHEREOF, the parties have executed and delivered this  $\ensuremath{\mathsf{Agreement}}$  as of the date set forth above.

AASTROM BIOSCIENCES, INC.

By: /s/ R. DOUGLAS ARMSTRONG R. Douglas Armstrong, Ph.D. President and Chief Executive Officer

Cobe BCT, INC.

By: /s/ EDWARD WOOD Edward Wood President

Cobe Laboratories, INC.

By: /s/ EDWARD WOOD

This Agreement is entered into as of December \_\_\_\_, 1998 by and among Aastrom Biosciences, Inc., a Michigan corporation ("Aastrom"), COBE BCT, Inc., a Colorado corporation ("COBE"), and COBE Laboratories, Inc., a Colorado corporation ("COBE Laboratories") with respect to the following facts:

- A. Aastrom, COBE and COBE Laboratories have entered into that certain Termination and Transition Agreement dated as of November 16, 1998.
- B. Pursuant to the Termination and Transition Agreement, and as partial consideration therefor, COBE Laboratories agreed to assign and transfer to Aastrom 825,000 shares of Aastrom common stock owned by COBE Laboratories (the "Transfer Shares").

WHEREFORE, the parties hereto mutually agree as follows:

1. In lieu of COBE Laboratories transferring to Aastrom the Transfer Shares, Aastrom hereby authorizes, approves and consents to COBE Laboratories selling the Transfer Shares at \$1.50 per share to the third party investors as listed on Sheet 1 attached hereto, on the condition that the proceeds from any such sale of the Transfer Shares shall be paid by COBE Laboratories to Aastrom immediately on receipt of the purchase price from the purchasing investor.

2. With respect to any sale of the Transfer Shares by COBE Laboratories pursuant to the foregoing, Aastrom hereby waives and releases COBE Laboratories with respect to any transfer restrictions, market standoff agreement or other limitation on the right of COBE Laboratories to sell the Transfer Shares in accordance with Section 1 above.

3. The parties agree that COBE Laboratories' payment to Aastrom of the proceeds from sale of the Transfer Shares shall substitute for the assignment and transfer of such shares pursuant to Section 3 of the Termination and Transition Agreement.

4. The parties shall cooperate and use good faith efforts to take such other actions and to execute and deliver such other documents as may be necessary or appropriate to carry out the purposes and intentions of this Agreement.

5. Except as otherwise expressly set forth herein, all other terms and provisions of the Termination and Transition Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date set forth above.

AASTROM BIOSCIENCES, INC.	COBE BCT, INC.
By: /s/ TODD E. SIMPSON	By: /s/ EDWARD C. WOOD, JR.
	COBE LABORATORIES, INC.
	By: /s/ KEVIN M. SMITH

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE COMPANY'S QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTERLY PERIOD ENDED DECEMBER 31, 1998, AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS

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