SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED DECEMBER 31, 2000, 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 incorporation or organization)	(I.R.S. employer 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.

[X] - Yes [_] - No

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	33,843,388
(Class)	Outstanding at February 9, 2001

AASTROM BIOSCIENCES, INC.
Quarterly Report on Form 10-Q
December 31, 2000

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements	Page
a) Consolidated Condensed Balance Sheets as of June 30, 2000 and December 31, 2000	3
b) Consolidated Condensed Statements of Operations for the three and six months ended December 31, 1999 and 2000 and for the period from March 24, 1989 (Inception) to December 31, 2000	4
c) Consolidated Condensed Statements of Cash Flows for the six months ended December 31, 1999 and 2000 and for the period from March 24, 1989 (Inception) to December 31, 2000	5
d) Notes to Consolidated Condensed Financial Statements	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	8
Item 3. Quantitative and Qualitative Disclosures About Market Risk	19
PART II - OTHER INFORMATION	
Item 1. Legal Proceedings	20
Item 2. Changes in Securities and Use of Proceeds	20
Item 3. Defaults Upon Senior Securities	20
Item 4. Submission of Matters to a Vote of Security Holders	20
Item 5. Other Information	21
Item 6. Exhibits and Reports on Form 8-K	21
SIGNATURES	22
EXHIBIT INDEX	23

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONSOLIDATED CONDENSED BALANCE SHEETS

	June 30, 2000	December 31, 2000
Assets		(Unaudited)
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,064,000	$ 2,926,000
Short-term investments	10,681,000	6,998,000
Receivables	242,000	172,000
Prepaid expenses and other	158,000	977,000
Total current assets	13,145,000	11,073,000
PROPERTY, NET	292,000	213,000
Total assets	13,437,000	$ 11,286,000
Liabilities and Shareholders' Equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 837,000	$ 685,000
Accrued employee expenses	165,000	109,000
Total current liabilities	1,002,000	794,000
SHAREHOLDERS' EQUITY:		
Common stock, no par value; shares authorized - 60,000,000; shares issued and outstanding - 33,607,659 and 33,843,388, respectively	92,367,000	92,726,000
Deficit accumulated during the development stage	(79,932,000)	(82,254,000)
Accumulated other comprehensive income	-	20,000
Total shareholders' equity	12,435,000	10,492,000
Total liabilities and shareholders' equity	$ 13,437,000	$ 11,286,000

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

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended December 31,		Six months ended December 31,		March 24, 1989 (Inception) to December 31,
	1999	2000	1999	2000	2000
REVENUES:					
Product sales and rentals	$ 55,000	$ 85,000	$ 169,000	85,000	$ 288,000
Grants	349,000	210,000	620,000	377,000	4,594,000
Research and development agreements	-	-	-	-	2,020,000
Total revenues	404,000	295,000	789,000	462,000	6,902,000
COSTS AND EXPENSES:					
Cost of product sales and rentals	21,000	13,000	1,251,000	13,000	1,270,000
Research and development	1,869,000	965,000	3,479,000	1,985,000	73,075,000
Selling, general and administrative	698,000	411,000	1,859,000	1,173,000	19,273,000
Total costs and expenses	2,588,000	1,389,000	6,589,000	3,171,000	93,618,000
LOSS FROM OPERATIONS	(2,184,000)	(1,094,000)	(5,800,000)	(2,709,000)	(86,716,000)
OTHER INCOME (EXPENSE):					
Other income	-	-	-	-	1,237,000
Interest income	58,000	178,000	139,000	387,000	4,460,000
Interest expense	-	-	-	-	(267,000)
Other income	58,000	178,000	139,000	387,000	5,430,000
NET LOSS	$(2,126,000)	$ (916,000)	$(5,661,000)	$(2,322,000)	$(81,286,000)
COMPUTATION OF NET LOSS APPLICABLE TO COMMON SHARES:					
Net loss	$(2,126,000)	$ (916,000)	$(5,661,000)	$(2,322,000)	
Dividends and yields on preferred stock	(92,000)	-	(188,000)	-	
Net loss applicable to common shares	$(2,218,000)	$ (916,000)	$(5,849,000)	$(2,322,000)	
NET LOSS PER COMMON SHARE (Basic and Diluted)	$ (.12)	$ (.03)	$ (.34)	$ (.07)	
Weighted average number of common shares outstanding	17,782,000	33,843,000	17,383,000	33,759,000	

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

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Six months ended December 31,		March 24, 1989 (Inception) to December 31,
	1999	2000	2000
OPERATING ACTIVITIES:			
Net loss	$(5,661,000)	$(2,322,000)	$(81,286,000)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	245,000	101,000	3,131,000
Loss on property held for resale	-	-	110,000
Amortization of discounts and premiums on investments	-	(47,000)	(521,000)
Stock compensation expense	5,000	120,000	664,000
Write down of inventory	-	-	1,027,000
Stock issue pursuant to license agreement	-	-	3,300,000
Changes in assets and liabilities:			
Receivables	(27,000)	70,000	(196,000)
Inventory	1,103,000	-	(1,027,000)
Prepaid expenses	(65,000)	(819,000)	(977,000)
Accounts payable and accrued expenses	299,000	(152,000)	685,000
Accrued employee expenses	231,000	(56,000)	109,000
Net cash used for operating activities	(3,870,000)	(3,105,000)	(74,981,000)
INVESTING ACTIVITIES:			
Organizational costs	-	-	(73,000)
Purchase of short-term investments	-	(1,500,000)	(56,624,000)
Maturities of short-term investments	-	5,250,000	50,167,000
Capital purchases	(127,000)	(22,000)	(2,607,000)
Proceeds from sale of property held for resale	-	-	400,000
Net cash provided by (used for) investing activities	(127,000)	3,728,000	(8,737,000)
FINANCING ACTIVITIES:			
Issuance of preferred stock	-	-	51,647,000
Issuance of common stock	19,000	239,000	32,689,000
Repurchase of common stock	-	-	(49,000)
Payments received for stock purchase rights	-	-	3,500,000
Payments received under shareholder notes	-	-	31,000
Principal payments under capital lease obligations	-	-	(1,174,000)
Net cash provided by financing activities	19,000	239,000	86,644,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(3,978,000)	862,000	2,926,000
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	7,528,000	2,064,000	-
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 3,550,000	$ 2,926,000	$ 2,926,000

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

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

1. Organization

Aastrom Biosciences, Inc. (Aastrom) was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in the development stage. We operate our business in one reportable segment - research and product development, conducted both on our own behalf and in connection with various collaborative research and development agreements with others, involving the development and sale of processes and products for the ex vivo production of human cells for use in cell and ex vivo gene therapy.

Successful future operations are subject to several technical and business risks, including our ability to obtain future funding, satisfactory product development, obtaining regulatory approval and market acceptance for our products.

2. Basis of Presentation

The condensed consolidated financial statements included herein have been prepared by us 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 in the United States have been omitted pursuant to such rules and regulations. The financial statements reflect, in the opinion of management, all 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, 2000, are not necessarily indicative of the results to be expected for the full year or for any other period.

The consolidated financial statements include the accounts of Aastrom and its wholly-owned subsidiary, Zellera AG ("Zellera"), which is located in Berlin, Germany (collectively, the "Company"). All significant inter-company transactions and accounts have been eliminated in consolidation. As of December 31, 2000, Zellera has only limited operations and is not a significant component of the consolidated financial statements.

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

3. Shareholders Equity

Accumulated Other Comprehensive Income in the accompanying consolidated condensed balance sheets consist of unrealized gains on securities that are available for sale. For the six-month period ended December 31, 2000, other comprehensive income was $20,000.

Research and Development Expense for the six months ended December 31, 2000 include non-cash charges totaling $120,000 relating to certain stock options awarded in December 1999 that are accounted for as variable stock options. The resulting charges, or credits, to expense are based on the market price of our common stock at the end of each quarter. Research and Development and Selling, General and Administrative Expenses for the quarter ended December 31, 2000 include a non-cash credit totaling $228,000 relating to these stock options.

4. Net Loss Per Common Share

Net loss per common share is computed using the weighted-average number of common 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. The computations of net loss per common share for the periods ended December 31, 1999 reflect dividends and yields on outstanding 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.

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

Overview of Aastrom

We are developing proprietary process technologies and devices intended for a broad range of cell therapy applications. Our lead product under development is the AastromReplicell(TM) System, which consists of a clinical cell culture system that operates single-use therapy kits tailored for patient therapy in the emerging cell therapy market. We are currently developing our SC-I Therapy Kit, CB-I Therapy Kit and CB-II Therapy Kit for use in stem cell therapy to restore blood and immune system function to cancer patients following chemotherapy or radiation therapy. We believe that the AastromReplicell(TM) System may offer significant advantages over traditional stem cell collection methods in settings where it is difficult to obtain the desired quantity of cells for transplant.

We are developing the DC-I Therapy Kit for the clinical-scale production of dendritic cells. Dendritic cells are a type of blood cell that have the ability to stimulate an immune response against specific targets, and are being widely pursued as a new potential treatment for cancer and viral diseases. We intend to make the DC-I Therapy Kit available to clinical researchers and centers that are developing dendritic cell-based vaccines designed to treat cancer and other disorders. We have also recently initiated a development program for an AastromReplicell(TM) System therapy kit for the production of bone-forming cells. The new OC-I Therapy Kit is intended for the treatment of patients with degenerative bone diseases such as osteoporosis. Recently, we initiated our first Phase I/II-Pilot clinical study for the OC-I Therapy Kit in patients with severe osteoporosis.

Our Product Pipeline

Our business model builds on two components: (i) proprietary procedures and devices to enable certain types of stem cells and other types of human cells to be produced with superior biological capabilities as compared with standard cell culture approaches, and (ii) the AastromReplicell(TM) System clinical platform that is designed to standardize and enable an effective commercialization pathway for bringing therapeutic cell production to medical practice. The product configuration of the AastromReplicell(TM) System consists of an instrumentation platform, to be integrated within the hospital or other centralized facility, that can operate a variety of single-use therapy kits that are specific to the desired medical application. This is intended to provide a product pathway for each cell therapy that is similar to a pharmaceutical product including regulatory approval, reimbursement, marketing and pricing. We believe that the product design of the AastromReplicell(TM) System will allow us to develop additional cell therapy kits to provide product standardization for a number of emerging cell therapies being developed by other researchers.

Although we may not market the AastromReplicell(TM) System in the United States for stem cell therapy unless and until approval is obtained from the U.S. Food and Drug Administration (FDA), production-level versions of the AastromReplicell(TM) System have been completed and we

have obtained permission to affix the CE Mark to such versions. CE Mark approval allows for marketing of the product in Europe. We may also market the AastromReplicell(TM) System in the U.S. for research and investigational use and we are developing our marketing plan to establish relationships with leading sites, initially in Europe, to build a customer foundation for the AastromReplicell(TM) System.

Since our inception, we have been in the development stage and engaged in research and product development, conducted principally on our own behalf, but also in connection with various collaborative research and development agreements with others. We commenced our initial European pilot-scale product launch of the AastromReplicell(TM) System in April 1999, but subsequently had to suspend those activities in October 1999 pending the receipt of additional financing. We do not expect to generate positive cash flows until more significant product sales commence, which could take several years. Until that time, we expect that our revenues will be limited to grant revenue and research funding, 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 our 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 portion of our revenues from product sales will be subject to our obligation to make aggregate royalty payments of up to 2% to certain licensors of our technology. Research and development expenses may fluctuate due to the timing of expenditures for the varying stages of our research, product development and clinical development programs and the availability of resources. Generally, product development expenses have decreased as we have transitioned from prototype-versions to production-level versions of the AastromReplicell(TM) System. Operating expenses have also decreased over the past year as a result of cost reduction efforts that we have implemented. Clinical development costs are expected to increase as we conduct our U.S. clinical trials, successful completion of which are necessary to submit for regulatory approvals to market our products in the U.S. and research and development costs are expect to increase in support of expanded product development activities. Similarly, marketing and other general and administrative expenses are expected to increase in support of European marketing activities as they resume. Under our license agreement with Immunex, the $1,000,000 annual renewal fees due in March 1998, 1999 and 2000 were each paid through the issuance of $1,100,000 of our common stock. As a result of these and other factors, our 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 results of operations for any future periods.

The scope and size of our operations has been tied to the availability of capital and other resources. For example, in October 1999, we were forced to implement significant cost reduction measures while we pursued corporate partnering activities, including merger or acquisition transactions, and sought additional capital. We completed the sale of equity securities in February 2000 and June 2000, providing aggregate net proceeds of $11,800,000 that allowed us to resume certain activities. With this funding, we have recommenced our U.S. clinical development program, and we are restoring production manufacturing capabilities and pilot-scale

marketing activities in Europe with targeted medical centers. We need to obtain additional financing and we continue to pursue our financing options.

In order for us to resume more expanded operations, we will need to hire more personnel to address requirements in the areas of product and customer support, research, clinical and regulatory affairs, quality systems, sales and marketing and administration. Our operating expenses are expected to increase as a result. At least until such time as we enter into arrangements providing research and development funding or achieve significantly larger levels of product sales, we will continue to incur net operating losses. As a development-stage company, we have never been profitable and we do not anticipate having net income unless and until significant product sales commence, which is unlikely to occur until we obtain significant additional funding. Through December 31, 2000, our accumulated losses total $81.3 million. There can be no assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, or complete a corporate partnering or acquisition transaction.

RESULTS OF OPERATIONS

Revenues for the quarter and six-month period ended December 31, 2000 were $295,000 and $462,000, respectively, compared to $404,000 and $789,000 for the same periods in 1999. Revenues consist primarily of grant funding and decreased to $210,000 and $377,000 for the quarter and six months ended December 31, 2000, from $349,000 and $620,000 for the same periods in 1999. The decreases in grant revenues reflect decreases in overall costs and expenses for the periods ended December 31, 2000, including grant funded activities, as a result of cost reduction measures that had been implemented in late 1999.

Costs and expenses for the quarter ended December 31, 2000 decreased to $1,389,000, compared to $2,588,000 in 1999. This decrease includes a reduction in research and development expense to $965,000 for the quarter ended December 31, 2000, from $1,869,000 for the same period in 1999, and a reduction in selling, general and administrative expenses to $411,000 from $698,000. Costs and expenses for the six months ended December 31, 2000 decreased to $3,171,000, compared to $6,589,000 in 1999. This decrease includes a reduction in research and development expense to $1,985,000 for the six months ended December 31, 2000, from $3,479,000 for the same period in 1999, and a reduction in selling, general and administrative expenses to $1,173,000 from $1,859,000. These planned decreases were the result of general expense reductions previously implemented to control expenditures, and included reductions in research activities, as well as European sales and marketing activities, while additional funding was being obtained. With the completion of additional funding during calendar year 2000, and the potential additional funding being pursued, we expect to increase the scope of our marketing activities, particularly with respect to Europe. Cost of product sales and rentals for the six months ended December 31, 1999 included a charge of $1,142,000 relating to the write down of AastromReplicell(TM) System inventory. Expenses for the six months ended December 31, 2000 include non-cash charges totaling $120,000 relating to certain stock options awarded in December 1999 that are accounted for as variable stock options. These stock options require charges, or credits, to expense based on the market price of our common stock at the end of each

quarter. Expenses for the quarter ended December 31, 2000 include a non-cash credit of $228,000 relating to these stock options.

Interest income was $139,000 and $387,000 for the quarter and six months ended December 31, 2000, respectively, compared to $58,000 and $178,000 for the same periods in 1999. These increases correspond to increased levels of invested cash and cash equivalents following the completion of equity financings in February and June of 2000.

The net loss for the quarter ended December 31, 2000 was $916,000, or $.03 per common share, compared to a net loss of $2,126,000, or $.12 per common share for the same period in 1999. The net loss for the six months ended December 31, 2000 was $2,322,000, or $.07 per common share compared to $5,661,000, or $.34 per common share in 1999. These decreases are primarily the result of decreased costs and expenses and increased interest income in 2000 and an increase in the weighted average number of common shares outstanding that resulted from the conversion of previously outstanding convertible preferred stock. The computations of net loss per common share for the periods ended December 31, 1999 include adjustment for dividends and yields on outstanding preferred stock. These adjustments affect only the computation of net loss per common share and are not included in the net loss for the period.

LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations since inception primarily through public and private sales of equity securities, which, from inception through December 31, 2000, have totaled approximately $93 million and, to a lesser degree, through grant funding, payments received under research agreements and collaborations and interest earned on cash, cash equivalents, and short-term investments.

Our combined cash, cash equivalents and short-term investments totaled $9,924,000 at December 31, 2000, a decrease of $2,821,000 from June 30, 2000. The primary uses of cash, cash equivalents and short-term investments during the six months ended December 31, 2000 included $3,058,000 to finance our operations and working capital requirements. The primary sources of cash, cash equivalents and short-term investments was from the exercise of stock options that totaled $239,000 during the period.

Our future cash requirements will depend on many factors, including continued scientific progress in our 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 and the cost of product commercialization. We do not expect to generate a positive cash flow until more significant product sales commence, which could take several years. We intend to seek additional funding through research and development, or distribution and marketing, agreements with suitable corporate collaborators, grants and through public or private financing transactions. Successful future operations are subject to several technical and business risks, including our continued ability to obtain future funding, satisfactory product development, obtaining regulatory approval and market acceptance for our products. Based on current funding and anticipated operating activities, we expect that our available cash will be sufficient to finance currently planned activities through the end of fiscal year 2001. 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 our Annual Report on Form 10-K. We are pursuing additional sources of financing. If we cannot obtain additional funding prior to our current cash reserves being depleted, we will be forced to make substantial reductions in the scope and size of our operations, and may be forced to curtail activities. In order to grow and expand our business, and to develop and introduce our product candidates into the marketplace, we will need to raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our product candidates for the expansion of additional cell types. We expect that our primary sources of capital for the foreseeable future will be through collaborative arrangements and through the public or private sale of our 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 our ability to raise additional funding, including, but not limited to, market volatility of our 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, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs, which may have a material

adverse effect on our business. See "Business Risks" and Notes to Consolidated Financial Statements in our 2000 Annual Report on Form 10-K and Notes to Consolidated Financial Statements included herein.

Certain Business Considerations

History of Operating Losses/Need for Additional Capital

We will require substantial capital resources in order to conduct our operations and develop our products. In October 1999, we were forced to reduce operations based on our declining level of capital resources and our limited financing alternatives available at that time. Although we have resumed certain operating activities, the previous reduction in our operating activities has negatively affected our ability to manufacture and develop our products and has delayed our product development programs. Based on current funding and anticipated operating activities, we expect that our available cash and expected interest income will be sufficient to finance our current activities through the end of fiscal year 2001. This is a forward-looking statement and could be negatively affected by funding limitations, the implementation of additional research and development programs and other factors discussed under this heading. We are currently pursuing additional sources of financing. If we cannot obtain additional funding prior to that time, we will be forced to make substantial reductions in the scope and size of our operations, and may be forced to curtail activities. In order to grow and expand our business, and to develop and introduce our product candidates into the marketplace, we will need to raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our new product candidates for the production of additional cell types.

Product Development Setbacks Would Hurt Our Ability to Raise Needed Capital

Commercialization in the U.S. of our lead product candidate, the AastromReplicell(TM) System, will require additional research and development as well as substantial clinical trials. While we have commenced initial marketing on a limited pilot-scale basis of the AastromReplicell(TM) System in Europe, we believe that the U.S. will be the principal market for our current products. We may not be able to successfully complete development of the AastromReplicell(TM) System or our other product candidates, or successfully market our technologies or product candidates. We, and any of our potential collaborators, may encounter problems and delays relating to research and development, regulatory approval and intellectual property rights of our technologies and product candidates. Our research and development programs may not be successful, and our cell culture technologies and product candidates may not facilitate the ex vivo production of cells with the expected biological activities in humans. Our technologies and product candidates may not prove to be safe and efficacious in clinical trials, and we may not obtain the intended regulatory approvals for our technologies or product candidates and the cells produced in such products. If any of these events occur, we may not have adequate resources to continue operations for the period required to resolve the issue delaying commercialization and we may not be able to raise additional capital to finance our continued operations during the period required for resolution of that issue. We cannot be certain that we will be able to raise the required capital to conduct our operations and develop our products.

Uncertainties of Clinical Trials

To be able to market products in the U.S. beyond research and investigational uses, we must demonstrate, through extensive pre-clinical studies and clinical trials, the safety and efficacy of our processes and product candidates, together with the cells produced by such processes in such products, for application in the treatment of humans. We are currently conducting clinical trials to demonstrate the safety and biological activity of patient-derived cells produced in the AastromReplicell(TM) System. Depending on the availability of resources, we intend to commence at least one additional clinical trial to demonstrate the safety and biological activity of umbilical cord blood cells produced in the AastromReplicell(TM) System. If our clinical trials are not successful, our products may not be marketable.

Our ability to complete our clinical trials in a timely manner depends on many factors, including the rate of patient enrollment. Patient enrollment can vary with the size of the patient population, the proximity of suitable patients to clinical sites, perceptions of the utility of the therapy for the treatment of certain diseases and the eligibility criteria for the study. We have experienced delays in patient accruals in our previous and current clinical trials. If we experience future delays in patient accruals, we could experience increased costs and delays associated with clinical trials that would impair our product development programs and our ability to market our products. Furthermore, the U.S. Food and Drug Administration (FDA) monitors the progress of clinical trials and it may suspend or terminate clinical trials at any time due to patient safety or other considerations.

Uncertainty of Regulatory Approval

Except for research and investigational uses, we must obtain the approval of the FDA before commercial sales of our product candidates may commence in the U.S., which we believe will be the principal market for our products. We may also be required to obtain additional approvals from foreign regulatory authorities to continue or increase our sales activities in those jurisdictions. If we cannot demonstrate the safety, reliability and efficacy of our product candidates, or of the cells produced in such products, we may not be able to obtain required regulatory approvals. Many of the patients enrolled in our stem cell therapy clinical trials will have previously undergone extensive treatment which will have substantially weakened the patients and may have irreparably damaged the ability of their blood and immune system to recover. Some patients undergoing the transplant recovery process have died, from causes that were, according to the physicians involved, unrelated to the AastromReplicell(TM) System procedure, and it is possible that other patients may die or suffer severe complications during the course of either the current or future clinical trials. In addition, patients receiving cells produced with our technologies and product candidates may not demonstrate long-term engraftment in a manner comparable to cells obtained from current stem cell therapy procedures. If we cannot demonstrate the safety or efficacy of our technologies and product candidates, including long-term sustained engraftment, or if one or more patients die or suffer severe complications, the FDA or other regulatory authorities could delay or withhold regulatory approval of our product candidates.

Finally, even if we obtain regulatory approval of a product, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA, other regulatory agencies, and governments in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, governmental regulatory agencies may establish additional regulations which could prevent or delay regulatory approval of our products.

Uncertainty of Market Acceptance of Product Candidates

Our product development efforts are primarily directed toward obtaining regulatory approval to market the AastromReplicell(TM) System as an alternative to, or as an improvement for, the bone marrow harvest and peripheral blood progenitor cell stem cell collection methods. These stem cell collection methods have been widely practiced for a number of years, and our technologies or product candidates may not be accepted by the marketplace as readily as these or other competing processes and methodologies. Additionally, our technologies or product candidates may not be employed in all potential applications being investigated, and any limited applications would limit the market acceptance of our technologies and product candidates and our potential revenues. As a result, even if we obtain all required regulatory approvals, we cannot be certain that our products and processes will be adopted at a level that would allow us to operate profitably.

Dependence on Third Parties for Materials

We rely solely on third parties to manufacture our product candidates and their component parts. We also rely solely on third party suppliers to provide necessary key mechanical components, as well as growth factors and other materials used in the cell expansion process. We would not be able to obtain alternate sources of supply for many of these items on a short-term basis. In October 1999, we suspended manufacturing of our products. Although we have resumed certain operating activities, the previous reduction in our operating activities has negatively affected our ability to manufacture and develop our products. Further, if any of our key manufacturers or suppliers fails to perform their respective obligations, or if our supply of growth factors, components or other materials is limited or interrupted, we would not be able to conduct clinical trials or market our product candidates on a timely and cost-competitive basis, if at all.

Furthermore, some of the compounds used by us in our current stem cell expansion processes involve the use of animal-derived products. Suppliers or regulatory authorities may limit or restrict the availability of such compounds for clinical and commercial use. Any restrictions on these compounds would impose a potential competitive disadvantage for our products. If we were not able to develop or obtain alternative compounds, our product development and commercialization efforts would be harmed.

Finally, we may not be able to continue our present arrangements with our suppliers, supplement existing relationships, establish new relationships or be able to identify and obtain the ancillary

materials that are necessary to develop our product candidates in the future. Our dependence upon third parties for the supply and manufacture of these items could adversely affect our ability to develop and deliver commercially feasible products on a timely and competitive basis.

Limited Internal Sales and Marketing Capabilities

While we have commenced initial marketing on a limited basis of the AastromReplicell(TM) System in Europe, we have only limited internal sales, marketing and distribution capabilities. We intend to market our products through collaborative relationships with companies for sales, marketing and distribution capabilities. If we cannot develop and maintain those relationships, we would have only a limited ability to market, sell and distribute our products. Even if we are able to enter into such relationships, they may not succeed or be sustained on a long-term basis, and termination would require us to develop alternate arrangements at a time when we need sales, marketing or distribution capabilities to meet existing demand. For example, in November 1998 Aastrom and COBE BCT terminated a strategic alliance for the worldwide distribution of the AastromReplicell(TM) System for stem cell therapy and related uses. We are now seeking to enter into other arrangements relating to the development and marketing of our product candidates.

Volatility of Our Stock Price May Limit our Ability to Raise Capital

The market price of shares of our common stock has been volatile. The price of our common stock may continue to fluctuate in response to a number of events and factors, any of which may cause the price of our shares to fall, and may adversely affect our business and financing opportunities. In addition, the stock market in general and the market prices for biotechnology companies in particular have experienced significant volatility that often has been unrelated to the operating performance or financial conditions of such companies. These broad market and industry fluctuations may adversely affect the trading price of our stock, regardless of our operating performance or prospects.

The exercise price of the warrants that we issued in February 2000 is subject to reduction in the event the price of our common stock goes down at specified times in the future or if we issue additional securities at less than the warrant exercise price. The warrants are currently exercisable for 1,382,816 shares of common stock, at a price of approximately $3.02 per share. This number of shares could increase to 2,614,386 shares of common stock and the exercise price could be reduced to as low as $1.60 per share. In connection with a financing completed in June 2000, we issued a warrant to purchase up to 3,348,915 shares of our common stock at $0.01 per share as a means of providing the investor with a limited price adjustment in June 2001 if the price of our common stock decreases. If all shares of common stock issuable under these warrants are issued, then holders of common stock could experience significant dilution of their investment.

In addition, sales, or the possibility of sales, of substantial numbers of shares of common stock in the public market could adversely affect prevailing market prices of shares of common stock.

Our employees hold a significant number of options to purchase shares, many of which are presently exercisable. Employees may exercise their options and sell shares shortly after such options become exercisable, particularly if they need to raise funds to pay for the exercise price of such options or to satisfy tax liabilities that they may incur in connection with exercising their options. Additionally, beginning January 1, 2001, COBE BCT will be able to sell all of its approximately 2.4 million shares of our common stock without restriction.

Nasdaq Listing Requirements

We are required to meet certain financial tests (including, but not limited to, a minimum bid price of our common stock of $1.00 and $4 million in tangible net worth) to maintain the listing of our common stock on the Nasdaq National Market. Within the last year, our common stock price has fallen below the minimum level for some periods and during other periods our tangible net worth has been below the amount required. In the future, our stock price or tangible net worth may fall below the Nasdaq requirements, or we may not comply with other listing requirements, with the result being that our common stock might be delisted. If that happened the market price and liquidity of our common stock would be impaired.

Forward-looking statements

This report contains certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. These forward-looking statements include statements regarding potential strategic collaborations, future capital needs and funding requirements, product development plans, clinical trials and market assessments. These statements are subject to risks and uncertainties, including those set forth in this section, and actual results could differ materially from those expressed or implied in these statements. These business considerations, and others, are discussed in more detail and should be read in conjunction with the Business Risks discussed in our 2000 Annual Report on Form 10-K. We assume no obligation to update any such forward-looking statement or reason why actual results might differ.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectability and establishment of appropriate allowances in connection with our internal controls and policies. We do not enter into hedging or derivative instruments.

We are also exposed to interest rate changes principally affecting our investments in interest rate sensitive instruments. An analysis of the impact on our interest rate sensitive financial instruments of a hypothetical 10% change in short-term interest rates compared to interest rates at December 31, 2000 indicates that it would not have a significant impact on expected fiscal year 2001 earnings.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time we receive threats or may be subject to litigation matters incidental to our business. However, we are not currently a party to any material pending legal proceedings.

Item 2. Changes in Securities and Use of Proceeds

None.

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 15, 2000.

(b) At the 2000 Annual Meeting of Shareholders, votes were cast on matters submitted to the shareholders, as follows:

The election of two directors whose terms expire at the 2002 Annual Meeting of Shareholders.

NOMINEE	FOR	WITHHELD
Joseph A Taylor	29,839,260	524,295
R. Douglas Armstrong, Ph.D.	29,879,477	484,078

In addition to the election of the above referenced directors, the following individuals continue as directors; Alan M. Wright and Fabrizio Bonanni, as Class I Directors, whose terms expire at the 2001 Annual Meeting of Shareholders and Mary L. Campbell and Arthur F. Staubitz as Class II Directors, whose terms expire at the 2002 Annual Meeting of Shareholders.

Approval of the amendment of the 1992 Incentive and Non-Qualified Stock Option Plan to increase the maximum aggregate number of shares reserved for issuance thereunder by 1,400,000.

FOR	AGAINST	ABSTAIN
29,282,433	1,040,245	40,877

Approval of the amendment of the 1996 Outside Directors Stock Option Plan to (i) increase by 150,000 the maximum number of shares of Aastrom's common stock that may be issued thereunder; and (ii) to increase the size of the Initial Option Grant and Annual Option granted after the date of the 2000 Annual Meeting of Shareholders from 5,000 to 10,000 shares.

FOR	AGAINST	ABSTAIN
29,237,539	1,063,090	62,926

The vote to approve the selection of PricewaterhouseCoopers LLP as the Company's independent public accountants for the year ending June 30, 2001.

FOR	AGAINST	ABSTAIN
30,114,952	212,588	36,015

Item 5. Other Information

None.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

See Exhibit Index.

(b) Reports on Form 8-K

The Company filed a Report on Form 8-K dated November 14, 2000.

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 13, 2001 /s/ R. Douglas Armstrong

R. Douglas Armstrong, Ph.D.
President, Chief Executive Officer
(Principal Executive Officer)

Date: February 13, 2001 /s/ Todd E. Simpson

Todd E. Simpson
Vice President, Finance and Administration,
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
3.1 *	Restated Articles of Incorporation of the Company
3.2 **	Bylaws of the Company

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* 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.