**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

# Form 10-Q

(Mark One)

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

**For the quarterly period ended December 31, 2001**

**or**

o **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.<br>P.O. Box 376<br>Ann Arbor, Michigan**<br>*(Address of principal executive offices)* | **48106**<br>*(Zip code)* |

**(734) 930-5555**

*(Registrant's telephone number, including area code)*

**N/A**

*(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. Yes ☑ No o

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** | **42,343,151** |
|---|---|
| *(Class)* | **Outstanding at February 8, 2002** |

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**AASTROM BIOSCIENCES, INC.**

**Quarterly Report on Form 10-Q**

**December 31, 2001**

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## PART I — FINANCIAL INFORMATION

**Item 1.** ***Financial Statements***

### AASTROM BIOSCIENCES, INC.

**(a development stage company)**

### CONSOLIDATED CONDENSED BALANCE SHEETS

| | June 30, 2001 | December 31, 2001 (Unaudited) |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 10,659,000 | $ 8,781,000 |
| Short-term investments | — | 4,502,000 |
| Receivables | 129,000 | 172,000 |
| Inventory | 725,000 | 846,000 |
| Other current assets | 213,000 | 348,000 |
| Total current assets | 11,726,000 | 14,649,000 |
| PROPERTY, NET | 179,000 | 161,000 |
| Total assets | $ 11,905,000 | $ 14,810,000 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| CURRENT LIABILITIES: | | |
| Accounts payable and accrued expenses | $ 856,000 | $ 764,000 |
| Accrued employee expenses | 155,000 | 222,000 |
| Total current liabilities | 1,011,000 | 986,000 |
| SHAREHOLDERS' EQUITY: | | |
| Common stock, no par value; shares authorized — 60,000,000; shares issued and outstanding — 37,681,235 and 42,343,351, respectively | 96,752,000 | 103,593,000 |
| Deficit accumulated during the development stage | (85,858,000) | (89,771,000) |
| Accumulated other comprehensive income | — | 2,000 |
| Total shareholders' equity | 10,894,000 | 13,824,000 |
| Total liabilities and shareholders' equity | $ 11,905,000 | $ 14,810,000 |

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, |
|---|---|---|---|---|---|
| | 2000 | 2001 | 2000 | 2001 | 2001 |
| REVENUES: | | | | | |
| Product sales and rentals | $ 85,000 | $ 80,000 | $ 85,000 | $ 80,000 | $ 368,000 |
| Grants | 210,000 | 187,000 | 377,000 | 338,000 | 5,369,000 |
| Research and development agreements | — | — | — | — | 2,020,000 |
| Total revenues | 295,000 | 267,000 | 462,000 | 418,000 | 7,757,000 |
| COSTS AND EXPENSES: | | | | | |
| Cost of product sales and rentals | 13,000 | 66,000 | 13,000 | 106,000 | 1,376,000 |
| Research and development | 965,000 | 1,396,000 | 1,985,000 | 2,603,000 | 78,676,000 |
| Selling, general and administrative | 411,000 | 931,000 | 1,173,000 | 1,850,000 | 22,432,000 |
| Total costs and expenses | 1,389,000 | 2,393,000 | 3,171,000 | 4,559,000 | 102,484,000 |
| LOSS FROM OPERATIONS | (1,094,000) | (2,126,000) | (2,709,000) | (4,141,000) | (94,727,000) |
| OTHER INCOME (EXPENSE): | | | | | |
| Other income | — | — | — | — | 1,237,000 |
| Interest income | 178,000 | 106,000 | 387,000 | 228,000 | 4,954,000 |
| Interest expense | — | — | — | — | (267,000) |
| Other income | 178,000 | 106,000 | 387,000 | 228,000 | 5,924,000 |
| NET LOSS | $ (916,000) | $ (2,020,000) | $ (2,322,000) | $ (3,913,000) | $ (88,803,000) |
| NET LOSS PER SHARE (Basic and Diluted) | $ (.03) | $ (.05) | $ (.07) | $ (.10) | |
| Weighted average number of shares outstanding | 33,843,000 | 42,343,000 | 33,759,000 | 41,139,000 | |

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, |
|---|---|---|---|
| | 2000 | 2001 | 2001 |
| OPERATING ACTIVITIES: | | | |
| Net loss | $(2,322,000) | $ (3,913,000) | $(88,803,000) |
| Adjustments to reconcile net loss to net cash used for operating activities: | | | |
| Depreciation and amortization | 101,000 | 62,000 | 3,263,000 |
| Loss on property held for resale | — | — | 110,000 |
| Amortization of discounts and premiums on investments | (47,000) | — | (543,000) |
| Stock compensation expense | 120,000 | — | 664,000 |
| Inventory reserves and write-offs | — | 106,000 | 1,133,000 |
| Stock issued pursuant to license agreement | — | — | 3,300,000 |
| Changes in assets and liabilities: | | | |
| Receivables | 70,000 | (43,000) | (196,000) |
| Inventory | — | (227,000) | (1,979,000) |
| Other current assets | (819,000) | (135,000) | (348,000) |
| Accounts payable and accrued expenses | (152,000) | (92,000) | 764,000 |
| Accrued employee expenses | (56,000) | 67,000 | 222,000 |
| Net cash used for operating activities | (3,105,000) | (4,175,000) | (82,413,000) |
| INVESTING ACTIVITIES: | | | |
| Organizational costs | — | — | (73,000) |
| Purchase of short-term investments | (1,500,000) | (4,500,000) | (61,124,000) |
| Maturities of short-term investments | 5,250,000 | — | 57,167,000 |
| Capital purchases | (22,000) | (44,000) | (2,687,000) |
| Proceeds from sale of property held for resale | — | — | 400,000 |
| Net cash provided by (used for) investing activities | 3,728,000 | (4,544,000) | (6,317,000) |
| FINANCING ACTIVITIES: | | | |
| Issuance of preferred stock | — | — | 51,647,000 |
| Issuance of common stock | 239,000 | 6,841,000 | 43,556,000 |
| 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 | 239,000 | 6,841,000 | 97,511,000 |
| NET INCREASE IN CASH AND CASH EQUIVALENTS | 862,000 | (1,878,000) | 8,781,000 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 2,064,000 | 10,659,000 | — |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | $ 2,926,000 | $ 8,781,000 | $ 8,781,000 |

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* (outside the body) production of human cells for use in cell and *ex vivo* gene therapy.

Since October 2000, we were approved to affix the CE Mark on the AastromReplicell™ System, our proprietary clinical platform designed to standardize and enable commercial pathway for bringing cell production to medical practice, and a variety of single-use cell production kits and products specific to a desired medical application (SC-I, CB-I, and DC-I), allowing us to sell and market our products in Europe. To develop and manage our European sales and marketing activities, Aastrom formed a wholly-owned subsidiary in Berlin, Germany, Zellera AG ("Zellera").

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

## 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, 2001, 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 (collectively, the "Company"). For the six months ended December 31, 2001, Zellera operations were limited and not considered material to our consolidated results of operations. All inter-company transactions and accounts have been eliminated in consolidation.

These financial statements should be read in conjunction with the audited financial statements and the notes thereto included in our 2001 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 sheet consists of unrealized gains on securities that are available for sale. For the six month period ended December 31, 2001, other comprehensive income was $2,000.

We obtained additional equity of $6,841,000 for the six months ended December 31, 2001 and issued 4,636,000 common shares in these transactions. This equity financing was transacted under our December 29, 2000 shelf registration, completing the shares available under this offering.

We filed a new shelf registration statement on November 16, 2001 for the issuance of up to 8,400,000 common shares. As of December 31, 2001, no shares have been issued under this shelf registration.

**AASTROM BIOSCIENCES, INC.**
**(A development stage company)**

**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

## 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 aggregate number of common equivalent shares that have been excluded from the computations of net loss per common share for the three and six months ended December 31, 2000 and 2001 is approximately 7,470,000 and 6,311,000, respectively.

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

**Overview of Aastrom**

We are pioneering the development of human cell therapy technologies intended for a broad range of medical applications based on our patented process and device capabilities for manufacturing proprietary cell mixtures. Our lead cell therapeutic products under development include Dendricell™ products (DC-I and DCV-I) for the clinical-scale production of dendritic cells intended for the emerging cancer vaccine market. We are also developing our SC-I, CB-I and CB-II products for use in stem cell therapy and our OC-I product for the generation of bone tissue.

Our business model builds on two complementary components: (i) proprietary procedures and devices to enable certain types of stem cells and other types of human cells to be produced with excellent biological capabilities as compared with standard cell culture approaches, and (ii) the AastromReplicell™ System clinical platform that is designed to standardize and enable an effective commercialization pathway for bringing therapeutic cell production to medical practice. The AastromReplicell™ System consists of an instrumentation platform, to be either sold to a hospital or other centralized facility, or alternatively, used by Aastrom, that can operate a variety of single-use cell production kits that are specific to the desired medical application. Each cell product is produced using a specific type of kit. The kit and the cell product produced with the kit share a common identifying nomenclature such as DC-I, OC-I, SC-I and CB-I. Through this product configuration, we intend to either directly commercialize cells for therapeutic use, or enable customers or potential collaborators with the capability to produce cells for therapeutic applications through sale of the AastromReplicell™ System instruments and kits. This approach 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™ System will allow us to develop additional cell therapy products to provide standardization for a number of emerging cell therapies being developed by other researchers.

We are investigating dendritic cells, a type of blood cell that have the ability to stimulate an immune response against specific targets as a potential new treatment for cancer and viral diseases. We intend to sell the DC-I cell product to clinical researchers and centers that are developing dendritic cell-based vaccines designed to treat cancer and other disorders. During the past year, we initiated our external site testing of the AastromReplicell™ System and the DC-I cell product with leading research centers. We have obtained approval to affix the CE Mark to the DC-I Cell Therapy Kit, allowing us to market and sell the product in Europe. We also plan to market the DC-I cell product to U.S. clinical and research groups that are developing dendritic cell-based cancer vaccines, and to develop our own proprietary vaccines pending additional funding or strategic partnerships. Our stem cell therapy products have received CE Mark approval allowing us to begin commercialization activities in Europe, and are in Phase III-Type clinical studies in the U.S. Additionally, we have recently initiated a development program for the production of bone-forming cells in the AastromReplicell™ System. Our OC-I cell product is being developed for the treatment of patients with degenerative bone diseases such as osteoporosis, for which a Phase I/II-Pilot clinical study is in process in the U.S., and for bone grafting applications.

Although we may not market the AastromReplicell™ System in the United States for stem cell therapy unless and until approval is obtained from the FDA, we have completed production-level versions of the AastromReplicell™ System and have begun European commercialization activities for the AastromReplicell™ System instrumentation and the SC-I, CB-I and DC-I kits. We may also market the AastromReplicell™ System and kits in the U.S. for research and investigational use and are developing our marketing plan to establish relationships with leading sites to build a customer foundation for the AastromReplicell™ System. The SC-I and CB-I kits are in phase III clinical trials and the OC-I is in Phase I/II clinical trials.

Our efforts to date have focused on using our technology to grow larger quantities of the desired therapeutic cells from small starting amounts of cells or a tissue. Our cell production processes are based on using the natural reproductive capabilities of cells outside the body, without various cloning approaches. Our

programs currently use bone marrow, cord blood and blood cells as starting sources of cells. As such, federal support or other factors relating to embryonal research has no direct impact on our current product programs.

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 pilot-scale product launch in Europe of the AastromReplicell™ Cell Production System in April 1999, but subsequently suspended those activities in October 1999 pending the receipt of additional financing. While these activities are now in process, we do not expect to generate positive cash flows from operations for at least the next several years and then only if more significant product sales commence. Until that time, we expect that our revenue sources will be limited to grant revenue and research funding, milestone payments and licensing fees from potential future corporate collaborators. To date, we have financed our operations through public and private sales of our equity securities. As a development-stage company, we have never been profitable and 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, 2001, we have accumulated losses of approximately $89 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, consisting of grant funding and products sales, for the quarter and six month period ended December 31, 2001 were $267,000 and $418,000, respectively, compared to $295,000 and $462,000 for the same periods in 2000. We continue to pursue grant-funded programs as well as European sales and marketing opportunities.

Costs and expenses for the quarter ended December 31, 2001 increased to $2,393,000 compared to $1,389,000 for the same period in 2000. Increases in costs and expenses include an increase in research and development expense to $1,396,000 for the quarter ended December 31, 2001, from $965,000 for the same period in 2000, and an increase in selling, general and administrative expenses to $931,000 from $411,000. Costs and expenses for the six months ended December 31, 2001 increased to $4,559,000 compared to $3,171,000 for the same period in 2000. Increases in costs and expenses include an increase in research and development expense to $2,603,000 for the six months ended December 31, 2001, from $1,985,000 for the same period in 2000, and an increase in selling, general and administrative expenses to $1,850,000 from $1,173,000. With the completion of additional funding in calendar year 2001, we have increased the scope of our research and development and marketing activities. Cost of product sales and rentals for the quarter and six months ended December 31, 2001 includes a charge of $66,000 and $106,000, respectively, relating to the reserve of AastromReplicell™ excess inventory.

Interest income was $106,000 and $228,000 for the quarter and six months ended December 31, 2001, respectively, compared to $178,000 and $387,000 for the same period in 2000. These decreases correspond to a decrease in yields from our investments.

Our net loss increased to $2,020,000, or $.05 per common share for the quarter ended December 31, 2001 compared to a net loss of $916,000, or $.03 per common share for the same period in 2000. For the six months ended December 31, 2001, our net loss increased to $3,913,000, or $.10 per common share compared to $2,322,000, or $.07 per common share for the same period in 2000. This increase is primarily the result of increased costs and expenses as the result of expanded research and market development activities offset by an increase in the weighted average number of common shares outstanding resulting from additional equity financing.

***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, 2001, have totaled approximately $104 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. These financing sources have historically allowed us to maintain adequate levels of cash and other liquid investments.

Our combined cash, cash equivalents and short-term investments totaled $13,283,000 at December 31, 2001, an increase of $2,624,000 from June 30, 2001. The primary uses of cash, cash equivalents and short-term investments during the six month period ended December 31, 2001 included $4,175,000 to finance our operations and working capital requirements. The primary source of cash, cash equivalents and short-term investments was from the equity financing transactions, of which $6,841,000 was raised during the six month period. This equity financing was transacted under our December 29, 2000 shelf registration, completing the shares available under this offering.

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 from operations for at least the next several years due to the expected spending for research and development programs and the cost of commercializing our product candidates. 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 at a minimum through the end of calendar year 2002. 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 2001 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 currently planned to be resumed. In order to grow and expand our business, and to 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 affect on our business. See “Business Risks” and Notes to Consolidated Financial Statements in our 2001 Annual Report on Form 10-K and Notes to Consolidated Financial Statements included herein.

***Revenue Recognition and Research and Development Costs***

Revenue from grants and research agreements is recognized on a cost reimbursement basis consistent with the performance requirements of the related agreement. Revenue from product sales is recognized when title to the product transfers to customers and there are no remaining obligations that will affect the customer’s final acceptance of the sale. Revenue from achievement of milestone events is recognized when the funding party agrees that the scientific or clinical results stipulated in the agreement have been met. Revenue from licensing fees under licensing agreements is recognized as revenue when there are no future performance obligations remaining with respect to such fees.

Research and development costs, conducted on our own behalf and sponsored by federal grant programs and various third-party collaborative agreements, are expensed as incurred. For the quarter and six month period ended December 31, 2001, research and development costs totaled $1,396,000, and $2,603,000,

respectively, of which $187,000 and $338,000, respectively, were related to federal and state grant programs and the remaining costs related to our own internal research and development programs.

**Certain Business Considerations**

***Our past losses and expected future losses cast doubt on our ability to operate profitably.***

We were incorporated in 1989 and have experienced substantial operating losses since inception. As of December 31, 2001, we have incurred net operating losses totaling approximately $89 million. These losses have resulted principally from costs incurred in the research and development of our cell culture technologies and the AastromReplicell™ System, general and administrative expenses, and the prosecution of patent applications. We expect to incur significant operating losses until product sales increase, primarily owing to our research and development programs, including pre-clinical studies and clinical trials, and the establishment of marketing and distribution capabilities necessary to support commercialization efforts for our products. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our product candidates, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, and raising sufficient funds to finance our activities. We may not be able to achieve or sustain profitability.

***Our inability to complete our product development activities successfully would severely limit our ability to operate or finance our operations.***

Commercialization in the United States of our lead product candidate, the AastromReplicell™ Cell Production System, will require additional research and development as well as substantial clinical trials. While we have commenced initial marketing on a very limited basis of the AastromReplicell™ System in Europe, we believe that the United States will be the principal market for our products. We may not be able to successfully complete development of the AastromReplicell™ 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 production of cells outside the human body with the expected result. 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 capital to finance our continued operation during the period required for resolution of that issue.

***We may not be able to raise the required capital to conduct our operations and develop our products.***

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 started to restore operating activities, the previous reduction in our operating activities has negatively affected our ability to 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 currently planned activities through at least the end of fiscal year 2002. We are currently pursuing additional sources of financing. Our inability to obtain additional funding prior to that time would force us to make substantial reductions in the scope and size of our operations and may force us to curtail activities that we currently plan to resume. In order to grow and expand our business, and to 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.

Our future capital requirements will depend upon many factors, including:

- continued scientific progress in our research and development programs;
- costs and timing of conducting clinical trials and seeking regulatory approvals and patent prosecutions;
- competing technological and market developments;
- our ability to establish additional collaborative relationships; and
- effective commercialization activities and facility expansions if and as required.

Because of our long-term funding requirements, we may attempt to access the public or private equity markets if and whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. Further, we may enter into financing transactions at rates which are at a substantial discount to market. This additional funding may not be available to us on reasonable terms, or at all. The unavailability of adequate funds may require us to further delay or terminate research and development programs, curtail capital expenditures, and reduce business development and other operating activities.

***We must successfully complete our clinical trials to be able to market our products.***

To be able to market products for clinical use in the United States, we must demonstrate, through extensive preclinical 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™ System. Depending on the availability of resources, we intend to commence additional clinical trials for cells produced in the AastromReplicell™ 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 stem cell therapy for the treatment of certain diseases and the eligibility criteria for the study. We have experienced delays in patient accrual in our previous and current clinical trials. If we experience future delays in patient accrual, we could experience increased costs and delays associated with clinical trials which would impair our product development programs and our ability to market our products. Furthermore, the 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.

***Failure to obtain and maintain required regulatory approvals would severely limit our ability to sell our products.***

We must obtain the approval of the FDA before commercial sales of our product candidates may commence in the United States, 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 the 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™ 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 limit our ability to market the product for a range of uses, as the approval may be for only specified uses of a product. 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.

***Even if we obtain regulatory approvals to sell our products, lack of commercial acceptance would impair our business.***

Our product development efforts are directed toward obtaining regulatory approval to market the AastromReplicell™ System as an alternative to, or as an improvement for, the standard bone marrow or blood stem cell transplant procedures. These procedures have been widely practiced for a number of years, and the market place may not accept our technologies or product candidates as readily as these or other competing processes and methodologies. Additionally, users of our products may not employ our technologies or product candidates 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, the market may not adopt our products and processes at a level that would allow us to operate profitably.

***Failure of third parties to manufacture component parts or provide limited source supplies would impair our new product development and our sales activities.***

We rely solely on third parties to manufacture our product candidates and their component parts. We also rely solely on third party suppliers such as Plexus, Moll, Biowhittaker and Immunex 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. If any of our key manufacturers or suppliers fail 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 bone marrow or cord blood 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. Our inability to develop or obtain alternative compounds would harm our product development and commercialization efforts.

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.

***Given our limited internal sales and marketing capabilities, we need to develop collaborative relationships to sell, market and distribute our products.***

While we have commenced initial marketing on a limited basis of the AastromReplicell™ System and SC-I, CB-I and DC-I therapy kits 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. Our inability to develop and maintain those relationships would limit our ability to market, sell and distribute our products. Our inability to enter into successful, long-term relationships could require us to develop alternate arrangements at a time when we need sales, marketing or

distribution capabilities to meet existing demand. We are now seeking to enter into arrangements relating to the development and marketing of our product candidates.

***Any changes in the governmental regulatory classifications of our products could prevent, limit or delay our ability to market or develop our products.***

The FDA establishes regulatory requirements based on the classification of a product. The AastromReplicell™ System may be regulated as a Class III medical device, or the FDA may ultimately choose to regulate the AastromReplicell™ System under another category. Because our product development programs are designed to satisfy the standards applicable to Class III medical devices, a change in the regulatory classification would affect our ability to obtain FDA approval of our products. The AastromReplicell™ System is capable of producing different cell mixtures, and at least some of these cell mixtures will be regulated as biologic products.

***If we do not keep pace with our competitors and with technological and market changes, our products may become obsolete and our business may suffer.***

The market for our products is very competitive, is subject to rapid technological changes and varies for different individual products. For each of our potential products, we believe that there are potentially many competitive approaches being pursued, including some by private companies for which information is difficult to obtain.

Many of our competitors have significantly greater resources, more product candidates and have developed product candidates and processes that directly compete with our products. Our competitors may have developed, or could in the future develop, new technologies that compete with our products or even render our products obsolete. As an example, some recently published studies have suggested that stem cell therapy may have limited clinical benefit in the treatment of breast cancer, which has been a significant portion of the current overall stem cell transplant market. This could result in a substantial decline in the current principal market for the AastromReplicell™ System with our SC-I kit. Our products are designed to improve and automate the processes for producing cells used in therapeutic procedures. Even if we are able to demonstrate improved or equivalent results, researchers and practitioners may not use our products and we will suffer a competitive disadvantage. As a result, we may be unable to recover the net book value of our inventory. Finally, to the extent that others develop new technologies that address the targeted application for our products, our business will suffer.

***If we cannot attract and retain key personnel, then our business will suffer.***

Our success depends in large part upon our ability to attract and retain highly qualified scientific and management personnel. We face competition for such personnel from other companies, research and academic institutions and other entities. Further, in an effort to conserve financial resources, we have implemented reductions in our work force on two separate occasions. As a result of these and other factors, we may not be successful in hiring or retaining key personnel. The Company only has a key man life insurance policy for R. Douglas Armstrong, the Chairman, Chief Executive Officer and President of Aastrom. Our inability to replace any other lost key employee could harm our operations.

***The warrants have the potential for substantial dilution.***

We have warrants to purchase 2,614,386 shares of common stock at $1.58 per share and options to purchase 3,696,426 shares at a weighted-average price of $1.61 per share outstanding. Holders of common stock would therefore experience dilution of their investment upon exercise of these warrants and options.

Our stock price has been volatile and future sales of substantial numbers of our shares could have an adverse affect on the market price of our shares.

The market price of shares of our common stock has been volatile ranging in price between $0.93 and $2.40, between June 30, 2001 and December 31, 2001. The price of our common stock may continue to fluctuate in response to a number of events and factors, such as:

- clinical trial results;
- the amount of our cash resources and our ability to obtain additional funding;
- announcements of research activities, business developments, technological innovations or new products by us or our competitors;
- changes in government regulation;
- disputes concerning patents or proprietary rights;
- changes in our revenues or expense levels;
- public concern regarding the safety, efficacy or other aspects of the products or methodologies we are developing; and
- changes in potential recommendations by securities analysts.

Any of these events may cause the price of our shares to fall, which 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. For example, within the last year, our stock price has experienced a day where it traded at approximately twice the previous day's closing price and another day when it dropped by over 20% from the previous day's closing price.

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.

***If our patents and proprietary rights do not provide substantial protection, then our business and competitive position will suffer.***

Our success depends in large part on our ability to develop or license and protect proprietary products and technologies. However, patents may not be granted on any of our pending or future patent applications. Also, the scope of any of our issued patents may not be sufficiently broad to offer meaningful protection. In addition, our issued patents or patents licensed to us could be successfully challenged, invalidated or circumvented so that our patent rights would not create an effective competitive barrier. Furthermore, we rely on three exclusive, world-wide licenses relating to the production of human cells granted to us by the University of Michigan for certain of our patent rights. If we materially breach such agreements or otherwise fail to materially comply with such agreements, or if such agreements expire or are otherwise terminated by us, we may lose our rights under the patents held by the University of Michigan. At the latest, these licenses will terminate when the patent underlying the license expires. The first of these underlying patents will expire on March 21, 2012. We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers and licensees. These agreements may be breached, and we might not have adequate remedies for any breach. If this were to occur, our business and competitive position would suffer.

***Intellectual property litigation could harm our business.***

Our success will also depend in part on our ability to develop commercially viable products without infringing the proprietary rights of others. Although we have not been subject to any filed infringement claims, other patents could exist or could be filed which would prohibit or limit our ability to market our products or maintain our competitive position. An intellectual property dispute may force us to litigate the dispute to protect or defend our interests. Intellectual property litigation would divert management's attention from developing our products and would force us to incur substantial costs regardless of whether we are successful. An adverse outcome could subject us to significant liabilities to third parties, and force us to curtail or cease the development and sale of our products and processes.

***The government maintains certain rights in technology that we develop using government grant money and we may lose the revenues from such technology if we do not commercialize and utilize the technology pursuant to established government guidelines.***

Certain of our, and our licensors', research has been or is being funded in part by government grants. As a result of such funding, the U.S. Government has certain rights in the technology developed with the grant. These rights include a non-exclusive, paid-up, worldwide license to use the technology for any governmental purpose. In addition, the government has the right to require us to grant an exclusive license to use the developed technology to a third party if the government determines that:

- we have not taken adequate steps to commercialize such technology;
- such action is necessary to meet public health or safety needs; or
- such action is necessary to meet requirements for public use under federal regulations.

In these instances, we would not receive revenues on the products we developed. Additionally, technology that was partially funded by a federal research grant is subject to the following government rights:

- products using the technology which are sold in the United States are to be manufactured substantially in the United States, unless a waiver is obtained;
- if we do not pursue reasonable commercialization of a needed product using the technology, the government may force the granting of a license to a third party who will make and sell the needed product; and
- the U.S. Government may use the technology for its own needs. If we fail to meet these guidelines, we would lose our exclusive rights to these products and we would lose potential revenue derived from the sale of these products.

***The market for our products will be heavily dependent on third party reimbursement policies.***

Our ability to successfully commercialize our product candidates will depend on the extent to which government healthcare programs, such as Medicare and Medicaid, as well as private health insurers, health maintenance organizations and other third party payors will pay for our products and related treatments. Reimbursement by third-party payors depends on a number of factors, including the payor's determination that use of the product is safe and effective, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. Reimbursement in the United States or foreign countries may not be available or maintained for any of our product candidates. If we do not obtain approvals for adequate third-party reimbursements, we may not be able to establish or maintain price levels sufficient to realize an appropriate return on our investment in product development. Any limits on reimbursement available from third-party payors may reduce the demand for, or negatively affect the price of, our products. For example, recently published studies have suggested that stem cell transplantation in breast cancer, which constitutes a significant portion of the overall stem cell therapy market, may have limited clinical benefit. The lack of reimbursement for these procedures by insurance payors would negatively affect the marketability of our products.

***Potential product liability claims could affect our earnings and financial condition.***

We face an inherent business risk of exposure to product liability claims in the event that the use of the AastromReplicell™ System during research and development efforts, including clinical trials, or after commercialization results in adverse affects. As a result, we may incur significant product liability exposure, which could exceed existing insurance coverage. We may not be able to maintain adequate levels of insurance at reasonable cost and/or reasonable terms. Excessive insurance costs or uninsured claims would increase our operating loss and affect our financial condition.

***Our corporate documents and Michigan law contain provisions that may make it more difficult for us to be acquired.***

Our board of directors has the authority, without shareholder approval, to issue additional shares of preferred stock and to fix the rights, preferences, privileges and restrictions of these shares without any further vote or action by our shareholders. This authority, together with certain provisions of our charter documents, may have the affect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire control of our company. This affect could occur even if our shareholders consider the change in control to be in their best interest.

***Our stock may be delisted from Nasdaq that could affect its market price and liquidity.***

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. Further, the National Association of Securities Dealers has recently adopted a change in the minimum listing requirements to include a new $10 million minimum net equity requirement. This new standard will replace the minimum tangible net worth requirement and becomes effective for us in November 2002. The result of such a change, or other changes, may be that it will become more difficult for us to maintain compliance with the listing standards, the result of which would be that our stock may be delisted.

***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:

- uncertainties related to potential strategic collaborations with others;
- future capital needs and uncertainty of additional funding;
- uncertainties related to product development and marketability;
- uncertainties related to clinical trials;
- manufacturing and supply uncertainties and dependence on third parties;
- anticipation of future losses;
- limited sales and marketing capabilities;
- uncertainty of regulatory approval and extensive government regulation;
- competition and technological change;
- uncertainty regarding patents and proprietary rights;

• no assurance of third party reimbursement; and

• potential product liability and availability of insurance.

These statements are subject to risks and uncertainties, including those set forth in this Business Risks 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 the Company's 2001 Annual Report on Form 10-K.

**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-collectibility 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, 2001 indicates that it would not have a significant impact on expected fiscal year 2002 results of operations.

## 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 14, 2001.

(b) At the 2001 Annual Meeting of Shareholders, votes were cast on matters submitted to the shareholders, as follows:

*Proposal 1:* Election of two directors whose terms expire at the 2004 Annual Meeting of Shareholders.

| Nominee | For | Withheld |
|---|---|---|
| Fabrizio Bonanni | 36,217,309 | 343,418 |
| Alan M. Wright | 36,228,913 | 331,814 |

In addition to the election of the above referenced directors, the following individuals continue as directors; Mary L. Campbell and Arthur F. Staubitz as Class II Directors, whose terms expire at the 2002 Annual Meeting of Shareholders; Joseph A. Taylor and R. Douglas Armstrong, as Class III Directors, whose terms expire at the 2003 Annual Meeting of Shareholders.

*Proposal 2:* Approval of Adoption of the Aastrom 2001 Stock Option Plan, with a maximum aggregate number of shares reserved for issuance thereunder of 2,100,000.

| For | Against | Abstain |
|---|---|---|
| 35,162,783 | 1,264,904 | 133,040 |

*Proposal 3:* Amend the Articles of Incorporation to increase the number of shares of authorized common stock up to a maximum of 50,000,000 additional shares.

| For | Against | Abstain |
|---|---|---|
| 34,741,945 | 1,707,357 | 111,425 |

*Proposal 4:* Approve the selection of PricewaterhouseCoopers LLP as the Company's independent accountants for the year ending June 30, 2002.

| For | Against | Abstain |
|---|---|---|
| 36,266,102 | 203,438 | 91,187 |

**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

None.

**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 8, 2002

/s/R. DOUGLAS ARMSTRONG

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

Date: February 8, 2002

/s/MICHAEL A. BRODEUR

Michael A. Brodeur
*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 |

* Incorporated by reference to the Company's Registration Statement on Form S-3 (File No. 333-39698) filed with the Commission on June 20, 2000.