



July 14, 2005

YOUR FILE NO. 000-22025  
OUR FILE NO. 332396-139747

BY EDGAR

Mr. Jim B. Rosenberg  
Senior Assistant Chief Accountant  
Securities and Exchange Commission  
450 Fifth Street, N.W.  
Washington, D.C. 20549

**Re: Aastrom Biosciences, Inc.**  
**Form 10-K for the fiscal year ended June 30, 2004**  
**File No. 000-2205**

Dear Mr. Rosenberg:

On behalf of Aastrom Biosciences, Inc. ("Aastrom" or the "Company"), we hereby submit the responses of Aastrom to the staff's comment letter of April 15, 2003 (the "Comment Letter"). For ease of review, we have included in italics each of the comments from the Comment Letter followed by Aastrom's response to that comment.

*Management's Discussion and Analysis of Financial Condition and Results of Operations, pg. 20.*

1. Please refer to the Division of Corporation Finance "Current Issues and Rulemaking Projects Quarterly Update" under section VIII — Industry Specific Issues — Accounting and Disclosure by Companies Engaged in Research and Development Activities. You can find it at the following website address:  
<http://www.sec.gov/divisions/corpfm/cfcrq032001.htm#secviii>

Please disclose the following information for each of your major research and development projects:

- a. *The current status of the project;*
- b. *The costs incurred during each period presented and to date on the project;*
- c. *The nature, timing and estimated costs of the efforts necessary to complete the project;*
- d. *The anticipated completion dates;*
- e. *The risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if the project is not completed timely; and finally*
- f. *The period in which material net cash inflows from significant projects are expected to commence.*

Regarding b., if you do not maintain any research and development costs by project,

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*disclose that fact and explain why management does not maintain and evaluate research and development costs by project. Provide other quantitative or qualitative disclosure that indicates the amount of the company's resources being used on the project.*

*Regarding c. and d., disclose the amount or range of estimated costs and timing to complete the phase in process and each future phase. To the extent that information is not estimable, disclose those facts and circumstances indicating the uncertainties that preclude you from making a reasonable estimate.*

**Response:**

Aastrom only has one major research and development project, with many initiatives focused on clinical trials and manufacturing process improvements. Aastrom's only major ongoing research and development project is focused on the development of bone-marrow derived stem and progenitor cells — Tissue Repair Cells (TRCs) — for use in orthopedic indications (bone grafting, spine fusion, and jaw bone reconstruction) and for use in vascular system regeneration. Clinical trials are underway in both the United States and the European Union to demonstrate bone formation in patients with large bone fractures, and clinical trials are underway in the European Union to demonstrate jaw bone reconstruction. Aastrom is developing clinical protocols for spine fusions and for treating limb ischemia resulting from peripheral vascular disease. All of these potential product applications use TRCs created by Aastrom's proprietary process and device technologies. Aastrom is also developing new variations of TRCs that are intended to improve the functionality of these cells for certain clinical indications, to improve storage and shelf life, or to decrease the cost of manufacturing the TRC products. Aastrom is also exploring the capability of TRCs to generate different types of human tissues, such as bone, vascular, cartilage and cardiac tissues.

Since Aastrom has twice changed its focus in response to evolving regulatory requirements and market conditions (see the discussion under the heading "Clinical Development — Previous Activities" in Part I, Item 1 of Aastrom's Annual Report on Form 10-K for the fiscal year ended June 30, 2004), it would be highly speculative and subjective to estimate the timing or costs to complete this project. Similarly, since Aastrom's products are pioneering a market with changing regulatory requirements and without established reimbursement guidelines, it would also be highly speculative and subjective to predict the commencement of material net cash inflows. Aastrom has addressed these risks in its existing filings, and the proposed addition for future filings identifies where the more significant risks in this area are discussed.

In future periodic filings, Aastrom will add disclosure in the Management's Discussion and Analysis section similar to that contained in Exhibit A attached hereto (with updates as necessary to reflect appropriate changes). Considering Aastrom's recent June 30 fiscal year end, Aastrom will add this disclosure in the Form 10-K for the fiscal year ending June 30,

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2005 and will update it in subsequent reports on Form 10-Q and 10-K (with a 10-Q report only containing fiscal year to date data for the interim periods presented). Since most of the disclosure to be added to the Management's Discussion and Analysis section is contained in other sections of the previous 10-K and since the Management's Discussion and Analysis discussion in the last 10-K relates to the Company's financial condition and operating results as of a date and for periods ending over a year ago, we respectfully submit that adding this additional language to an old 10-K would be of little value when compared to the benefit obtained from current disclosure in the upcoming 10-K (which will be filed in approximately eight weeks).

Critical Accounting Policies, page 21.

2. We acknowledge your systematic approach to determine your reserves for obsolete and excess inventory. Please tell us how this complies to GAAP, specifically Chapter 4 of ARB 43.

**Response:**

During the applicable periods, the Company had finished goods inventories consisting of AastromReplicell Systems (equipment used to produce cells) and Cell Cassettes and Base Medium (disposable items used in the production of cells). As of June 30, 2003 and 2004, the Company's inventories consisted of the following:

	June 30, 2003	June 30, 2004
AastromReplicell Systems, net (1)	\$ 390,000	\$ 162,000
Cell Cassettes and Base Medium	\$ 416,000	\$ 227,000
Total Inventory	\$ 806,000	\$ 389,000

- (1) Included in AastromReplicell Systems inventories were \$86,000 and \$162,000 related to systems under evaluation by potential customers at June 30, 2003 and 2004, respectively.

Until late in fiscal year 2004, the Company's business strategy was to sell AastromReplicell Systems ("ARS"), a combination of equipment components that would allow the operator of the system to produce cells for the treatment of various conditions. Under this business model, it was the Company's plan to sell ARS to its customers and to continue to supply peripheral elements (i.e. Cell Cassettes and Base Medium used in the production of cells) of the cell production process to these customers who would independently produce their own doses of cells. During fiscal year 2004, the Company altered its strategy, in response to changing regulatory requirements and perceived markets, such that the Company's current focus is to establish Company-owned cell production sites and to produce cells on behalf of its customers. The Company continues to sell Cell Cassettes and Base Medium to existing customers of the ARS.

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The Company periodically evaluates the carrying value of its Cell Cassettes and Base Medium inventories in order to carry such inventories at the lower of their purchase cost or market value. Specifically, the Company considers projected sales of these inventories compared to quantities on hand and the label expiration dates. Whenever quantities on hand exceed expected sales volumes, or the timing of expected sales indicates that inventories will not be sold before the end of their shelf lives, the Company records a write-off of the carrying value of such inventories.

The "systematic approach" to determining excess and obsolete inventory referred to in the Company's accounting policy relates to the ARS inventories. The net carrying value of ARS inventories at June 30, 2004 consisted of three systems under evaluation by potential customers, all of which the Company believed carried a high probability of being purchased by the respective customers. During the third quarter of fiscal year 2005 one of these systems was sold and the other two systems were returned. The remaining carrying value of the returned systems was written down to zero. Accordingly, as of March 31, 2005, the Company had no remaining ARS inventory balance. In fact, since the end of the first quarter of fiscal 2004 (September 30, 2003), the Company's inventory balance contained no value attributable to ARS inventories, other than those units under evaluation by potential customers. In addition, as a result of the change in strategy to focus on hosted cell production sites, any future ARS systems purchased by the Company will be classified as fixed assets.

As more fully described below, the Company believes that its accounting policy complies with ARB 43, Chapter 4, and is appropriate in the Company's circumstances involving the design, development and marketing of novel technologies in new markets.

Prior to fiscal year 2002, the Company evaluated the carrying value of its ARS inventories based upon the estimated sales volumes and selling prices of the ARS. During 1998 the Company purchased its first significant volume of ARS inventories in anticipation of significant projected sales. The Company's lower of cost or market analysis of the ARS inventories resulted in no identified write-downs because the Company's sales projections continued to indicate that the ARS would be sold at prices that would generate positive margins. However, in light of the evolving potential markets for the associated cell therapies and regulatory changes and challenges, the Company had significant difficulty marketing the systems as a stand alone product. In the second quarter of fiscal year 2000, management concluded that it would not be able to successfully sell its remaining ARS inventories, in part due to a change in strategy which involved eliminating its European sales effort. Accordingly, the Company recorded a \$1,027,000 charge to cost of goods sold, to reduce the carrying value of the ARS inventories to zero.

During the third quarter of fiscal year 2002, the Company began to receive newly-purchased ARS inventories in preparation for a new US and European launch of the ARS product with new target markets for its new cell therapies. The Company recorded the ARS inventories at

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their purchase cost based upon the Company's expectation of generating profitable sales to identified potential customers.

By the end of fiscal year 2002, the Company's ARS inventory balance was approximately \$772,000. Despite the focus on a new set of cell therapies, the Company again experienced difficulties in selling the ARS as a stand alone product. The Company's three-year projection of ARS sales in the US and Europe indicated that 46 units would be sold between 2003 and 2005. Actual sales in this period were 3 units (6 units have been sold since the Company's inception). Although management believed that the Company would have greater success selling ARS with the focus on a new and different set of cell therapies, management's awareness of the past experience of failing to meet sales forecasts and the large inventory write-off in 2000, led them to seek a reserve methodology that was not as dependent on estimates of future sales (which management had concluded contained a high degree of imprecision given the Company's limited track record and novel technologies), but, rather, would be based on the absence of sales and the passage of time (both of which are objectively determinable). Based on the available information as to the Company's sales results and the difficulty in developing reliable sales forecasts, management considered the passage of time without sales to be the best available predictor of the decline in inventory value.

In developing the reserve methodology based on absence of sales and passage of time, management considered the Company's historical experience that had culminated in the second quarter of 2000 write off of all ARS inventories originally purchased during 1998. This historical information provided evidence that the probability of achieving forecast sales of any single ARS from the aggregate pool of all ARS inventories declined as time passed without successful penetration of the market. Specifically, this information indicated that the likelihood of selling any individual ARS item within the aggregate pool began to decline if meaningful sales success was not achieved within 12 months of the date the inventories were purchased. Furthermore, this historical experience and management's awareness of the technological and regulatory challenges of the market led management to estimate that the probability of selling any single ARS held for 12 months, declined significantly over the next six months such that the estimated likelihood of sale of an ARS 18 months after the initial purchase was zero. In spite of the evidence indicating that probability of sale declined over time, the Company's historical sales experience and market intelligence indicated that the ARS inventories did not suffer an obsolescence-based diminution in value. In fact, for those ARS that the Company has sold throughout its history, regardless of the period of time on hand before sale, the selling price was always in excess of the original purchase cost of the inventories. Instead, management concluded that the market value of its aggregate ARS inventories declined over time based on market factors such as customer adoption of the technology and regulatory challenges faced by customers in gaining approval for the production of cells. That is, a customer's buying decision was significantly affected by factors other than the price of the Company's products.

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ARB 43, Chapter 4, Statement 7, indicates that the lower-of-cost or market rule may properly be applied either directly to each item or to the total of the inventory. As described above, because the probability-weighted selling price is inversely correlated with the passage of time, the "market" value of the inventory estimated by management for use in the LCM calculation declined as further time passed without a sale of an ARS system. Accordingly, in the fourth quarter of fiscal year 2002, the Company adopted an inventory valuation policy designed to reduce the aggregate carrying value of its ARS inventories based on the declining probability of commercial success in selling the ARS inventories as time passed. Management believes that its approach to reducing the carrying value of ARS inventories is consistent with ARB 43 Chapter 4, Statements 5, 6 and 7 as it provides a reasonable basis to estimate the decrease in utility of the aggregate ARS inventories below their cost. In light of the novel nature of the Company's ARS products and the developing nature of the market for those products, estimating the selling price of any individual ARS was virtually impossible. In addition, because of the lack of empirical, historical data, due to the company's limited operating history, from which to estimate "excess" ARS inventories, the Company believes that its method of applying the principles of ARB 43, Chapter 4, was the most appropriate approach in the circumstances.

The Company supplementally advises the Staff that the carrying value of ARS inventories has been reduced to zero by the end of the Company's third quarter of fiscal year 2005 and, as a result of the decision to focus on hosted cell production sites rather than the manufacture and sale of ARS, the Company no longer intends to hold ARS inventory.

Results of Operations, page 22.

3. *We acknowledge your disclosure about increased grant activity and additional grant awards. Considering the significance of your grant revenue, please quantify and elaborate your discussion about the factors causing the increase. Additionally, please disclose the nature and provisions of these contracts.*

**Response:**

In future filings, the Company will expand its discussion of grant revenue, including elaboration on the factors causing increases or decreases in grant revenues and the nature of the contracts. The Company has provided expanded discussion in the "Results of Operations" portion of the Management's Discussion and Analysis section of the Company's Form 10-Q for the quarter ended March 31, 2005. The disclosure included in this recent filing was as follows:

"Grant revenues decreased for the quarter and nine months ended March 31, 2005 to \$102,000 and \$436,000, respectively, from \$331,000 and \$972,000 for the same periods in fiscal year 2004. Grant revenues have decreased from the prior year as a result of reduced grant program activities; however, we continue to pursue grant-funded programs. Grant revenues accounted for 54% of total revenues for the nine months ended March 31, 2005 and 89% for the same period in fiscal year 2004 and are

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recorded on a cost-reimbursement basis. Grant revenues may vary in any period based on timing of grant awards, grant-funded activities, level of grant funding and number of grants awarded.”

Since this disclosure is in Aastrom's most recent 10-Q, we respectfully submit that there would be little value gained from amending the discussion in the old 10-K.

Consolidated Statements of Operations, page 35.

4. *It appears that you have not complied with Rule 5-03 of Regulations S-X in regards to your presentation of product sales and rentals. Please reclassify separately, revenue generated from the sale of products from rental revenue. Please reclassify the costs incurred to generate these products sales and rental income, including the provision for obsolete and excess inventory, to correspond to the revenue classification. Please revise your financial statements accordingly.*

**Response:**

The Company acknowledges the Staff's comment and the requirements of Rule 5-03 of Regulation S-X. However, considering the small amounts of rental revenues generated by the Company in historical periods and the expectation that the Company will not generate rental revenue in future periods, the Company does not feel it is necessary or meaningful to provide separate presentation of these revenues and the related costs of sales on the Statements of Operations. However, in future filings, the Company will include a disclosure in the revenue recognition accounting policy footnote of the amount of rental revenues included in each period presented, which disclosure will be similar to the disclosure added to the Management's Discussion and Analysis section of the recently filed Form 10-Q (as discussed below).

The Company supplementally advises the Staff that there were no rental revenues in fiscal year 2002. In fiscal years 2003 and 2004 rental revenues were \$37,191 and \$30,429, respectively. These amounts represent only 4% and 2% of aggregate consolidated revenues in fiscal years 2003 and 2004 respectively. Product sales revenues were \$80,000, \$276,809 and \$18,571 in fiscal years 2002, 2003 and 2004, respectively, representing 9%, 33% and 1% of consolidated revenues, respectively.

Because the product rental revenues and product sales revenues are each less than 10 percent of the sum of all revenue classes in fiscal year 2004, the Company is permitted to combine the rental revenues with product revenues and to combine the associated costs of sales, in accordance with Rule 5-03 of Regulation S-X.

In fiscal year 2003, although product sales revenues exceeded 10% of consolidated revenues, it is the Company's preference not to amend its prior 10-K to reclassify the rental revenues and associated costs on the Statement of Operations. The Company notes that:

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(1) although product sales revenues exceeded 10% of consolidated revenues in fiscal year 2003, the product rental revenues of \$37,191 were not significant to the trend in total product and rental revenues which increased from \$80,000 in fiscal 2002 to \$314,000 in fiscal 2003 and declined to \$49,000 in fiscal 2004, (2) the rental revenues have not exceeded the 10% threshold in any of the years presented in the Statements of Operations, and (3) rental revenues are not expected to exceed 10% of consolidated revenues in any future period. In fact, the Company does not expect to generate any rental revenue after the third quarter of fiscal year 2004 because: (1) the single, remaining rental agreement for the Company's AastromReplicell System was terminated in the third quarter of fiscal year 2004, and (2) as addressed in the response to Comment 2, the Company's operating strategy has changed such that the Company is no longer marketing the AastromReplicell System for sale. The Company has disclosed that this rental agreement has expired and that future rental revenues are not anticipated in the "Results of Operations" portion of the Management's Discussion and Analysis section of the Company's Form 10-Q for the quarter ended March 31, 2005. The disclosure included in this recent filing was as follows:

*"Revenues include rental revenue of \$10,000 and \$30,000 for the quarter and nine months ended March 31, 2004, respectively. This revenue was generated from an AastromReplicell System rental agreement that has been terminated. Based upon our current business strategy, we do not expect rental revenue in future periods."*

The Company intends to provide similar disclosure in its future Forms 10-K and 10-Q to the extent such disclosure is relevant. Since this disclosure is in Aastrom's most recent 10-Q, we respectfully submit that there would be little value gained from amending the old 10-K.

**Closing Remarks:**

Finally, as requested in the Comment Letter, Aastrom acknowledges that

- it is responsible for the adequacy and accuracy of the disclosure in its filings;
  - staff comments or changes to disclosure in response to staff comments in the filings reviewed by the staff do not foreclose the Commission from taking any action with respect to the filing; and
  - it may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.
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We appreciate the willingness of the staff to discuss various aspects of the comment letter prior to our filing this response. We believe that this response addresses the comments raised by the staff. To assist you in your review, we have provided a copy of this response letter by facsimile to Ms. Christine Allen of the SEC staff.

Very truly yours,

**DLA Piper Rudnick Gray Cary US LLP**

/s/ Douglas J. Rein

Douglas J. Rein  
Attorney  
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Admitted to practice in California

DJR:sar  
Enclosure

cc: Gerald Brennan, Aastrom Biosciences (by fax)  
Alan Wright, Aastrom Biosciences (by fax)  
Ms. Christine Allen, SEC Staff (by fax)

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FORM OF PROPOSED ADDITION TO  
MANAGEMENT'S DISCUSSION AND ANALYSIS SECTION

Our only major ongoing research and development project is focused on the development of bone-marrow derived stem and progenitor cells — Tissue Repair Cells (TRCs) — for use in orthopedic indications (bone grafting, spine fusion, and jaw bone reconstruction) and for use in vascular system regeneration. Clinical trials are underway in both the United States and the European Union to demonstrate bone formation in patients with large bone fractures, and clinical trials are underway in the European Union to demonstrate jaw bone reconstruction. We are developing clinical protocols for spine fusions and for treating limb ischemia resulting from peripheral vascular disease. All of these potential product applications use TRCs created by our proprietary process and device technologies. We are also developing new variations of TRCs that are intended to improve either the functionality for certain clinical indications, improve storage and shelf life, or to decrease the cost of manufacturing of the TRC products. We are also exploring the capability of TRCs to generate different types of human tissues, such as bone, vascular, cartilage and cardiac tissues. Research and development expenses outside of the TRC program consist primarily of \_\_\_\_.

The following table summarizes our research and development expenses for each of the three fiscal years ended June 30, 2005:

<u>R&amp;D Project</u>	<b>Research and Development Expenses for Year Ended June 30,</b>		
	<u>2003</u>	<u>2004</u>	<u>2005</u>
TRCs			
Other			
Total			

Because of the uncertainties of clinical trials and the evolving regulatory requirements applicable to TRCs, estimating the completion dates or cost to complete our major research and development program would be highly speculative and subjective. The risks and uncertainties associated with developing our products, including significant and changing governmental regulation and the uncertainty of future clinical study results, are discussed in greater detail in the "Any changes in governmental regulatory classifications of our products could present, limit or delay our ability to market and develop our products," "Our inability to complete our product development activities successfully would severely limit our ability to operate and finance operations," and "We must successfully complete our clinical trials to be able to market certain of our products," sections under the heading "Business Risks" following Item 7a of this report. The lengthy process of seeking regulatory approvals for our product candidates, and the subsequent compliance with applicable regulations, will require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. We cannot be certain when any net cash inflow from our major research and development project will commence.