HEMISPHERX BIOPHARMA INC
Form 10-Q/A
August 17, 2001

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q/A

Quarterly Report Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

For the Quarterly Period Ended June 30, 2001

Commission File Number: 0-27072

HEMISPHERx BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	52-0845822
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1617 JFK Boulevard, Suite 660, Philadelphia, PA 19103

(Address of principal executive offices) (Zip Code)

(215) 988-0080

(Registrant's telephone number, including area code)

Not Applicable

(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

30,330,382 shares of common stock issued and outstanding as of June 30, 2001.

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PART I - FINANCIAL INFORMATION

ITEM 1: Financial Statements

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2000	June 30, 2001
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$3,721	$2,585
Short Term investments	4,657	2,395
Accounts receivable	60	11
Prepaid expenses and other current assets	607	536
Total current assets	9,045	5,527
Property and equipment, net	373	302
Patent and trademark rights, net	1,204	1,051
Investments in unconsolidated affiliates	2,421	2,392
Other assets	24	55
Total assets	$13,067	$ 9,327
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,341	$ 919
Accrued expenses	154	203
Total current liabilities	1,495	1,122
Commitments and contingencies		
Stockholders' equity:		
Common stock	30	31
Additional paid-in capital	97,984	99,798
Accumulated other comprehensive income	34	38
Treasury stock - at cost	(3,910)	(4,273)
Accumulated deficit	(82,566)	(87,389)
Total stockholders' equity	11,572	8,205
Total liabilities and stockholders' equity	$13,067	$ 9,327

See accompanying notes to condensed consolidated financial statements.

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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	For the Three months ended June 30,
	(Unaudited)

	2000	2001
Revenues:		
Cost recovery - clinical treatment programs	$ 216	$ 101
Costs and expenses:		
Research and development	1,587	1,468
General and administrative	823	1,036
Total cost and expenses	2,410	2,504
Interest and other income	160	86
Equity in loss of unconsolidated affiliate (Note4)	(26)	(26)
Net loss	$(2,060)	$(2,343)
Basic and diluted loss per share	$ (.07)	$ (.08)
Basic and diluted weighted average common shares outstanding	29,031,926	30,109,219

See accompanying notes to condensed consolidated financial statements.

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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	For the Six months ended June 30,	
	(Unaudited)	
	2000	2001
Revenues:		
Cost recovery - clinical treatment programs	$ 426	$ 228
Costs and expenses:		
Research and development	3,022	3,176
General and administrative	1,722	2,004
Total cost and expenses	4,744	5,180
Interest and other income	312	180
Equity in loss of unconsolidated affiliate (Note 4)	(26)	(51)

Net loss	$(4,032)	$ (4,823)
Basic and diluted loss per share	$ (.14)	$ (.16)
Basic and diluted weighted average common shares outstanding	28,801,993	30,035,522

See accompanying notes to condensed consolidated financial statements.

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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Six months ended June 30, (Unaudited)	
	2000	2001
Cash flows from operating activities:		
Net loss	$ (4,032)	$(4,823)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	62	71
Amortization of patents rights	132	191
Write-off of patent rights	2	29
Stock option and warrant compensation and service expense	322	595
Equity in loss of unconsolidated affiliate	26	51
Changes in assets and liabilities:		
Accounts receivable	(13)	49
Prepaid expenses and other current assets	(225)	71
Accounts payable	13	(422)
Accrued expenses	(259)	49
Advances to affiliates	(500)	-
Other assets	17	(21)
Net cash (used in) operating activities	(4,455)	(4,160)
Cash flows from investing activities:		
Purchase of property and equipment	(119)	-
Additions to patent rights	(64)	(67)
Maturity of short term investments	2,153	4,657
Purchase of short term investments	(2,237)	(2,401)
Investments in unconsolidated affiliates	(411)	(22)
Other investments	(34)	-
Net cash (used in) provided by investing activities	(712)	2,167
Cash flows from financing activities:		
Proceeds from issuance of common stock	2,250	73

Proceeds from exercise of warrants	7,989	1,147
Purchase of warrants	(113)	-
Purchase of treasury stock	(3,107)	(363)
Net cash provided by financing activities	7,019	857
Net increase(decrease) in cash and cash equivalents	1,852	(1,136)
Cash and cash equivalents at beginning of period	6,397	3,721
Cash and cash equivalents at end of period	$ 8,249	$ 2,585

See accompanying notes to condensed consolidated financial statements.

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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
For the Six Months Ended June 30, 2001
(in thousands, except share data)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Treasury Stock	Treasury Stock	Accumulat
	Shares	Amount	Capital	Income	shares		deflict
Balance 12/31/2000	30,367,888	$30	$97,984	$34	395,646	$(3,910)	$(82,566)
Common Stock Issued	441,800	1	1,219				
Treasury Stock Purchased					83,660	(363)	
Stock issued for R&D expenses			87				
Stock warrant Compensation			508				
Net Comprehensive loss				4			(4,823)
Balance 6/30/2001	30,809,688	$31	$99,798	$38	479,306	$(4,273)	$(87,389)

See accompanying notes to condensed consolidated financial statements.

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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: BASIS OF PRESENTATION

The accompanying consolidated financial statements include the accounts of Hemispherx BioPharma, Inc., a Delaware corporation and all its wholly owned subsidiaries. All significant intercompany accounts

and transactions have been eliminated.

In the opinion of management, all adjustments necessary for a fair presentation of such consolidated financial statements have been included. Such adjustments consist of normal recurring items. Interim results are not necessarily indicative of results for a full year.

The interim consolidated financial statements and notes thereto are presented as permitted by the Securities and Exchange Commission, and do not contain certain information which will be included in our annual consolidated financial statements and notes thereto.

These consolidated financial statements should be read in conjunction with our 2000 consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2000, as amended on Form 10K/A, second amendment, filed with the SEC on June 19, 2001.

Prior year amounts have been reclassified to conform to current period presentations.

NOTE 2: STOCK COMPENSATION:

Stock compensation expense was $595,000 in the six month period ended June 30, 2001.
The expiration date of certain non-public stock warrants was extended by the Board of Directors. The extension produced non-cash stock/warrant compensation of $262,000 in the three month period ended March 31, 2001. Stock/warrant compensation expense in the three month period ended March 31, 2000 was $155,000. Stock/warrant compensation expense was $333,000 during the three month period ended June 30, 2001 versus $167,000 in the three month period ended June 30, 2000. Stock/warrant compensation expense had no effect on total shareholders equity as it is offset by an increase in additional paid in capital.

In 2001 we retained a nationally based consultant group with expertise in executive compensation in the biotechnology sector to analyze the compensation of both the Chairman of the Board and Chief Executive Officer and the Chief Financial Officer. In accordance with the review, the Company granted 376,650 warrants to purchase our common stock to William A. Carter for services performed and to be performed and 30,000 warrants to the Chief Financial Officer. The Chief

Financial Officer's warrants are exercisable at $5.00 per share. The 376,650 warrants granted to the Chairman of Board and CEO consist 188,325 that are exercisable at $6.00 per share and 188,325 that are exercisable at $9.00 per share. We applied APB Opinion No. 25 in accounting for stock-based compensation of our company employees and directors and, accordingly, no compensation expense has been recognized for stock

warrants rights issued to employees and directors in the financial statements because the exercise prices of the warrants exceeded the quoted market price of our stock on the dates of grant.

NOTE 3: COMPREHENSIVE INCOME:

In January, 1998, we adopted Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income ("Statement 130"), Statement 130 establishes new rules for the reporting and display of comprehensive income and its components; however, the adoption of this Statement had no impact on our net loss or stockholders' equity. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. It includes all changes in equity during a period except those resulting from investments by owners and distributions to owners. The term "other comprehensive income" refers to revenues, expenses, gains and losses that under generally accepted accounting principles are included in comprehensive income but excluded from net income.

The components of comprehensive (loss) are:

	(000's omitted)	
	For six months ending	
	June 30, 2000	June 30, 2001
Net Loss	$(4,032)	$(4,823)
Unrealized gain on short term investments		4
Total comprehensive loss	$(4,032)	$(4,819)

Note 4: INVESTMENTS:

Investments in unconsolidated affiliates:

In 1998, we invested $1,074,000 for a 3.3% equity interest in R.E.D. Laboratories ("R.E.D."). R.E.D. is a privately held biotechnology company for the development of diagnostic markers for Chronic Fatigue Syndrome and other chronic immune diseases. We have a research collaboration agreement with R.E.D. to assist in this development. R.E.D. is headquartered in Belgium. The investment has been recorded at cost.

On May 11, 1999, we acquired a 15% interest in California Institute of Molecular Medicine ("CIMM")

for $375,000. On May 16, 2000, we acquired an

additional 15% interest in CIMM for an additional $375,000. The Company currently has a total interest of 30% in CIMM for a total of $750,000. CIMM is developing therapy for Hepatitis C virus. The investment has been recorded by the equity method. The balance at June 30, 2001 was $619,000.

Other investments include an initial equity investment of $290,625 in Chronix Biomedical ("Chronix"). Chronix focuses upon the development of diagnostics for chronic diseases. This initial investment was made in May 31, 2000 by the issuance of 50,000 shares of Hemispherx Biopharma, Inc. common stock from the treasury. On October 12, 2000, we issued an additional 50,000 shares of Hemispherx Biopharma, Inc. common stock and on March 7, 2001 we issued 12,000 more shares of Hemispherx Biopharma, Inc. common stock from our the treasury to Chronix for an aggregate equity investment of $700,000. Pursuant to a strategic alliance agreement, we provided Chronix with $250,000 during 2000 to conduct research in an effort to develop intellectual property on potential new products for diagnosing and treating various chronic illnesses such as chronic fatigue syndrome. The strategic alliance agreement provides us certain royalty rights with respect to certain diagnostic technology developed from this research and a right of first refusal to license certain therapeutic technology developed form this research.

Note 5: LIQUIDITY:

Our current cash and cash equivalents should fund operations through March 2002. In the event that our warrantholders do not exercise warrants at the level of funding needed to support our operations, we will seek access to the private or public equity market for the funding capital needed. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, competitive and technological advances, the regulatory process, and higher than anticipated expenses and lower than anticipated revenues from certain of the our clinical trials for which cost recovery from participants has been approved.

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

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

Certain statements in this Report on Form 10-Q ("Form 10-Q"), constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of

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1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 (collectively, the "Reform Act"). Certain, but not necessary all, of such forward-looking statements can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," or "anticipates" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, including but not limited to, the risk factors discussed below, which may cause the actual results, performance or achievements of Hemispherx Biopharma, Inc. and its subsidiaries (collectively, the "Company", "we or "us") to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements and other factors referenced in this Form 10-Q. The Company does not undertake and specifically declines any obligation to publicly release the results of any revisions which may be made to any forward-looking statement to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

Overview

We have spent almost thirty years in the exploration, understanding, and mastering the mechanism of ribonucleic acid (RNA) drug technology. The Company's longevity as a biomedical research and drug development institution, coupled with its record of enduring scientific achievement, is evidence of long-term commitment to these promising new classes of drugs for the chronically ill and to bring new therapeutic choices to the global health care community. Using nucleic acid technologies to develop therapeutic products for the treatment of viral diesease and certain cancers, the company has pioneered a new class of specially-configured ribonucleic acid (RNA) which targets the potential treatments of chronic fatigue syndrome (CFS), HIV associated disorders, chronic hepatitis B&C infection and cancers which include kidney cancer and metastatic malignant melanoma. Hemispherx and its predecessor (HEM Pharmaceuticals) is believed to be the only globally-operating biotechnology company using nucleic acid drug methodology which targets the body's natural anti-viral defense system. The company's intellectual property consists of over 350 patents issued and approximately 90 patents pending worldwide, which represents one of the larger patent portfolios in the worldwide biopharmaceutical sector.

A Food and Drug Administration authorized, randomized, double-blind, placebo-controlled Phase III clinical

trial is currently underway at multiple locations in the United States to test the efficacy of Ampligenr in the treatment of 230 patients afflicted with CFS. Some 85% of the required patients have completed the pre-trial clinical phase and have been admitted to the program. Upon completion of this trial, we will evaluate the clinical data collected and submit the results to the FDA for review and approval. Our European subsidiary, Hemispherx Biopharma Europe, is

engaged in establishing and conducting clinical trials in Europe for the treatment of patients afflicted with CFS.

The Food and Drug Administration has authorized us to commence two phase II clinical trials designed to evaluate the use of Ampligenr in augmenting immunologic gains in patients receiving intense antiviral therapy for HIV disease. We expect to enroll over 200 patients in these clinical trials, which will be partly conducted in Europe.

We were incorporated in Maryland in August 1966 under the name HEM Research, Inc. and originally served as a supplier of research support products. We redirected our focus in the early 1980's to the development of nucleic acid pharmaceutical technology and the commercialization of RNA drugs. We were reincorporated in Delaware and changed our name to HEM Pharmaceutical Corp. in January 1991. In June, 1995 we became Hemispherx Biopharma, Inc. The Company has three domestic subsidiaries BioPro Corp., BioAgean Corp.and Core BioTech Corp., all of which are incorporated in Delaware. Our foreign subsidiary, Hemispherx Biopharma-Europe was established in 1998.

We expect to continue our research and clinical efforts for the next several years and may continue to incur losses due to clinical costs incurred in the continued development of Ampligenr for commercial application. Possible losses may fluctuate from quarter to quarter as a result of differences in the timing of significant expenses incurred and receipt of licensing fees and/or cost recovery treatment revenues in Europe, Canada and in the United States.

Our research, development, clinical trials and the manufacturing and marketing of the Company's products are subject to extensive regulation by numerous governmental agencies in the United States and other countries. None of our products have been approved for commercial sale by the Food and Drug Administration or other foreign regulatory authorities.

RISK FACTORS

The following cautionary statements identify important factors that could cause our actual results to differ

materially from those projected in the forward-looking statements made in this report. Among the key factors that have a direct bearing on our results of operations are:

Our drug and related technologies are investigational and subject to regulatory approval.

All of our drugs and associate technologies are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. Our principal development efforts are currently focused on Ampligen, which has not been approved for commercial use. Our products, including Ampligenr are subject to

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extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the Food and Drug Administration in the U.S., the Health Protection Branch of Canada, and the European Medical Evaluation Agency in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We cannot assure you that the drug will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligenr is authorized for use in clinical trials in the United States and other countries, we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. If Ampligenr or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations will be materially adversely effected.

We may continue to incur substantial losses and our future profitability is uncertain.

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses. As of June 30, 2001 our accumulated deficit was approximately $87,389,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts

will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or profitability.

Additional financing requirements.

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. Based on our current operating plan, we anticipate receipt of limited revenues from the sales of Ampligenr under the Cost Recovery Clinical Programs and investors exercising our Class A Redeemable Warrants. The Company may need to raise substantial additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes and begin commercializing its products. There can be no assurances that our Class A Redeemable Warrants will be exercised or that we will raise any proceeds from possible equity financing, which may have a material effect on our ability to develop our products.

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No regulatory agency has approved the full commercial sale of any of the our products.

We cannot assure you that Ampligenr will ultimately be demonstrated to be safe or efficacious. While Ampligenr is authorized for use in clinical trials in the United States and other countries, we cannot assure you that additional clinical trial approvals will be authorized in the United States, or in other countries in a timely fashion or at all or that we will complete these clinical trials. If Ampligenr or one of our other products does not receive regulatory approval in the United States or elsewhere, our operations will be significantly affected.

We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents.

We need to acquire enforceable patents covering the use of Ampligenr for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligenr for such disease. Our success depends, in large part, on our ability to obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. We have been issued certain patents on the use of Ampligenr and Ampligenr in combination with certain other drugs for the treatment of HIV. We have also been issued patents on the use of Ampligenr in combination with certain other drugs for the treatment of chronic hepatitis B virus, chronic hepatitis C virus, and a patent which affords

protection on the use of Ampligenr in patients with chronic fatigue syndrome. We have not been issued any patents in the United States for the use of Ampligen as a sole treatment for any of the cancers which we have sought to target. If we cannot protect our patents covering the use of Ampligenr for a particular disease, or obtain additional pending patents, we may not be able to successfully market Ampligenr.

The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves complex legal and factual questions.

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no assurance that patent applications relating to our products or technology will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. It is generally anticipated that there may be significant litigation in the industry regarding patent and intellectual property rights. Such litigation could require substantial resources from us. No assurance can be made that our patents will provide competitive advantages for our products or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed which would have a materially adverse effect on our ability to market our products or to obtain or maintain any competitive position the we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products using related technology.

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There can be no assurance that we will have the financial resources necessary to enforce patent rights we may hold.

If we cannot enforce the patent rights we currently hold we may be required to obtain licenses from others to develop, manufacture or market our products. There can be no assurance that we would be able to obtain any such licenses on commercially reasonable terms, if at all. We currently license certain proprietary information from third parties, some of which may have been developed with government grants under circumstances where the government maintained certain rights with respect to the proprietary information developed. No assurances can be given that such third parties will adequately enforce any rights they may have or that the rights, if any, retained by the government will not adversely affect the value of our license. Certain of our know-how and technology is not patentable, particularly the procedures for the manufacture of our drug product which are carried out according to standard operating procedure manuals.

We may not be profitable unless we can produce

Ampligenr in commercial
quantities at costs acceptable to us.

We have never produced Ampligenr or any other products in large commercial quantities. Ampligenr is currently produced only for use in clinical trials. We must manufacture our products in compliance with regulatory requirements in commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligenr or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected.

If our distributors do not market our product successfully, we may notgenerate significant revenues or become profitable.

We have limited marketing and sales capability. We need to enter into marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. To the extent that we enter into co-marketing or other licensing arrangements, any revenues received by us will be dependent on the efforts of third parties, and there is no assurance that these efforts will be successful. Our agreement with Gentiva Health Services offers the potential to provide significant marketing and distribution capacity in the United States while licensing and marketing agreements with certain foreign firms should provide an adequate sales force in South America, Africa, United Kingdom, Australia and New Zealand, Canada and Austria.

Gentiva Health Services is able to deliver treatment and services to chronic disease patients including infusion services, home nursing and other medical services through a national network of more than 500 locations. We cannot assure that Gentiva Health Services or our foreign marketing partners will be able to successfully distribute our products, or

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that we will be able to establish future marketing or third party distribution agreements on terms acceptable to us, or that the cost of establishing these arrangements will not exceed any product revenues. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a materially adverse effect on us. If we cannot enter into future marketing and distribution agreements at terms acceptable to us, or if these distributors cannot effectively market and distribute our products, our operations will be negatively affected.

No assurance of successful product development of

Ampligenr.

The development of Ampligenr and our other products is subject to a number of significant risks. Ampligenr may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary rights of third parties. Our products are in various stages of clinical and pre-clinical development and, require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, or if ever, Ampligenr will be generally available for commercial sale for any indication for at least the next several years, if at all. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale.

Ampligenr safety profile.

We believe that Ampligenr has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15% of patients treated in our various studies. This reaction is occasionally accompanied by erythema, a tightness of the chest, tachycardia, anxiety, shortness of breath, subjective reports of ''feeling hot,'' sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by slowing the infusion rate. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, urticaria (swelling of the skin), bronchospasm, hypotension, photophobia, rash, bradycardia, transient visual disturbances, transient arrhythmias, decreased visual activity in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months.

There is no assurance that successful manufacture of a drug on a limited scale basis for investigational use will lead to a successful transition to commercial, large-scale production.

Small changes in methods of manufacturing may

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affect the chemical structure of Ampligen and other such RNA drugs, as well as their safety and efficacy. Changes in methods of manufacture, including commercial scale-up may affect the chemical structure of Ampligen

and, can, among other things, require new clinical studies and affect orphan drug status, particularly, market exclusivity rights, if any, under the Orphan Drug Act. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and will require additional management and technical personnel and capital to the extent such manufacturing is not handled by third parties. There can be no assurance that our efforts will be successful or that any given product will be determined to be safe and effective, capable of being manufactured economically in commercial quantities or successfully marketed.

Rapid technological change.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Most of these entities have significantly greater research and development capabilities than us, as well as substantial marketing, financial and managerial resources, and represent significant competition for us. There can be no assurance that developments by others will not render our products or technologies obsolete or noncompetitive or that we will be able to keep pace with technological developments.

Substantial competition.

Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments will offer competition to our products. Furthermore, many of our competitors have significantly greater experience than us in pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA and HPB product approvals more rapidly than us. If any of our products receive regulatory approvals and we commence commercial sales of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have no experience. Our competitors may possess or obtain patent protection or other intellectual property rights that prevent, limit or otherwise adversely affect our ability to develop or exploit our products.

Limited manufacturing experience and capacity.

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Ampligenr is currently produced only in limited quantities for use in our clinical trials and we are dependent upon certain third party supplies for key components of our products and for substantially all of the production process. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a material adverse affect on us. Also, to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. To the extent we are involved in the production process, our current facilities are not adequate for the production of our proposed products for large-scale commercialization, and we currently do not have adequate personnel to conduct commercial-scale manufacturing. We intend to utilize third-party facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. We will need to comply with regulatory requirements for such facilities, including those of the FDA and HPB pertaining to Good Manufacturing Practices ("GMP") regulations. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, that such facilities, if used, built, or acquired, will be adequate for our long-term needs.

We may be subject to product liability claims from the use of Ampligen or other of our products which could negatively affect our future operations.

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligenr or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively effected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure. Although we currently maintain worldwide product liability insurance coverage in the amount of $1,000,000, there can be no assurance that this insurance will provide adequate coverage against product liability claims. While no product liability claims are pending or threatened against us to date, a successful product liability claim against us in excess of our insurance coverage could have a negative effect on our business and financial condition.

Members of our Scientific Advisory Board may have conflicting interests and
may disclose data and technical know how to our competitors.

All of our Scientific Advisory Board members are employed by other entities, which may include our

competitors. Although we require each of our Scientific Advisory Board members to sign a non-disclosure and non-competition agreement with respect to the data and information that he or she receives from us, we cannot assure you that members will abide by them. If a member were to reveal this information to outside sources, accidentally or otherwise, our operations could be negatively effected.

Since our business depends in large part on our ability to keep our technical expertise confidential, any revelation of this information to a competitor or other source could have an adverse effect on our operations.

There is no guarantee that our trade secrets will not be disclosed or known by our competitors.

To protect our rights, we require certain employees and consultants to enter into confidentiality agreements with us. There can be no assurance that these agreements will not be breached, that we would have adequate and enforceable remedies for any breach, or that any trade secrets of ours will not otherwise become known or be independently developed by competitors.

The loss of Dr. Carter's services could hurt our chances for success.

Our success is dependent on the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligenr, and his knowledge of the company's overall activities, including patents, clinical trials, corporate relationships and relationships with governmental agencies which regulate our business. The loss of Dr. Carter's services could have a material adverse effect on our operations and chances for success. While we have an employment agreement with Dr. William A. Carter, and have secured key man life insurance in the amount of $2 million on the life of Dr. Carter, the loss of Dr. Carter or other personnel, or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement and potential legislation.

Our ability to successfully commercialize our products will depend, in part, on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and from time to

time legislation is proposed, which, if adopted, could further restrict the prices charged by and/or amounts reimbursable to manufacturers of pharmaceutical products. We cannot predict what, if any, legislation will ultimately be adopted or the impact of such legislation on us. There can be no assurance that third party insurance companies will allow us to charge and receive payments for products sufficient to realize an appropriate return on our investment in product development.

Hazardous materials.

Our business involves the controlled use of hazardous materials, carcinogenic chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with the standards prescribed by applicable regulations, the

risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident or the failure to comply with applicable regulations, we could be held liable for any damages that result, and any such liability could be significant. The company does not maintain insurance coverage against such liabilities.

Exercise of Class A Redeemable Warrants may have dilutive effect on market.

Holders of the Class A Redeemable Warrants may exercise the Class A Redeemable Warrants and purchase the underlying Common Stock at a time when we may be able to obtain capital by a new offering of securities on terms more favorable than that provided by such Class A Redeemable Warrants, in which event our ability to obtain additional capital would be affected adversely.

Litigation in Pennsylvania involving us and Manuel Asensio and Asensio & Company,Inc.

In 1998, we filed a multi-count complaint against Manuel P. Asensio, Asensio & Company, Inc., and others in the United States District Court for the Eastern District of Pennsylvania. The action presently includes claims of defamation, disparagement, tortious interference with existing and prospective business relations and conspiracy, arising out of the current defendants' false and defamatory statements. The complaint further alleges that defendants defamed and disparaged the Company in furtherance of a manipulative, deceptive and unlawful short-selling scheme between August, 1998, and the present.

In 1999, Manuel P. Asensio, and Asensio & Company, Inc., and others filed an answer and counterclaim

against the Company. The counterclaim alleges that in or around September 1998, and in response to defendants' strong sell recommendation and other press releases about the Company and its officers and directors, the Company made defamatory statements about defendants, including statements that defendants' attack and manipulative short-selling scheme may have constituted criminal wrongdoing on the part of defendants. The Company has denied the material allegations of the counterclaim and is vigorously defending against the counterclaim. In July 2000, following dismissal in federal court for lack of subject matter jurisdiction, we transferred the action to the Pennsylvania State Court. In March 2001, the defendents responded to the complaint as amended. In May 2001, the defendents moved for a summary judgement on all counts of the amended complaint. The motion is presently pending and no trial date has been set.

Litigation in New York involving us and Manuel Asensio, Asensio & Company Inc., and Asensio.com Inc.

In May 2000, we received notice of a claim by Manuel P. Asensio and Asensio & Company, Inc., in the Supreme Court of the State of New York against the Company, the Chairman and Chief Executive Officer, William A. Carter, and our prior auditors (the "first New York action") in which they allege that defendants defamed them in oral and written communications made in

March 2000. The allegations of Manuel P. Asensio and Asensio & Company, Inc. in the first New York action are similar in substance to the alleged defamation which is the subject of the counterclaims filed by them in the action presently pending in Pennsylvania State Court. In March 2001, Dr. Carter's motion to dismiss was granted. In July 2001, the company moved to dismiss the action based on the prior pendency of the action of the Pennsylvania State Court. The motion is presently pending.

In June 2000, Manuel P. Asensio, Asensio & Company, Inc. and Asensio.com Inc.,("Asensio plaintiffs") filed a second action against the Company and Dr. William Carter, the Company's Chairman and Chief Executive Officer in the Supreme Court of the State of New York. (the "second New York action"). In September 2000, we were served with a complaint in this action. The second New York action purports to seek a declaratory judgment that the Asensio plaintiffs statements regarding the Company constituted protected speech, and that they did not engage in any actionable interference with our existing or prospective business relations. In June 2001, Asensio plaintiffs voluntarily withdrew the second New York action. We intend to vigorously defend against the claims asserted in the first New York actions. However, this litigation could subject us to significant liability for damages and, even if it does

not subject us to liability for damages, it could be time-consuming and expensive to defend, and could result in the diversion of management time and attention.

Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which will arise. In addition, we cannot assess the impact of each factor on our business of the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

RESULTS OF OPERATIONS

Three months ended June 30, 2001 versus Three months ended June 30, 2000

Our net loss for the three months ended June 30, 2001 was $2,343,000 or approximately $283,000 more than recorded for the same period in 2000. Overall costs and expenses were higher by some $94,000 and cost recovery treatment revenue and interest income was down by $189,000.

Revenues from Cost Recovery Clinical Treatment programs in the U.S. and Europe were down $115,000 primarily due

to our focus on recruiting patients for the double blind, placebo controlled phase III CFS clinical trial. Interest income was down by $74,000 due to lower money market interest rates and a smaller amount of invested funds.

Overall Research and Development costs in the three months ended June 30, 2001 were lower by $119,000 compared to the same period in 2000. Most of this decrease relates to lower clinical trial and related costs. The costs related to the CFS phase III clinical trial were down some $379,000 as this trial nears completion. Costs related to cost recovery treatment revenues were lower by $73,000 due to lower revenues recorded in the three months ended June 30, 2001. Clinical costs related to the new HIV clinical trials were $42,000. Manufacturing and quality control costs increased $329,000 reflecting the increased cost of working with a new liquid Ampligenr producer as well

as increased product testing and release efforts.

General and Administrative expenses were $760,000 exclusive of $276,000 recorded for stock compensation in the three months ended June 30, 2001 compared to $656,000 exclusive of $167,000 of stock compensation recorded for the same period in 2000. The net increase in expenses of $104,000 basically reflects an increase in professional fees in the amount of $214,000 with offsets in lower Public Relations expenses of $50,000, lower temporary help costs of $20,000 and lower cost related to telephone, travel and other expenses.

Stock Compensation expense was $276,000 in the three months ended June 30, 2001. This is an increase of $109,000 over the same period in 2000. Stock Compensation expense is a non-cash expense that reflects the fair value of common stock or warrants granted to non-employees of the Company.

Six months ended June 30, 2001 versus six months ended

June 30,2000

Our net loss was approximately $4,823,000 for the six months ended June 30, 2001. This reflects an increase in losses in the amount of $791,000 compared to the same period in 2000. Elements contributing to the increase in losses include lower cost recovery treatment revenues totaling $198,000, increased R&D costs of $241,000, higher stock compensation expenses of $186,000, and lower interest income of $132,000.

CFS cost recovery treatment revenues were $228,000 in the six months ended June 30, 2001 compared to $426,000 in the same period in 2000. This decline in revenue is reflected in the U.S. as well in Europe. U.S. revenues were down primarily due to our focus on recruiting CFS patients for the Phase III CFS trial. European revenues are basically produced by one clinic located in Belgium. Enrollment in the Belgium program has been slowed to allow the clinical investigator to compile and review the clinical data collected in the treatment of approximately 150 patients over the past several years. This data, when finalized, will be used to supplement the data collected from the phase III CFS

clinical trial in the U.S. Our European personnel are working to establish CFS cost recovery treatment programs in other European countries.

Research & Development costs were $3,176,000 in the six months ended June 30, 2001 versus $3,022,000 for the same period in 2000. This increase of $154,000 is primarily due to costs related to the increased production and testing of Ampligenr in 2001. Compared to the first six months of 2000, the need for Ampligenr has increased in 2001 due to increased clinical trial

activity.

General and Administrative Expenses before charges for stock compensation, were $1,409,000 in the six months ended June 30, 2001 compared to expense of $1,400,000 for the same period in 2000. Basically, General and Administrative expenses in 2001 remained flat when compared to the six month period ended June 30,2000.

Stock Compensation expense of $595,000 in the six months ended June 30, 2001 is $273,000 higher than recorded for the same period in 2000. The 2001 expense includes a cost of $262,000 due to the extension of the expiration dates of certain warrants granted to officers and Directors.

Interest income of $180,000 in the six month end June 30, 2001 was down by $132,000 due to lower interest rates earned on money market instruments as well as less funds were available to invest.

LIQUIDITY AND CAPITAL RESOURCES

Our cash, cash equivalents and short term investments were $4,980,000 as of June 30, 2001 compared to $8,378,000 million at December 31, 2000 reflecting a net decrease of cash in the amount of $3,398,000 in the first six months of 2001.

Operating activities consumed $4,160,000 million reflecting major cash outlays in support of the ME/CFS phase III clinical trial as well as support of the European clinical efforts. All clinical trial drug products were fully expensed although some of the costs are expected to be recovered under the expanded access, cost-recovery, pre-marketing programs authorized by FDA and various regulatory bodies in other countries. As the clinical testing effort in the United States accelerates and the European market development activity increases, the operating burn rate may increase periodically. However, certain of the operating, as well as the non-operating cash outlays are of a one time nature and are expected to decline. Also revenues from expanded access cost recovery treatments are expected to improve in the coming months.

Proceeds from the exercise of warrants totaled $1,147,000 which is significantly lower than

experienced in the first six months of 2000. The decline in warrants being exercised is primarily due to the depressed market price of biotech stocks including ours. In the six months ended June 30,2001, our stock price traded in a range of $3.01 to $7.15. We have 3,916,208 outstanding publicly traded class A preferred redeemable warrants exercisable at $4.00 per share and

8,122,510 non-public warrants that are exercisable at an weighted average price of $4.12. The shares of common stock underlying 4,269,000 shares of the oustanding non-public warrants have been registered for sale under the Securities Act of 1933, as amended, by the holders thereof. We expect warrantholders to continue exercising both the public and non-public warrants from time to time depending on the trading price of our common stock. The publicly traded class A redeemable preferred warrants expire on November 2, 2001.

Our current cash and cash equivalents should fund operations through April 2002. In the event that our warrantholders do not exercise warrants at the level of funding needed to support our operations, we will seek access to the private or public equity markets for the funding capital needed. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, competitive and technological advances, the regulatory process, and higher than anticipated expenses and lower than anticipated revenues from certain of our clinical trials for which cost recovery from participants has been approved.

New Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board finalized FASB Statements No. 141, Business Combinations (SFAS 141), and NO. 142, Goodwill and Other Intangible Assets (SFAS 142). SFAS 141 requires the use of the purchase method of accounting and prohibits the use of the pooling-of-interests method of accounting for business combinations initiated after June 30, 2001. SFAS 141 also requires that the Company recognize acquired intangible assets apart from goodwill if the acquired intangible assets meet certain criteria. SFAS 141 applies to all business combinations initiated after June 30, 2001 and for purchase business combinations completed on or after July 1, 2001. It also requires, upon adoption of SFAS 142, that the Company reclassify the carrying amounts of intangible assets and goodwill based on the criteria in SFAS 141.

SFAS 142 requires, among other things, that companies no longer amortize goodwill, but instead test goodwill

for impairment at least annually. In addition, SFAS 142 requires that the Company identify reporting units for the purposes of assessing potential future

impairments of goodwill, reassess the useful lives of other existing recognized intangible assets, and cease amortization of intangible assets with an indefinite useful life. An intangible asset with an indefinite useful life should be tested for impairment in accordance with the guidance in SFAS 142. SFAS 142 is required to be applied in fiscal years beginning after December 15, 2001 to all goodwill and other intangible assets recognized at that date, regardless of when those assets were initially recognized. SFAS 142 requires the Company to complete a transitional goodwill impairment test six months from the date of adoption. The Company is also required to reassess the useful lives of other intangible assets within the first interim quarter after adoption of SFAS 142.

The Company's investment in CIMM was accounted for using the equity method. As of June 30, 2001, the net carrying amount of goodwill included in the investment balance was $503,000. Other intangible assets are primarly patents which currently have a net value of $1,051,000. Amortization expense of goodwill and patents during the six-month period ended June 30, 2001 was $18,000 and $191,000 respectively. Currently, the Company is assessing but has not yet determined how the adoption of SFAS 141 and SFAS 142 will impact its financial position and results of operations.

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had $4,980,000 in cash, cash equivalents and short term investments at June 30, 2001. To the extent that our cash and cash equivalents exceed our near term funding needs, we invest the excess cash in three to six month high quality financial instruments. The Company employs established policies and procedures to manage any risks with respect to investment exposure.

Part II - OTHER INFORMATION

ITEM 1: Legal Proceedings

In September, 1998, we filed a multi-count complaint against Manuel P. Asensio, Asensio & Company, Inc., and others in the United States District Court for the Eastern District of Pennsylvania. In October 1998 and August 1999, we amended the complaint to add additional counts and to add Asensio.com, Inc. (formerly known as Asensio Holding, Inc.), the holding company of the defendant, Asensio & Company Inc., and

to add a conspiracy charge against the remaining defendants and certain unnamed John Does. As amended, our complaint seeks recovery on common law theories of intentional interference with existing and prospective business relations, defamation, commercial disparagement, and conspiracy on account of

defendants' short selling of our stock and the publication, by defendants Asensio and ACI, of defamatory statements regarding the Company. In April 1999, defendants Asensio and ACI answered the complaint and asserted defamation and disparagement counterclaims against us seeking damages in an unspecified amount. Defendants' counterclaims allege that we, through our officers, defamed Asensio in oral and written communications accusing Asensio and ACI of having engaged in possibly criminal behavior with respect to the short selling of our stock and the subsequent publication of various defamatory statements regarding us . In May 1999, we filed an answer, including affirmative defenses, to these counterclaims.

In June 2000, the United States District Court dismissed the Company's complaint and the defendants' counterclaims for lack of federal subject matter jurisdiction over the action. In July 2000, we transferred the action to the Pennsylvania State Court. In May 2001, the defendants moved for summary judgement on all counts. The motion is presently pending. No trial date has been re-set for this action.

In May 2000, Asensio and ACI filed a separate action in the Supreme Court of the State of New York against our company, our Chairman and Chief Executive Officer, William A. Carter and our prior auditors ("the first New York action"). The action was commenced by Summons. In July 2000, Asensio and ACI filed a Complaint in which they alleged that the defendants defamed them in oral and written communications made in March 2000. Plaintiff's allegations in the first New York action are similar in substance to the alleged defamations which are the subject of the counterclaim filed by them in the action presently pending in Pennsylvania State Court. In August 2000, we filed an answer, including affirmative defenses to these claims, and Dr. Carter moved to dismiss the claims. In March 2001, Dr. Carter's motion to dismiss was granted. In July 2001, the Company moved to dismiss the action based on the prior pendency of the action of the Pennsylvania State Court. The motion is presently pending.

In June 2000, Asensio, ACI and Asensio.Com, Inc. filed a second action against us and Dr. Carter in the Supreme Court of the State of New York ("the second New York action"). The action was commenced by Summons. In September 2000, plaintiffs filed a Complaint in the second New York action which purports to seek a declaratory judgment that the statements of Asensio, ACI and Asensio.com, Inc. about the Company constituted protected speech, and that plaintiffs did not engage in any actionable interference with existing or prospective business relations of the Company. In essence, the second New York action seeks to establish the validity of the affirmative defenses asserted by the defendants in the action now being

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litigated in the Pennsylvania State Court. In June 2001, the plaintiffs voluntarily withdrew the second New York action.

We intend to vigorously defend against the "claims" asserted by Asensio, ACI and Asensio.com, Inc. in the New York actions and we have moved to consolidate and dismiss the first New York action.

Cook Imaging Corp. ("Cook") commenced action against us in March 2000, in the United States District Court for the Eastern District of Pennsylvania. From approximately 1997 through 1999, Cook manufactured the drug Ampligenr (as well as Ampligenr placebo) for us. Cook sued for in excess of $300,000 in unpaid invoices, including interest, related to four Ampligenr batches manufactured by Cook and delivered to us in 1999. The Company denied that such amounts are owed and asserted a counterclaim for failure to consistently manufacture Ampligenr in strict conformance with federal regulations known as current good manufacturing practices ("cGMP"). The court awarded Cook Imaging approximately $248,000 which reflects the amount of the unpaid invoices plus interest, less approximately $63,800 awarded the Company on its counterclaims. We paid this amount to Cook during the quarter ended June 30, 2001.

ITEM 2: Changes in Securities

None

ITEM 3: Defaults in Senior Securities

None

ITEM 4: Submission of Matters to a Vote of Security Holders

None

ITEM 5: Other Information

None

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ITEM 6: Exhibits and Reports on Form 8K

(a)Exhibits

3.1* Amended and Restated Certificate of Incorporation of the Company, as amended, along with Certificates of Designations

3.1.1** Series E Preferred Stock

3.2	By-laws of Registrant, as amended and restated
4.1*	Specimen certificate representing our common stock
4.2*	Form of Class A Redeemable Warrant Certificate
4.3*	Form of Underwriter's Unit Option Purchase Agreement
4.4*	Form of Class a Redeemable Warrant Agreement with Continental Stock and Transfer and Trust Company
10.1	Amended and Restated Employment Agreement by and between the Company and Dr. William A. Carter, dated as of December 3, 1998
10.2	Amended and Restated Engagement Agreement by and between the Company and Robert E. Peterson, dated April 1, 2001.

* These exhibits were filed with the Securities and Exchange Commission ("SEC") as exhibits to the Company's Form S-1 Registration Statement (No. 33-93314) or amendments thereto and are hereby incorporated by reference.

** This exhibit was filed with the SEC as Exhibit 3.1.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999 and is hereby incorporated by reference.

(b) Reports on Form 8-k

None

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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.

HEMISPHERx BIOPHARMA, INC.

/S/ William A. Carter

Date: August 14, 2001 William A. Carter, M.D.
Chief Executive Officer & President

/S/ Robert E. Peterson

Date: August 14, 2001 Robert E. Peterson
Chief Financial Officer