



information in time



Time is precious.
It can be measured
in seconds or heartbeats
or gasps of breath.

At Biosite, we provide
information in time
to speed diagnosis,
to save lives.

Time is value.



discovery

Biosite is a leading provider of Immediate Response Diagnostics that aid in the diagnosis of critical diseases with time-sensitive therapeutic pathways. Since 1988, our team of skilled researchers has applied its considerable talents to developing products that quickly and definitively diagnose the presence of cardiac markers, drugs of abuse and infectious diseases in the human body.

Our business objective has always been to meet the significant market need for immediate diagnostic information, but in 1999, we added another dimension to our business. We launched Biosite Discovery, a program that encompasses internal discovery programs and collaborative research efforts.

Biosite Discovery aims to identify new protein markers for acute diseases. In addition to our internal discovery efforts, we offer our expertise in antibody development to biotechnology and pharmaceutical partners seeking to accelerate their drug research programs. In return, we intend to obtain diagnostic rights to the proteins under study.

It is an ideal situation in which everyone can gain. Our Omniclonal™ antibody technology enables our partners to perform their drug research more efficiently and effectively. We benefit by gaining access to new protein markers that can be evaluated for diagnostic utility. Upon successful execution of our model, we intend to use these markers in new diagnostic tools that would potentially aid in better management and treatment of diseases.

Through Biosite Discovery, our scientists will lead the effort to find new protein markers for diseases, focusing on cardiovascular, cerebrovascular, oncology and infectious disease categories. Leveraging our substantial capabilities in phage display

and marker mining technology, we are launching a research endeavor that may distinguish us from others in our field and lay a foundation for future growth.

With the capacity to evaluate up to 400 targets each year, we believe our opportunities are broad. We have formed Biosite Discovery partnerships with Corixa Corp., Scios Inc., diaDexus LLC and Morphosys AG giving us access to a diversified array of targets. Our most active Biosite Discovery project, however, is an internal program for stroke, a highly disabling disease. Currently, Biosite Discovery is evaluating 20 proteins that our researchers have identified as potential markers for stroke.

Traditionally, diagnostic companies have competed on the basis of testing platforms. This has led to the development of larger, more complex mechanical testing systems,

and more recently to the emergence of smaller rapid systems. We recognize the need for platform development, but, with Biosite Discovery, we are demonstrating our strong commitment to finding new markers of disease. No longer should platforms be the differentiating factor in diagnostics. At Biosite, we believe content will be key.

At first glance, investment in research and commitment to stockholder value may seem to be mutually insupportable, but Biosite Discovery represents a market approach to research. We have not embarked upon research just for research's sake. We determine what clinical needs are unmet and focus our research resources on fulfilling those needs. And, we believe we are poised to be among the first to develop some new diagnostic categories, a market position that holds great promise.

searching for signs of stroke



Dr. Daniel Laskowitz

Stroke is a leading cause of death and long-term disability in the United States. Yet, for a condition so common, it is often difficult to diagnose stroke in time for early treatment. While the causes and signs of stroke are well known, they are not always obvious.

"Stroke is a huge problem, and research has generally focused on treatments," says Dr. Daniel Laskowitz, a neurologist at Duke University Medical Center in Durham, North Carolina. "No one has focused on diagnosis and the limitations of current methods, until now.

"Currently, stroke is diagnosed through a combined evaluation of patient history, presentation symptoms and a CT scan. It may take up to 90 minutes to get results from a CT scan, and the sensitivity of a scan upon presentation is too low to benefit the majority of patients."

Says Dr. Hilary Grocott, a Duke anesthesiologist studying neurologic injuries after heart surgery, "We asked ourselves the question, 'Is there a biochemical marker, or panel of markers, that can quickly identify an incident of stroke, help us differentiate between blockage and bleeding events and lead to a faster diagnosis and, therefore,

more appropriate treatment?' That's where our research with Biosite Discovery comes in."

Drs. Laskowitz and Grocott are collecting blood from hundreds of Duke patients who have undergone cardiopulmonary bypass heart surgery, suffered stroke or presented with neurocognitive deficits that may have been caused by stroke. Samples from these patients are sent to Biosite, where feasibility studies are underway for 20 potential stroke markers. Once the potential diagnostic value of such markers is assessed, Biosite will use high throughput screening technology to test the most promising potential markers against the Duke samples. From that analysis, Biosite hopes to validate a panel of markers for use in developing diagnostic tests for stroke patients.



Dr. Hilary Grocott

"Every minute matters in the case of stroke," says Dr. Laskowitz. "A point-of-care test like the one Biosite hopes to develop could make all the difference in terms of patient outcome and the cost to the patient and the hospital."

discovery

development

deployment



d e v e l o p m e n t Biosite Discovery represents a long-term commitment to research. While this program is unique in the diagnostics industry, Biosite's other efforts, especially those regarding products currently in development, are equally important.

The development process at Biosite reflects our overall business approach. Each development program at Biosite is carefully selected to fill a market need. Efforts are targeted toward diseases for which rapid diagnosis is as important as appropriate treatment. Once opportunities are identified, we bring our scientific expertise into play to develop sensitive and specific tests as quickly as possible.

Our technology, which is based on several proprietary advances in the biological and physical sciences, makes possible the development and manufacture of accurate and cost-effective Immediate Response Diagnostics that can be used in laboratories or at the point-of-care. The Company's products integrate our expertise in several core scientific and engineering disciplines, including antibody development, analyte cloning and synthesis, and micro capillary fluidics. By combining research capabilities in each of these areas, we are able to create novel diagnostics that overcome the limitations of traditional rapid diagnostic technologies and address the significant unmet need for timely and effective diagnostic information.

Our market-driven process has been evident in the development of the Triage® BNP Test, which is intended to aid in the diagnosis of congestive heart failure (CHF). We recognized the need for better diagnostic methods for CHF and licensed the BNP technology from Scios Inc., after gaining confidence that BNP could meet the diagnostic need. Using our expert technology, we were able to devise and develop

finding faults with failing hearts



Dr. Alan Maisel

Congestive heart failure (CHF) impedes the heart's ability to pump enough blood to meet the needs of the body's organs. This disabling condition afflicts nearly 5 million Americans, with 400,000 new cases reported each year. Annually, 3 million hospital admissions cite CHF as the primary or secondary diagnosis. Compounding the problem, the financial burden of diagnosing and treating heart failure can be staggering, with estimated costs for 2000 totaling \$20.3 billion.

"Better and more cost-effective diagnosis of CHF is needed," says Dr. Alan Maisel, Director of the CCU at the Veterans Affairs Health Care System in San Diego, California. "The Triage BNP Test may help accomplish this by giving us an objective blood test to aid in earlier diagnosis, thereby reducing the need for repeated x-rays and other less definitive tests.

"Currently, we diagnose CHF using patient history, symptoms and an echocardiogram, which costs about \$500 in our institution," says Dr. Maisel. "Treatment is most effective when

the disease is diagnosed in the early stages, however, clinical diagnosis of CHF in these stages is difficult because its symptoms, such as fatigue and shortness of breath, are non-specific and can point to a number of other illnesses."

Biosite's Triage BNP Test is designed to provide rapid, precise, quantitative measurements of B-type Natriuretic Peptide, a hormone released into the bloodstream as a result of CHF. Distinct pilot studies performed in 1999 by Dr. Maisel and presented at the American College of Cardiology Scientific Session in March 2000 suggest that BNP may have versatile utilities.

According to one study, BNP demonstrated high sensitivity and specificity in differentiating CHF from other similar medical problems encountered in the emergency room. Another suggested that evaluation of BNP levels can be useful in predicting the likelihood of a patient being readmitted or suffering an adverse event after discharge.

While these are early studies, Dr. Maisel is encouraged by the results. "The potential for saving lives and health care costs with accurate BNP detection is substantial," he says. "We are looking forward to further investigating BNP through follow-up studies, which might produce important information for physicians and our patients."

the test and submit it for FDA approval in less than three years. Although our initial effort to obtain a recommendation for approval was unsuccessful, we are already at work gathering additional data needed to fully validate the test as an aid in the diagnosis of CHF.

We have also launched a separate extensive international multi-center trial to investigate the Triage BNP Test's utility in both differentiating CHF from other conditions associated with shortness of breath, and in assessing efficacy of therapy. These studies, underway at the Henry Ford Healthcare System in Detroit, the University of Cincinnati Medical Center in Cincinnati, the Veterans Affairs Health Care System in San Diego, the Assistance Hopitaux Publique De Paris

in Paris and the Ullevaal Hospital in Oslo, may provide valuable data regarding potential uses for our test.

In the past, we have dedicated up to 36% of revenues to acquire talent, fund research, develop manufacturing processes, perform studies and improve existing technology in an effort to ensure that our product pipeline is fueled and development is successfully executed. With proven qualitative and quantitative platform technologies and the potential for new markers from Biosite Discovery, we are positioned to generating exciting, well-designed products, even as we reduce research and development spending (as a percentage of net sales.)

discovery

development

deployment

d e p l o y m e n t

While we have invested in our long-term future through Biosite Discovery and are strengthening our short-term prospects through products in development, we have already commercialized and successfully deployed four products, which generated \$43 million in net sales in 1999.

One of our most recent additions to the market is the Triage Cardiac System, a portable, quantitative, rapid diagnostic that aids in the detection of acute myocardial infarction (AMI), or heart attack. The System measures the presence of three cardiac protein markers: CK-MB, myoglobin and troponin I.

We believe that rapid, serial, quantitative measurements of multiple cardiac markers can positively impact a physician's ability to make medical decisions. Furthermore, we feel that the information is even more useful when delivered in the shortest amount of time. For this reason, we designed the Triage Cardiac System to be portable — meaning physicians can receive cardiac marker measurements in the emergency room close to the point-of-care.

Central to our effort to deploy the Triage Cardiac System is one-on-one communication with cardiologists, emergency room physicians, laboratory clinicians and nurses. These customers all contributed to the product's design as we researched the needs and frustrations associated with diagnosing a life-threatening disease in a time-compressed environment.



Today, we intensively train our sales force to confidently communicate with our diverse customers and to understand their unique needs. Account Executives are supported by our Professional Education Department and are equipped with clinically-oriented sales tools containing substantive

information useful to potential customers. Our sales force is also complemented by regional Clinical Specialists, Biosite's newest addition to the customer support system.

Clinical Specialists, providers of value-added services for potential and existing customers, are key to our deployment efforts. These experienced nurses and clinicians can relate to their colleagues in the medical community, enabling them to effectively educate customers on changing practices, support implementation of new diagnostic tools and protocols, and solicit feedback along the way. Together marketing, sales, customer support personnel and Clinical Specialists form a highly qualified resource network for our customers.

Of course, deployment of the Triage Cardiac System could not succeed without well-executed operations to accomplish manufacturing, quality assurance and product support. In the first

quarter of 1999, Biosite formed a separate manufacturing group for quantitative platform products. As a result, we achieved greater manufacturing efficiency for the Triage Cardiac System, resulting in continued reductions in product costs during the year. The Operations group also improved its ability to respond to technical issues, thereby minimizing customer inconvenience.

Our deployment strategy encompasses an integrated system of processes and people who come together to support the highest level of customer service. While the introduction of new technology, like the Triage Cardiac System, can initially be disruptive to customers who are uncomfortable with change, we have seen that with support and assurance of quality, many of these same customers embrace innovation and find new ways to put it to use in their institutions.

aiming for answers for AMI



More than 6 million people present to emergency rooms every year with symptoms of acute myocardial infarction (AMI), or heart attack. Yet, only 11% of those will actually

suffer a heart attack. The others are usually suffering from something else, often less life threatening. According to published studies, inappropriate hospitalization for chest pain costs \$4 billion annually in the United States alone. Inappropriate patient discharge presents a problem as well. In fact, it is estimated that each year 35,000 patients are sent home after being misdiagnosed, only to suffer an AMI later.

Currently, AMI is diagnosed through patient history, symptoms and an electrocardiogram (EKG). Yet, EKG is only sensitive in diagnosing a heart attack 50% of the time. AMI can also be diagnosed through the measurement of cardiac markers in the blood, but the most prevalent testing methods are automated immunoassays. Response time to the physician is usually one to two hours, delaying the use of this critical diagnostic information.

The Triage Cardiac System provides rapid, quantitative analysis of three cardiac markers — CK-MB, myoglobin and troponin I. The product provides physicians with valuable information within 20 minutes and can be used to speed decision making at the point-of-care.

"A three-marker panel has a unique diagnostic capability that is absent from other methodologies, such as patient history or EKG," says Dr. James McCord, cardiology director of the chest pain unit at Henry Ford Healthcare System in Detroit, Michigan. "Cardiac marker tests are critical as roughly 40-50% of the people who come into the emergency department do not have a definitive AMI, based on their EKG. Patient history can be very deceptive too, because people, especially elderly people, come in with very non-specific symptoms.

"The bottom line is that we depend on cardiac marker tests to define AMI in a large percentage of people. The presence or absence of protein markers in the blood can determine the course of treatment when a patient presents to the emergency department and can impact how a patient will respond."

discovery

development

deployment

delivering value

Every company has its goal, and at Biosite, our goal is to use a strategy of Discovery, Development and Deployment to deliver to our customers and stockholders the value they expect.

discovery

Scios Inc.
Initiated Biosite Discovery partnership in the area of cardiovascular disease.

Corixa Corp.
Formed Biosite Discovery partnership in the areas of cancer, infectious and autoimmune diseases.

Duke University
Initiated partnership with Duke to gain access to stroke patient samples.

diaDexus LLC
Formed Biosite Discovery partnership.

Morphosys AG
Licensed phage display technology to Morphosys AG, gained access to potential diagnostic targets.

development

The Triage BNP Test
Completed clinical studies and submitted a pre-market approval application (PMA) to the FDA. In March 2000, an FDA Advisory Panel recommended that our PMA not be approved. Additional clinical studies are underway, with the aim of submitting an amended filing.

The Triage LBP Test
Continued clinical studies to gather data for a PMA submission.

deployment

The Triage Drugs of Abuse Panel
Achieved net sales of \$33.8 million, an increase of 5% over the prior year.

The Triage Cardiac Panel
Completed full-scale launch and achieved net sales of \$6.6 million for the year.
Completed the year with approximately 300 customers.
Launched the product in international markets.

The Triage Microbiology Panels (*C. difficile* and Parasites)
Issued U.S. Patent No. 5,965,375 entitled "Diagnostic Tests and Kits for *Clostridium difficile*."
Achieved net sales of \$2.7 million for 1999.



The Triage Panel



The Triage Meter System



from the management Today, Biosite is a different company than it was a mere three years ago when we completed our initial public offering. We continue to develop and deploy a series of Immediate Response Diagnostics that may alter the way testing is done in hospitals and health care centers worldwide. But, thanks to our novel test platforms, proven clinical validity of key protein markers and the establishment of Biosite Discovery, we have a vision for long-term, sustainable growth.

Now, we have raised the bar on what we can be. We not only develop the rapid tests that can improve clinical practice, but we work to discover the biology behind some of medicine's most significant diagnostic dilemmas. Today, we believe we are poised to improve upon the gains made in 1999 and to step up to the next level in 2000 and beyond.

the year in review

Due to the outstanding efforts of our employees, 1999 was a year that demonstrated our commitment to profitability as well as our commitment to sustainable growth through research innovation. For Biosite, 1999 brought two important milestones. The first was our return to profitability. For the year ended December 31, 1999, we reported net income of \$1.1 million, or \$.08 per share on a diluted basis, compared with a net loss of \$1.1 million, or \$.09 per diluted share, in 1998. The second milestone was our achievement of 25% top line growth, as net sales of our products increased to \$43 million from \$34 million in 1998.

We attribute our progress in 1999 largely to our ability to achieve sales targets for the Triage Drugs of Abuse Panel, while establishing markets for our new products – the Triage Cardiac System and the Triage Microbiology Panels. Among those products, the Triage Cardiac System emerged as the leader, contributing 15% of total net sales for 1999 – or \$6.6 million. The growth in net sales primarily resulted from the increase in customer adoptions, with the number of customers growing from approximately 100 at December 31, 1998 to approximately 300 at the end of 1999. While our present customer base is weighted toward smaller hospitals, we believe it serves as a good foundation for our activities in the coming year.

In 1999, our other new products, the Triage *C. difficile* Panel and Triage Parasite Panel, posted combined net sales totaling \$2.7 million. Although the sales ramps for these products are more modest than that of the Triage Cardiac System, we continue to believe that they provide value for microbiology labs seeking rapid and accurate methods of diagnosis.

While pleased with the performance of new products, we cannot discount the value of our core product, the Triage Panel for Drugs of Abuse. Worldwide, the Triage Panel for Drugs of Abuse business increased by \$1.6 million in 1999, demonstrating that after eight years this product continues to provide value. Growth resulted largely from activities in international markets, where sales grew by 64% as a result of our transition to an international multi-distributor sales and marketing strategy. Despite increased competition in the domestic clinical market, the Triage Panel for Drugs of Abuse business remained stable, and the product maintained its market leadership among rapid drug screening panels.

In 1999, we also made substantial progress in reducing manufacturing costs for new products. This achievement resulted from improved manufacturing efficiencies in the production of our quantitative test platform, which is used for the Triage Cardiac System. Margins for that product improved to 55% by the fourth quarter of 1999, while production in the fourth quarter of 1999 increased by 314% over the fourth quarter of 1998.

This progress was achieved through the restructuring of our manufacturing group, greater utilization of analytical processes and benchmarks, and through cross-functional teamwork between research and development and operations personnel. In 2000, we hope to further build productivity and capacity through process improvements and through capital investment in assembly automation.

Profitability in 1999 was also aided by the continued favorable margins posted by the Triage Panel for Drugs of Abuse. With a gross margin of 79% for 1999, the Triage Panel for Drugs of Abuse not only contributed to our return to profitability, but also provided the cash flow to fund many of our new product commercialization and development activities.

While activities surrounding commercialized products captured a great deal of interest in 1999, Biosite did not back off from its recognized commitment to research and development. In fact, we took a bold step in launching Biosite Discovery, a program dedicated to the rational discovery of new high value markers of disease. What makes this program possible is the Company's expertise in phage display technology, which has yielded the Omniclonal antibody.

Fast, certain and economical, Biosite's Omniclonal antibody is valued by biotechnology and pharmaceutical partners seeking high affinity antibodies for use in their drug research. In return for providing these antibodies and/or other technology, Biosite receives access to protein targets from which it can potentially mine novel proteins that may enable better diagnosis and monitoring of diseases that, today, are difficult to detect.

Biosite Discovery represents our long-term commitment to sustainable growth, since the most highly valued diagnostic categories will likely be those created by companies who are able to discover and lock-up new protein markers. To this end, we believe Biosite is well positioned to create a flow of novel, medically important tests over the coming years.

the year to come

The year 2000 promises to be a crucial year for Biosite in many regards. Preservation of our drugs of abuse business will be a key objective. To that end, we are launching targeted initiatives intended to increase our presence in larger hospitals and secure business in our core base of current customers.

Another key objective is to achieve our sales targets for the Triage Cardiac System, which means increasing market share and volume of sales. In 2000, we are deploying dual strategies aimed at boosting utilization of tests and furthering market penetration among high volume customers. Education of clinicians will be key to this effort, as we introduce the clinical community to new accelerated care pathways that can substantially reduce the assessment time for chest pain patients in emergency departments.

In the area of product development, our goal is to achieve the final milestones for our Triage BNP Test – FDA approval and product launch. Following submission of our pre-market approval application (PMA) in December 1999, the FDA Clinical Chemistry and Clinical Toxicology Panel reviewed the Triage BNP Test at a meeting held in March 2000. At the conclusion of that meeting the Panel issued a recommendation to the FDA to not approve the test. The Panel also provided guidance as to how Biosite could bring the PMA into an approvable form.

While we are disappointed by the Panel's decision, we have already initiated efforts directed toward submission of an amended filing. During its meeting, the Panel expressed concerns regarding the lack of information on non-diseased individuals in older age groups

and diseased female patients. We are gathering this required data and believe we will be prepared to submit an amended filing by the end of 2000, but possibly sooner.

In spite of this setback, our efforts to educate the market on the potential use of BNP continue. We are developing professional education programs aimed at increasing clinicians' understanding of BNP and are conducting market research that will be utilized in deploying marketing strategies. We also have initiated a five-center international clinical trial in March 2000 to further study possible utilities of BNP.

Our final objective falls in the area of discovery, where we are hopeful of harvesting new markers from the Biosite Discovery activities initiated in 1999. A primary goal is to identify a panel of markers for stroke – a disease that each year affects one million Americans and that costs our health care system nearly \$31 billion annually. In addition to stroke, however, we also are close to identifying other important markers that may play a role in improved diagnosis of cardiovascular diseases.

We see the Biosite Discovery program as an important cornerstone of our future and look forward to reporting further on this program throughout the current year.



in conclusion

You have seen what Biosite does and, more importantly, you have seen what we are poised to do.

We are proud of our achievements and we continue to devote significant resources to improving current products and developing those in their infancy. We also remain committed to building value through a combination of growth and profitability. In the coming year, we are prepared to drive cost management initiatives that will enable continued investment in growth without compromising the bottom line.

For Biosite, 1999 was a remarkable year and we look forward to the potential of 2000. We have embarked on exciting new ventures that may someday afford physicians even better means of diagnosis and patients the possibility of even better care. To our stockholders, we thank you for your interest and continued support. We hope you share our belief that for Biosite the best is yet to come.

Kim D. Blickenstaff

President and Chief Executive Officer

Gunars E. Valkirs, Ph.D. (not photographed)

Vice President, Research and Development and Chief Technical Officer

Thomas M. Watlington

Senior Vice President, Commercial Operations

Kenneth F. Buechler, Ph.D.

Vice President, Research

James E. Douglas

Vice President, Marketing

Christopher R. Hibberd

Vice President, Strategic Planning and Business Development

Nadine E. Padilla

Director, Investor Relations and Corporate Communications

Charles W. Patrick

Vice President, Sales

Christopher J. Twomey

Vice President, Finance and Chief Financial Officer

Peter Witerzens, Ph.D.

Vice President Operations

Except for the historical information contained herein, the matters discussed in this Annual Report are forward-looking statements that involve risks and uncertainties, including the timely development, introduction and acceptance of new products, dependence on others, the impact of competitive products, patent issues, changing market conditions and the other risks detailed throughout this Annual Report. Actual results may differ materially from those projected. These forward-looking statements represent the Company's judgement as of the date of this Annual Report. The Company disclaims, however, any intent or obligation to update these forward-looking statements.

f i n a n c i a l s t a t e m e n t s

selected financial data

Year Ended December 31,
(in thousands, except per share data)

	1995	1996	1997	1998	1999
Statement of Operations Data:					
Net sales	\$ 25,147	\$ 28,206	\$ 31,677	\$ 34,424	\$ 43,011
Cost of sales	5,649	5,983	6,926	10,513	13,636
Gross profit	19,498	22,223	24,751	23,911	29,374
Selling, general and administrative	7,134	8,623	11,549	15,469	17,581
Research and development	6,553	9,268	11,662	11,167	13,347
Defense of patent matters	1,217	2,368	331	4,861	—
Total operating expenses	14,904	20,259	23,542	31,497	30,928
Income (loss) from operations	4,594	1,964	1,209	(7,586)	(1,553)
Interest and other income, net	1,647	1,846	3,435	5,026	2,491
Reacquisition of distribution rights	—	—	(3,364)	—	—
Income (loss) before benefit (provision)					
for income taxes	6,241	3,810	1,280	(2,560)	938
Benefit (provision) for income taxes	1,667	(261)	(82)	1,448	166
Net income (loss)	\$ 7,908	\$ 3,549	\$ 1,198	\$ (1,113)	\$ 1,104
Basic net income (loss) per share	\$ 6.46	\$ 2.48	\$ 0.11	\$ (0.09)	\$ 0.08
Diluted net income (loss) per share	\$ 0.79	\$ 0.34	\$ 0.09	\$ (0.09)	\$ 0.08
Common and common equivalent shares used					
in computing per share amounts(1)					
Basic	1,225	1,431	11,249	12,939	13,032
Diluted	10,004	10,392	13,081	12,939	13,728
December 31,					
	1995	1996	1997	1998	1999

Balance Sheet Data:

Cash, cash equivalents and marketable securities	\$ 13,979	\$ 9,916	\$ 39,257	\$ 34,229	\$ 32,272
Working capital	14,428	14,305	46,611	41,214	39,978
Total assets	27,935	30,089	63,311	65,809	68,148
Long-term obligations, less current portion	2,739	3,253	3,797	4,038	4,069
Stockholders' equity	18,526	22,153	55,090	54,683	56,885

(1) Computed on the basis described in Note 1 of Notes to Financial Statements.

management's discussion and analysis of financial condition and results of operations

The matters discussed in this Management's Discussion and Analysis of Financial Condition and Results of Operations contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the sections entitled "Business" and "Risk Factors," as well as those discussed elsewhere in the Annual Report on Form 10-K. We disclaim any intent or obligation to update these forward-looking statements.

Overview

We were established in 1988. We develop, manufacture and market rapid, accurate and cost-effective diagnostic products that improve the quality of patient care and simplify the practice of laboratory medicine. Our two product platforms are designed to provide rapid results through either qualitative visual readings or quantitative meter readings. In 1992, we launched our first qualitative platform product, the Triage DOA Panel. In 1998, we began selling two additional qualitative platform products, the Triage *C. difficile* Panel and the Triage Parasite Panel. Also, in 1998, we launched our first quantitative platform product, the Triage Cardiac System. We followed these product launches with the introduction of our second quantitative platform product, the Triage BNP System, in certain international countries in December 1999.

We market our products worldwide primarily through distributors supported by our direct sales force. Our principal markets are hospital laboratories, emergency departments and other point-of-care locations. In addition to focusing our attention on commercial activities associated with these products, we continue to invest in the research and development of additional rapid tests designed to aid in the diagnosis of several critical diseases or conditions in four core areas: cardiovascular, cerebrovascular, infectious diseases and oncology.

Our sales to date have primarily been attributed to sales of the Triage DOA Panel product line. The Triage DOA Panel products are marketed pursuant to exclusive distribution agreements in the U.S. hospital market segment by Fisher,

which accounted for 83% of product sales in 1999, and internationally by country-specific and regional distributors. Since the launch of the Triage DOA Panel in fiscal 1992, we experienced continued revenue growth from our Triage DOA Panel product line. The growth in sales of Triage DOA Panel products has slowed and we believe it may decline as the available U.S. market becomes saturated and competitive pressures become more and more prominent in a maturing market.

We returned to operating profitability during the third and fourth quarters of 1999. However, we incurred an operating loss during the prior seven quarters. We may not be able to maintain operating profitability on a quarterly or annual basis in the future and our operating results may not be consistent with predictions made by securities analysts.

We anticipate that our results of operations may fluctuate for the foreseeable future due to several factors, including:

- whether and when new products are successfully developed and introduced by us
- market acceptance of current or new products
- manufacturing inefficiencies
- progress of research and development projects including clinical trials and regulatory delays
- seasonal customer demand, the timing or cancellation of significant orders, product recalls and shipment problems
- changes in reimbursement policies
- competitive pressures on average selling prices
- changes in the mix of products sold.

Operating results would also be adversely affected by a downturn in the market for our current and future products. We continue to increase our operating expenses, primarily for personnel, capital equipment and activities supporting newly-introduced products and new product development. Our operating results would be adversely affected if our net sales or gross profit did not correspondingly increase or if our product development

efforts were unsuccessful or are subject to delays. Our limited operating history makes accurate prediction of future operating results difficult or impossible. We may not sustain revenue growth or maintain profitability on a quarterly or annual basis.

Recent Developments

New Products

New product sales of the Triage Cardiac System and the Triage Microbiology Panels were approximately \$9.2 million in 1999. The Triage Cardiac System is the first product line of our new quantitative measurement product platform. Sales of the Triage Cardiac System totaled approximately \$6.6 million in 1999. During the first quarter of 1999, we experienced manufacturing inefficiencies related to the production of the Triage Cardiac System. We addressed those issues, initiated a focused-factory approach and reorganized our manufacturing operations to better suit the two different product platforms. The manufacturing costs of the Triage Cardiac System improved significantly during the last three quarters of 1999, which resulted in corresponding increases in the gross margin of that product.

In December 1999, we began initial shipments of our second quantitative platform product, the Triage BNP System, to certain international customers. The Triage BNP System is a rapid, quantitative diagnostic test that may aid in the diagnosis of congestive heart failure, CHF, and therefore potentially enable earlier therapeutic intervention. Additionally, we filed a pre-market approval application (“PMA”) with the FDA, seeking approval to market the Triage BNP Test in the United States. At the present time, in the United States, there is no blood test available to aid in diagnosing CHF. On March 24, 2000,

the FDA Clinical Chemistry and Clinical Toxicology Device Panel (“Advisory Panel”) recommended not to approve our PMA for the Triage BNP Test. In voting, the Advisory Panel indicated the need for additional data, including data concerning people in higher age groups that do not have CHF. Despite this outcome, we continue to believe in the potential utility, safety and effectiveness of the Triage BNP Test. We will work with the FDA to answer any questions they may have. We intend to submit an amendment to our PMA application if we develop the additional data requested by the FDA. We will continue to market the Triage BNP Test internationally.

Biosite Discovery Program

In March 1999, we introduced our Biosite Discovery program, a collaborative research and diagnostics development program focused on the identification of new protein markers for acute diseases. We use our expertise in antibody development to help pharmaceutical and biotechnology partners accelerate their research programs. In return, we obtained and seek to continue to obtain diagnostic rights to the proteins under study. We utilize our proprietary Omniconal antibody development technology to develop high affinity antibodies for the characterization and validation of protein targets. Initially, we focused on disease target markers in four core areas: cardiovascular, cerebrovascular, infectious diseases and oncology. If the diagnostic utility of a marker is established, it will then be assessed for commercialization potential, with high value markers being added to our product development pipeline. We have executed collaborative agreements under the Biosite Discovery program with several partners in the areas of cardiovascular, cerebrovascular, infectious disease and oncology.

Results of Operations

The following table sets forth operating data as a percentage of net sales:

	Year ended December 31,		
	1997	1998	1999
Net sales	100%	100%	100%
Cost of sales	22	31	32
Gross profit	78	69	68
Operating expenses:			
Selling, general and administrative	36	45	41
Research and development	37	32	31
Defense of patent matters	1	14	—
Total operating expenses	74	91	72
Income from operations	4	(22)	(4)
Other income, net	11	15	6
Reacquisition of distribution rights	(11)	—	—
Income before benefit (provision) for income taxes	4	(7)	2
Benefit (provision) for income taxes	—	4	—
Net income (loss)	4%	(3)%	2%

Years ended December 31, 1999 and 1998

Net Sales. Net sales increased 25% to \$43.0 million in 1999 from \$34.4 million in 1998. The increase in net sales was primarily attributable to the growth in net sales of new products. The Triage *C. difficile* Panel and Triage Parasite Panel were launched in March 1998 and October 1998, respectively. The Triage Cardiac System was introduced in May 1998. New product sales for 1999 were approximately \$9.2 million, as compared to \$2.3 million for 1998. Net sales of the Triage DOA Panel for 1999 were 5% higher than net sales of the product for 1998. Growth in sales of the Triage DOA Panel products has slowed and we believe it may begin to decline as the available U.S. market becomes saturated and competitive pressures become more prominent in a maturing market.

Gross Profit. Gross profit increased 23% to \$29.4 million in 1999 from \$23.9 million in 1998. The increase in gross profit was primarily attributable to the overall sales growth and the realization of higher gross margins in 1999 as compared to 1998 for our newer products. The overall gross margin decreased to 68% for 1999 from 69% for 1998. The overall gross margin for 1999 decreased primarily as a result of a greater proportion of net sales representing the newer products, which experienced lower gross margins than the Triage DOA Panel. Also, during

the first quarter of 1999, we experienced significant inefficiencies related to the production of the Triage Cardiac System, resulting in negative gross profits related to that product during that quarter. Gross margins increased to profitable levels during the remaining quarters of 1999, primarily as a result of efficiencies achieved in the manufacturing operations. As a result of efficiencies achieved, we were able to utilize some of our manufacturing resources for new product scale-up and validation activities related to the Triage BNP and Triage LBP tests, two products under development. The costs of new product scale-up and validation activities were charged to research and development expenses, contributing to higher gross margins during the remaining quarters of 1999. Our newer products are expected to continue to realize lower gross margins than the Triage DOA Panel during the early stages of their commercialization as incremental manufacturing costs are spread over smaller sales volumes and efficiency issues are addressed. We also expect that the overall gross margins will continue to decrease as a result of competitive pricing pressures related to the maturing Triage DOA Panel product line and the changing mix of net sales of products with different gross margins.

Selling, General and Administrative Expenses. Selling, general and administrative (“SG&A”) expenses increased 14% to \$17.6 million in 1999 from \$15.5 million in 1998. Increases in SG&A expenses were primarily associated with additional marketing activities relating to new products, the expanded sales activities related to our broader product lines and the increased administrative costs to support our expanded operations and business development activities. Additionally, SG&A expenses for 1999 included administrative costs associated with the reorganization of our manufacturing operations totaling approximately \$300,000 and costs related to a business development opportunity that we decided to forego totaling approximately \$425,000. We expect SG&A costs in 2000 to be significantly higher than in 1999, as we continue to expand our overall operations, including sales and marketing activities for our new products, business development activities and administrative support functions. The timing of such increased expenditures and their magnitude are primarily dependent on the commercial success and sales growth of our new products and the progress of business development activities.

Research and Development Expenses. Research and development expenses increased 20% to \$13.3 million in 1999 from \$11.2 million in 1998. Significant manufacturing scale-up and validation expenses were incurred during 1998 related to the Triage Cardiac System and Triage Microbiology Panels. The Triage Cardiac System was the first product on our new quantitative product platform and required significant investments in the scale-up and validation of its manufacturing and quality processes. Manufacturing scale-up and validation expenses decreased during 1999. The decreases in manufacturing scale-up and validation costs were offset by increases in other product development expenses. During 1999, our research and development resources were focused primarily on the development, clinical studies, manufacturing scale-up and validation of products under development, potential improvements to our existing products and research activities associated with the Biosite Discovery program. We expect that our research and development expenses will increase in 2000, as compared to 1999 levels. The increased expenditures are expected to primarily relate to pre-clinical and clinical studies,

product development efforts, the Biosite Discovery program and manufacturing scale-up activities. The costs associated with the clinical trials are expected to be significant. Some of our potential products are subject to more complex regulatory approval requirements than our previous products. The timing of the increased expenditures and their magnitude are primarily dependent on the progress and success of the research and development and the timing of potential product launches.

Defense of Patent Matters. Legal expenses associated with the Dade Behring and Spectral Diagnostics litigation totaled \$4.9 million in 1998. In February 1999, a settlement agreement was executed that resolved all disputes between Spectral Diagnostics and us without a material adverse financial impact to us. In March 1999, to avoid protracted litigation and continued significant legal defense costs, we executed a settlement agreement with Dade Behring that resolved all disputes outstanding between the companies. Accordingly, all settlement costs were known prior to filing our 1998 Form 10-K and therefore were expensed as of December 31, 1998.

Other Income (Expenses). Interest and other income decreased 25% to \$1.8 million in 1999 from \$2.4 million in 1998. Interest income decreased 19% to \$1.9 million in 1999 from \$2.3 million in 1998. The decrease in interest income resulted primarily from the lower average balance of cash and marketable securities and lower overall interest rates on marketable debt securities during 1999 as compared to 1998. Contract revenue decreased to \$703,000 in 1999 from \$2.6 million in 1998. Contract revenues recognized during 1999 related to activities associated with a research and development feasibility study being performed by us and research and development activities related to the Biosite Discovery program. In 1998, we recognized \$1.3 million from Kyoto Dai-Ichi Kagaku C., Ltd. (“KDK”) related to milestones achieved in the development of the Triage Cardiac System, \$1.1 million from Novartis related to milestones achieved in the development of the NeoralChek System and \$192,000 related to an SBIR (Small Business Innovation Research) grant from the U.S. Government for research related to potential microbiology products.

Benefit (Provision) for Income Taxes. For 1999 and 1998, as a result of the pre-tax income (loss) and the estimated tax credits generated in each year, we recorded a benefit for income taxes of \$166,000 and \$1.4 million, respectively. The benefit for income taxes recognized in the fourth quarter of 1999 included \$112,000 of benefit resulting from the recognition of research and development credits generated during the first three quarters of 1999. Recognition of these credits had been deferred until management determined that their realization had become more likely than not. At December 31, 1999, we had net deferred tax assets of \$4.4 million. The realization of the deferred tax assets is dependent upon the generation of future taxable income of approximately \$10.9 million. We will continue to assess the likelihood of realization of our net deferred tax assets. If future events occur which do not make the realization of such assets more likely than not, a valuation allowance will be established against all or a portion of the net deferred tax assets.

Years ended December 31, 1998 and 1997

Net Sales. Net sales increased 9% to \$34.4 million in 1998 from \$31.7 million in 1997. The increase was primarily attributable to the introduction of new products in 1998 and the continued market acceptance of our higher-priced Triage DOA Plus TCA Panel products. Net sales for the products introduced in 1998 totaled approximately \$2.3 million.

Gross profit. Gross profit decreased 3% to \$23.9 million in 1998 primarily as a result of experiencing negative gross profits related to the new products introduced in 1998. The overall gross margin decreased to 69% for 1998 from 78% for 1997. The gross margins decreased during the year primarily as a result of the introduction of the Triage *C. difficile* and Parasite Panels and Triage Cardiac System. During 1998, we experienced manufacturing scale-up and capacity constraint issues related to the Triage Cardiac System that resulted in a backlog of orders during the fourth quarter that was filled by February 1999.

Selling, General and Administrative Expenses. SG&A expenses increased 34% to \$15.5 million in 1998 from \$11.5 million in 1997. The 1998 increases resulted primarily from the cost of our expanded sales force,

increased marketing activities associated with new products and potential new products, and the expansion of administrative functions to support our expanded operations and business development activities. Additionally, our expended efforts related to transitioning our product distribution in Europe from E. Merck to a network of regional distributors.

Research and Development Expenses. Research and development expenses decreased 4% to \$11.2 million in 1998 from \$11.7 million in 1997. Although manufacturing scale-up and optimization expenses were significantly higher in 1998 than 1997, the timing of clinical trials and other product development expenses in 1997 resulted in an overall decrease in 1998 research and development expenses as compared to 1997. There were significant product development activities associated with the Triage Cardiac System in the fourth quarter of 1997.

Defense of Patent Matters. In 1998, we recorded a charge of approximately \$4.9 million associated with the defense and settlement of two separate patent litigations. Settlement agreements were executed during the first quarter of 1999 that resolved both matters. Under the terms of the Dade Behring agreement, we obtained a license to the patent and provided Dade Behring the option to evaluate certain proprietary antibodies, resulting in a net payment of \$1,050,000 to Dade Behring by Biosite. We charged to defense of patent matters in the 1998 statements of operations the applicable license costs related to years prior to 1998 of \$604,000.

Other Income. Contract revenue increased \$1.4 million in 1998 from \$1.2 million to \$2.6 million. In 1998, we recognized \$1.3 million from KDK related to milestones achieved in the development of the Triage Cardiac System, \$1.1 million from Novartis related to milestones achieved in the development of the NeoralChek System and \$192,000 related to an SBIR (Small Business Innovation Research) grant from the U.S. Government for research related to potential microbiology products. In 1997, we recognized \$778,000 from Merck related to the development of the Triage Cardiac System and \$400,000 from Novartis related to milestones in the development of the NeoralChek System.

Benefit (Provision) for Income Taxes. As a result of the pre-tax loss recorded for 1998 and the pre-tax income for 1997, as well as the estimated tax credits generated in each year, we recorded a benefit for income taxes of \$1.4 million in 1998 and a provision for income taxes of \$82,000 in 1997.

Liquidity and Capital Resources

We have financed our operations through revenues from operations, private and public placements of equity securities, debt and capital lease financing, cash received under collaborative agreements and interest income. At December 31, 1999, the Company had cash, cash equivalents and marketable securities of approximately \$32.3 million compared to \$34.2 million at December 31, 1998.

The decrease in cash, cash equivalents and marketable securities during 1999 is largely attributable to the net payment of \$1,050,000 made to Dade Behring as part of the settlement of litigation between Dade Behring and Biosite in March 1999, an additional \$1.0 million payment made under a technology licensing arrangement previously entered into and the purchases of equipment and leasehold improvements totaling approximately \$5.2 million. These significant uses of cash were offset by the cash generated from operating activities and proceeds from equipment financing and issuances of common stock under our stock plans.

Cash generated from operating activities totaled \$4.4 million for 1999 compared to \$674,000 for 1998. Other significant sources of cash for 1999 included the receipt of \$5.5 million from the sale of marketable securities that were not reinvested in other marketable securities, the receipt of \$2.1 million in proceeds from equipment financing and \$1.3 million in proceeds from the issuance of common stock under our stock plans. These proceeds were used to meet our cash requirements during 1999.

During the year ended December 31, 1998, we generated \$674,000 in cash from operating activities despite significant investment of cash into our defense of patent matters and new product launch activities such as

manufacturing scale-up tasks, inventory buildup for new products and sales and marketing activities. Other significant business activities affecting cash included the purchase of license rights to patented technologies totaling \$3.7 million, the expenditure of \$3.1 million for capital equipment and leasehold improvements, the receipt of \$2.0 million in proceeds from equipment financing and payments under equipment financing agreements of \$1.5 million.

Our primary short-term needs for capital, which are subject to change, are for the support of its commercialization efforts related to new products, expansion of our manufacturing capacity and efficiency for new products, potential licensing of technologies patented by others, potential procurement and enforcement of patents and the continued advancement of research and development efforts. We executed agreements to license technologies patented by others which call for cash payments and future royalties based on product sales utilizing the licensed technologies. We may enter into additional licensing agreements that may include up-front and annual cash payments and future royalties based on product sales utilizing the licensed technologies. We utilized and may continue to utilize credit arrangements with financial institutions to finance the purchase of capital equipment. Additionally, we may utilize cash generated from operating activities, if any, to meet our capital requirements.

We are evaluating various alternatives in addressing our future facilities expansion needs. The alternatives being evaluated include negotiations with various parties for the leasing of additional facility space, which would be adequate for our foreseeable future needs. Leasing of additional facility space would be expected to result in an increase in rent upon occupancy.

We believe that our available cash, cash from operations and funds from existing credit arrangements will be sufficient to satisfy our funding needs for at least the next 24 months. Thereafter, if cash generated from operations is insufficient to satisfy our working capital and capital expenditure requirements, we may be required to sell additional equity or debt securities or obtain

additional credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Furthermore, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants. Our future liquidity and capital funding requirements will depend on numerous factors, including:

- the extent to which our new products and products under development are successfully developed, gain market acceptance and become and remain competitive
- the costs and timing of further expansion of sales, marketing and manufacturing activities, facilities expansion needs
- the timing and results of clinical studies and regulatory actions regarding our potential products
- changes in third-party reimbursement policies
- the costs and timing associated with business development activities, including potential licensing of technologies patented by others.

Our failure to raise capital on acceptable terms, when needed, could have a material adverse effect on our business.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to changes in interest rates, primarily from its variable-rate long-term debt arrangements and, to a lesser extent, our investments in available-for-sale marketable securities. Under our current policies, we do not use interest rate derivatives instruments to manage this exposure to interest rate changes. We do have the option to convert our variable-rate long-term debt arrangements to fixed-rate debt arrangements for a nominal transaction fee. At December 31, 1999, we had variable-rate debt totaling approximately \$1.5 million. A hypothetical 1% adverse move in interest rates along the entire interest rate yield curve would not materially effect the fair value of our financial instruments that are exposed to changes in interest rates.

Additionally, our purchases of Triage Meters from LRE Technology Partner GmbH (“LRE”) are denominated in German Deutsche Marks (DM) and sales of some products to some international customers are denominated in the local currency of customers. We have on occasion purchased forward exchange contracts to manage this exposure to exchange rate changes. As of December 31, 1999, we had no outstanding forward exchange contracts. Total receivables and payables denominated in foreign currencies at December 31, 1999 were not material.

market for registrant’s common equity and related stockholder matters

Our common stock is traded in the over-the-counter market on the Nasdaq National Market, the NNM, under the symbol BSTE. The following tables set forth the high and low sale prices, for our common stock as reported on the NNM for the periods indicated.

1999	High	Low
First Quarter	\$ 14.375	\$ 9.500
Second Quarter	\$ 11.000	\$ 7.000
Third Quarter	\$ 10.125	\$ 7.500
Fourth Quarter	\$ 17.875	\$ 7.625
1998	High	Low
First Quarter	\$ 17.750	\$ 8.125
Second Quarter	\$ 16.313	\$ 9.250
Third Quarter	\$ 11.000	\$ 3.563
Fourth Quarter	\$ 12.500	\$ 4.250

There were approximately 101 holders of record of common stock as of February 29, 2000. We have not paid any cash dividends to date and do not anticipate any being paid in the foreseeable future.

report of Ernst & Young LLP, independent auditors

The Board of Directors and Stockholders
Biosite Diagnostics Incorporated

We have audited the accompanying balance sheets of Biosite Diagnostics Incorporated as of December 31, 1998 and 1999, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1999. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Biosite Diagnostics Incorporated at December 31, 1998 and 1999, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1999 in conformity with accounting principles generally accepted in the United States.

ERNST & YOUNG LLP

San Diego, California
January 26, 2000

balance sheets

	December 31,	
	1998	1999
Assets		
Current assets:		
Cash and cash equivalents	\$ 762,337	\$ 4,594,217
Marketable securities, available-for-sale	33,466,841	27,677,307
Accounts receivable	6,573,735	6,192,161
Inventories	4,364,367	6,058,856
Deferred income taxes	1,666,000	1,165,000
Prepaid expenses and other current assets	1,467,960	1,484,607
Total current assets	48,301,240	47,172,148
Property, equipment and leasehold improvements, net	7,313,673	9,936,429
Deferred income taxes	2,360,000	3,186,000
Patents and license rights, net	7,203,433	7,555,771
Deposits and other assets	630,765	297,632
	<u>\$ 65,809,111</u>	<u>\$ 68,147,980</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,503,354	\$ 1,831,282
Accrued salaries and other	2,699,663	3,423,541
Accrued costs for defense of patent matters	1,248,191	—
Current portion of long-term obligations	1,636,265	1,939,372
Total current liabilities	7,087,473	7,194,195
Long-term obligations	4,038,444	4,068,814
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value, 5,000,000 shares authorized; no shares issued and outstanding at December 31, 1998 and 1999	—	—
Common stock, \$.01 par value, 25,000,000 shares authorized; 12,926,706, and 13,141,302 shares issued and outstanding at December 31, 1998 and 1999, respectively	129,267	131,413
Additional paid-in capital	54,250,324	55,398,048
Unrealized net gain (loss) on marketable securities, net of related tax effect of \$23,510 and \$(87,611) at December 31, 1998 and 1999, respectively	35,266	(131,416)
Deferred compensation	(207,845)	(93,086)
Retained earnings	476,182	1,580,012
Total stockholders' equity	54,683,194	56,884,971
	<u>\$ 65,809,111</u>	<u>\$ 68,147,980</u>

See accompanying notes.

statements of operations

Year Ended December 31,

	1997	1998	1999
Net sales	\$ 31,676,630	\$ 34,424,461	\$ 43,010,764
Cost of sales	6,925,318	10,513,524	13,636,286
Gross profit	24,751,312	23,910,937	29,374,478
Operating expenses:			
Selling, general and administrative	11,549,734	15,469,717	17,581,015
Research and development	11,661,894	11,166,702	13,346,949
Defense of patent matters	330,537	4,860,857	—
	23,542,165	31,497,276	30,927,964
Operating income (loss)	1,209,147	(7,586,339)	(1,553,486)
Other income (expense):			
Interest income and other income	2,190,837	2,395,957	1,788,316
Contract revenue-related parties	777,767	—	—
Contract revenue-unrelated parties	466,500	2,629,800	703,000
Reacquisition of distribution rights	(3,364,134)	—	—
	70,970	5,025,757	2,491,316
Income (loss) before benefit (provision)			
for income taxes	1,280,117	(2,560,582)	937,830
Benefit (provision) for income taxes	(82,000)	1,448,000	166,000
Net income (loss)	\$ 1,198,117	\$ (1,112,582)	\$ 1,103,830
Net income (loss) per share:			
Basic	\$ 0.11	\$ (0.09)	\$ 0.08
Diluted	\$ 0.09	\$ (0.09)	\$ 0.08
Shares used in calculating per share amounts:			
Basic	11,249,000	12,939,000	13,032,000
Diluted	13,081,000	12,939,000	13,728,000

See accompanying notes.

statements of stockholders' equity

	Preferred Stock	
	Shares	Amount
Balance at December 31, 1996	8,328,847	\$ 83,288
Comprehensive income:		
Net income	—	—
Other comprehensive income, net of tax		
Change in unrealized net gain (loss) on marketable securities	—	—
Comprehensive income	—	—
Issuance of common stock from initial public offering (IPO), net of offering costs of \$3,291,630	—	—
Conversion of preferred stock into common stock in connection with IPO	(8,328,847)	(83,288)
Conversion of convertible debenture into common stock in connection with IPO	—	—
Issuance of common stock under employee stock plans	—	—
Amortization of deferred compensation	—	—
Income tax benefit from exercise of stock options	—	—
Balance at December 31, 1997	—	—
Comprehensive loss:		
Net loss	—	—
Other comprehensive income, net of tax		
Change in unrealized net gain (loss) on marketable securities	—	—
Comprehensive loss	—	—
Conversion of convertible debenture into common stock	—	—
Issuance of common stock under employee stock plans	—	—
Repurchase and retirement of common stock	—	—
Amortization of deferred compensation	—	—
Income tax benefit from exercise of stock options	—	—
Balance at December 31, 1998	—	—
Comprehensive income:		
Net income	—	—
Other comprehensive income, net of tax		
Change in unrealized net gain (loss) on marketable securities	—	—
Comprehensive income	—	—
Issuance of common stock under employee stock plans	—	—
Repurchase and retirement of common stock	—	—
Deferred compensation related to cancelled stock options	—	—
Amortization of deferred compensation	—	—
Income tax benefit from exercise of stock options	—	—
Balance at December 31, 1999	—	—

See accompanying notes.

Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Deferred Compensation	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
Shares	Amount					
1,473,573	\$ 14,736	\$ 22,094,711	\$ (2,754)	\$ (427,345)	\$ 390,647	\$ 22,153,283
—	—	—	—	—	1,198,117	1,198,117
—	—	—	8,412	—	—	8,412
—	—	—	—	—	—	<u>1,206,529</u>
2,760,000	27,600	29,800,770	—	—	—	29,828,370
8,328,847	83,288	—	—	—	—	—
92,575	926	1,109,978	—	—	—	1,110,904
209,750	2,097	618,896	—	—	—	620,993
—	—	—	—	109,750	—	109,750
—	—	59,947	—	—	—	59,947
12,864,745	128,647	53,684,302	5,658	(317,595)	1,588,764	55,089,776
—	—	—	—	—	(1,112,582)	(1,112,582)
—	—	—	29,608	—	—	29,608
—	—	—	—	—	—	<u>(1,082,974)</u>
41,666	417	499,575	—	—	—	499,992
142,695	1,427	812,620	—	—	—	814,047
(122,400)	(1,224)	(841,173)	—	—	—	(842,397)
—	—	—	—	109,750	—	109,750
—	—	95,000	—	—	—	95,000
12,926,706	129,267	54,250,324	35,266	(207,845)	476,182	54,683,194
—	—	—	—	—	1,103,830	1,103,830
—	—	—	(166,682)	—	—	<u>(166,682)</u>
—	—	—	—	—	—	937,148
252,596	2,526	1,331,538	—	—	—	1,334,064
(38,000)	(380)	(358,261)	—	—	—	(358,641)
—	—	(19,553)	—	19,553	—	—
—	—	—	—	95,206	—	95,206
—	—	194,000	—	—	—	194,000
13,141,302	\$ 131,413	\$ 55,398,048	\$ (131,416)	\$ (93,086)	\$ 1,580,012	\$ 56,884,971

statements of cash flows

	Year ended December 31,		
	1997	1998	1999
Operating activities:			
Net income (loss)	\$ 1,198,117	\$ (1,112,582)	\$ 1,103,830
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	2,738,230	4,608,081	3,660,580
Amortization of deferred compensation	109,750	109,750	95,206
Deferred income taxes	(931,000)	(1,378,000)	(325,000)
Changes in operating assets and liabilities:			
Accounts receivable	(674,428)	(1,291,235)	381,574
Inventory	(437,716)	(2,194,471)	(1,694,489)
Prepaid expenses and other current assets	(467,788)	528,314	94,474
Accounts payable	452,995	82,385	327,928
Accrued liabilities	(860,205)	1,321,558	719,687
Net cash provided by operating activities	1,127,955	673,800	4,363,790
Investing activities:			
Proceeds from sales and maturities of marketable securities	37,340,473	33,898,842	29,082,267
Purchase of marketable securities	(65,947,956)	(30,389,170)	(23,570,536)
Purchase of property, equipment and leasehold improvements	(5,221,969)	(3,091,536)	(5,179,893)
Patents, license rights, deposits and other assets	1,108,389	(3,677,057)	(2,172,648)
Net cash used in investing activities	(32,721,063)	(3,258,921)	(1,840,810)
Financing activities:			
Proceeds from issuance of convertible debenture	—	500,000	—
Proceeds from issuance of equipment loans payable	3,077,701	1,993,123	2,093,464
Principal payments under long-term obligations	(1,213,543)	(1,447,589)	(1,759,987)
Proceeds from issuance of stock, net	30,449,363	814,047	1,334,064
Repurchase of common stock, net	—	(842,397)	(358,641)
Net cash provided by financing activities	32,313,521	1,017,184	1,308,900
Increase (decrease) in cash and cash equivalents	720,413	(1,567,937)	3,831,880
Cash and cash equivalents at beginning of year	1,609,861	2,330,274	762,337
Cash and cash equivalents at end of year	\$ 2,330,274	\$ 762,337	\$ 4,594,217
Supplemental disclosures of cash flow information:			
Interest paid	\$ 356,694	\$ 320,008	\$ 441,454
Income taxes paid	\$ 1,203,900	\$ 5,400	\$ 2,061
Supplemental schedule of non-cash investing and financing activities:			
Conversion of convertible debenture into common stock	\$ 1,110,904	\$ 499,992	\$ —
Accrued liability for license rights acquired	\$ —	\$ 1,050,000	\$ —

See accompanying notes.

notes to financial statements

1 Organization and Summary of Significant Policies

Organization and Business Activity

Biosite Diagnostics Incorporated (the “Company”) was established in 1988. The Company develops, manufactures and markets rapid, accurate and cost-effective diagnostic products that are designed to improve the quality of patient care and simplify the practice of laboratory medicine. In 1992, the Company began commercial sales of its first qualitative platform product, the Triage DOA Panel (“Triage DOA Panel”). In 1998, the Company began selling two additional qualitative platform products, the Triage *C. difficile* Panel and the Triage Parasite Panel. Also, in 1998, it launched its first quantitative platform product, the Triage Cardiac System. The Company followed these product launches with the introduction of its second quantitative platform product, the Triage BNP System, in certain European countries in December 1999.

The Company markets its products worldwide primarily through distributors supported by its direct sales force. The Company’s principal markets are hospital laboratories, emergency departments and other point-of-care locations. In addition to focusing its attention on commercial activities associated with these products, the Company continues to invest in the research and development of additional rapid tests designed to aid in the diagnosis of several critical diseases or conditions in four core areas: cardiovascular, cerebrovascular, infectious diseases and oncology.

Revenue Recognition and Significant Customers

The Company recognizes sales upon shipment. The Company’s U.S. distributor accounted for 80%, 86% and 83% of the product sales in 1997, 1998 and 1999, respectively.

Export sales to international customers amounted to \$2,982,000, \$2,749,000 and \$4,820,000 in 1997, 1998 and 1999, respectively. Sales to a stockholder amounted to approximately \$2,013,000 in 1997. The stockholder disposed of its Biosite common stock holding in 1998.

The Company records revenues under collaborative development agreements, based on the performance criteria of each contract, either as milestones are earned or on the percentage of completion basis as costs are incurred.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments in debt securities with maturities of 90 days or less when purchased.

Marketable Securities

Financial Accounting Standards Board (“FASB”) Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, requires that investments in equity securities that have readily determinable fair values and investments in debt securities be classified in three categories: held-to-maturity, trading and available-for-sale. Based on the nature of the assets held by the Company and management’s investment strategy, the Company’s investments have been classified as available-for-sale. Management determines the appropriate classification of debt securities at the time of purchase. Securities classified as available-for-sale are carried at estimated fair value, as determined by quoted market prices, with unrealized gains and losses, net of tax, reported in a separate component of comprehensive income. At December 31, 1999, the Company had no investments that were classified as trading or held-to-maturity as defined by the Statement. The amortized cost of debt securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses are included in interest income. The cost of securities sold is based on the specific identification method. Interest on securities classified as available-for-sale is included in interest income.

notes to financial statements (continued)

Inventories

Inventories are carried at the lower of cost (first-in, first-out) or market.

Property, equipment and leasehold improvements are stated at cost.

Depreciation and Amortization

Depreciation of property and equipment is computed using the straight-line method over three to five years. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the estimated useful lives of the assets or the remaining lease term.

Patents and License Rights

The Company has been issued patents covering its threshold immunoassay and other related technologies. Capitalized patent costs associated with issued patents are amortized over five to seventeen years. License rights related to products for sale are amortized to cost of sales over the life of the license, not to exceed ten years, using a systematic method based on the estimated revenues generated from products during such license period.

Stock Options

The Company has elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25) and related interpretations in accounting for its stock options. For options granted during the one-year period prior to the Company's initial public offering of common stock, the Company recorded and amortizes, over the related vesting periods, deferred compensation representing the excess of the value for accounting purposes of the options granted over their aggregate exercise price.

Concentration of Credit Risk

The Company sells its products primarily to its U.S. distributor. Credit is extended based on an evaluation

of the customer's financial condition, and generally collateral is not required. Credit losses have been minimal and within management's expectations.

The Company invests its excess cash in debt instruments of the U.S. Government, financial institutions and corporations with strong credit ratings. The Company has established guidelines relative to diversification and maturities that maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates. The Company has not experienced any significant realized losses on its marketable securities.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Earnings Per Share

Earnings per Share ("EPS") is computed in accordance with Statement of Financial Accounting Standards No. 128, Earnings per Share ("FAS 128"). FAS 128 requires dual presentation of basic and diluted earnings per share. Basic EPS includes no dilution and is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution of securities that could share in the earnings of the Company, such as common stock equivalents which may be issuable upon exercise of outstanding common stock options. Common stock equivalents are not considered in loss years as the effect is antidilutive.

Shares used in calculating basic and diluted net income per share were as follows:

notes to financial statements (continued)

	Year Ended December 31,		
	1997	1998	1999
Shares used in calculating per share amounts – Basic (Weighted average common shares outstanding)	11,249	12,939	13,032
Effect of common share equivalents:			
Assumed conversion of preferred shares	1,110	–	–
Assumed conversion of convertible debenture	12	–	–
Net effect of dilutive common stock options using the treasury stock method	699	–	696
Contingently issuable shares	11	–	–
Shares used in calculating per share amounts – Diluted	13,081	12,939	13,728

Comprehensive Income

Financial Accounting Standards Board’s Statement No. 130, Comprehensive Income, (“FAS 130”) establishes rules for the reporting and display of comprehensive income and its components. FAS 130 requires the change in net unrealized gains or losses on marketable securities be included in comprehensive income. Included in the Company’s statements of Stockholders’ equity, other comprehensive income consisting of unrealized gains and losses on investments are reported.

Segment Information

Financial Accounting Standards Board’s Statement No. 131, Segment Information, (“FAS 131”) amends the requirements for public enterprises to report financial and descriptive information about its reportable operating segments. Operating segments, as defined in FAS 131, are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company in deciding how to allocate resources and in assessing performance. The Company believes it currently operates in one business and operating segment.

Effect of New Accounting Standards

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, which will be effective January 1, 2001. This Statement establishes accounting and reporting standards requiring that every derivative instrument, including certain derivative instruments imbedded in other contracts, be recorded in the balance sheet as either an asset or liability measured at its fair value. The Statement also requires that changes in the derivative’s fair value be recognized in earnings unless specific hedge accounting criteria are met. The Company has not yet determined what impact SFAS No. 133 will have on the financial statements.

2 Licensing Agreements

The Company has entered into licensing agreements to utilize certain antibodies and/or technologies in exchange for up-front, annual, milestone, or royalty payments or a combination thereof. Certain of the up-front and annual payments are creditable towards future royalties payable. Royalties may be payable at various rates for product sales derived from the licensed technologies.

The Company purchased license rights for technologies utilized in products for sale of \$5.0 million and \$1.1 million during the years ended December 31, 1998 and 1999, respectively. Accumulated amortization of license rights at December 31, 1998 and 1999 was approximately \$4.0 million and \$4.7 million, respectively.

3 Biosite Discovery Program and Collaborative and Distribution Agreements

In March 1999, the Company introduced its Biosite Discovery program, a collaborative research and diagnostics development program focused on the identification of new protein markers for acute diseases. The Company uses its expertise in antibody development to help pharmaceutical and biotechnology partners accelerate their research programs. In return, Biosite has obtained and seeks to continue to obtain diagnostic rights to the proteins under study. Initially, Biosite has focused on disease target markers in four core areas:

notes to financial statements (continued)

cardiovascular, cerebrovascular, infectious disease and oncology. The Company executed collaborative agreements under the Biosite Discovery program with several partners in all of these core areas. During 1999, the Company recognized \$703,000 related to the achievement of milestones under the collaborative agreements.

In 1997, the Company successfully completed feasibility studies for the NeoralChek System under its antibody license agreement with Novartis Pharma AG (“Novartis”). As a result of this milestone achievement, Novartis invested, in January 1998, an additional \$500,000 in Biosite in exchange for a convertible debenture. The convertible debenture was immediately converted into 41,666 shares of common stock of the Company based on the IPO price of \$12.00 per share. Additionally, the Company and Novartis entered into an agreement to expand the scope of the collaborative development of the NeoralChek System. For the years ended December 31, 1997 and 1998, the Company recognized contract revenues of \$400,000 and \$1.1 million, respectively. The expansion of the collaboration may result in additional payments to Biosite upon attainment of milestones.

In February 1995, the Company entered into a collaborative development and distribution agreement that included the Asian marketing rights to the Triage Cardiac Panel under development. Under this agreement, the Company will receive up to \$2.0 million upon the completion of certain milestones. Recognition of revenue under this agreement will occur as the milestones are

attained. For the year ended December 31, 1998, the Company recognized contract revenues of \$1.3 million for the completion of certain milestones under the agreement.

In June 1994, the Company entered into a collaborative development agreement and a distribution agreement with Merck KgaA (“Merck”), a former stockholder, for the development and marketing of the Triage Cardiac Panel and under such agreements, Merck was to fund a portion of the development costs. The Company recognized revenue under this agreement on the percentage of completion basis as costs were incurred. For the year ended December 31, 1997, the Company incurred \$2,866,000 in expenses under this agreement and recognized \$778,000 as contract revenue.

As a result of a decision by Merck to refocus away from certain aspects of the human diagnostic business, in 1997, the Company terminated agreements with Merck for the development and distribution of the Triage Cardiac System and the distribution of the Triage DOA Panel product line. Upon termination, the Company paid a \$2.1 million cash payment and forgave approximately \$1.3 million owed to the Company by Merck related to the development of the Triage Cardiac System. Such expenses were charged to reacquisition of distribution rights in the accompanying statements of operations. During the last half of 1998, the Company finalized alliances with several European partners, forming a network of distributors to market its products in certain European countries.

notes to financial statements (continued)

4 Cash, Cash Equivalents and Marketable Securities

The following is a summary of cash, cash equivalents and available-for-sale securities by balance sheet classification at December 31, 1998:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	\$ 449,352	\$ —	\$ —	\$ 449,352
Corporate debt securities	312,985	—	—	312,985
	762,337	—	—	762,337
Marketable securities:				
Certificate of deposit	2,005,724	1,784	—	2,007,508
U.S. Government debt securities	499,182	1,133	—	500,315
Corporate debt securities	30,903,159	79,836	(23,977)	30,959,018
	33,408,065	82,753	(23,977)	33,466,841
Total cash, cash equivalents and available-for-sale marketable securities	\$ 34,170,402	\$ 82,753	\$ (23,977)	\$ 34,229,178

The following is a summary of cash, cash equivalents and available-for-sale marketable securities by balance sheet classification at December 31, 1999:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	\$ 3,120,725	\$ —	\$ —	\$ 3,120,725
Money market fund	1,473,492	—	—	1,473,492
	4,594,217	—	—	4,594,217
Marketable securities:				
Certificates of deposit	1,000,338	81	—	1,000,419
U.S. Government debt securities	5,320,156	—	(54,187)	5,265,969
Corporate debt securities	21,575,839	1,413	(166,333)	21,410,919
	27,896,333	1,494	(220,520)	27,677,307
Total cash, cash equivalents and available-for-sale marketable securities	\$ 32,490,550	\$ 1,494	\$ (220,520)	\$ 32,271,524

The amortized cost and estimated fair value of available-for-sale securities at December 31, 1999, by contractual maturity, are as follows:

	Amortized Cost	Estimated Fair Value
Marketable securities:		
Due in one year or less	\$ 8,768,875	\$ 8,726,607
Due after one year through two years	16,135,957	15,975,190
Due after two years	2,991,501	2,975,510
	\$ 27,896,333	\$ 27,677,307

notes to financial statements (continued)

5 Balance Sheet Information

Inventories consist of the following:

	December 31,	
	1998	1999
Raw materials	\$ 1,405,176	\$ 2,088,530
Work in process	2,938,548	3,058,179
Finished goods	20,643	912,147
	\$ 4,364,367	\$ 6,058,856

Property, equipment and leasehold improvements consist of the following:

	December 31,	
	1998	1999
Machinery and equipment	\$ 12,936,671	\$ 17,505,021
Furniture and fixtures	986,368	1,083,906
Leasehold improvements	3,225,746	4,095,532
	17,148,785	22,684,459
Less accumulated depreciation and amortization	(9,835,112)	(12,748,030)
	\$ 7,313,673	\$ 9,936,429

Depreciation expense was approximately \$2,106,000, \$3,071,000 and \$2,987,000 for years ended December 31, 1997, 1998, and 1999, respectively.

6 Debt and Commitments

Debt consisted of the following:

	December 31,	
	1998	1999
Equipment financing notes, payable \$222,134 monthly including interest at 6.60% to 8.98% due October 2000 to December 2004; secured by equipment	\$ 5,674,709	\$ 6,008,186
Less current portion	1,636,265	1,939,372
Total long-term obligations	\$ 4,038,444	\$ 4,068,814

As a result of the attainment of one of the milestones (the successful completion of feasibility studies for the NeoralChek System under development), the Company received \$500,000 from Novartis, in January 1998, in exchange for a convertible debenture. The convertible debenture was immediately converted into 41,666 shares of common stock of the Company based on the IPO price of \$12.00 per share. The Company is obligated to sell to Novartis an additional \$500,000 five-year 8% convertible debenture upon the attainment of a certain milestone. The debenture would be convertible, at the sole option of the Company, into shares of Biosite common stock at \$12.00 per share.

notes to financial statements (continued)

As of December 31, 1999, approximate future principal payments of the equipment financing notes are due as follows: 2000 - \$1,939,000; 2001 - \$1,700,000; 2002 - \$1,304,000; 2003 - \$746,000; and 2004 - \$319,000.

Interest charged to expense to arrive at operating income (loss) was approximately \$357,000, \$320,000, and \$441,000 for the years ended December 31, 1997, 1998, and 1999, respectively.

The Company leases its office, manufacturing and research facilities under operating leases. The minimum annual rent on the facilities is subject to increases based on changes in the Consumer Price Index, taxes, insurance and operating costs, subject to certain minimum and maximum annual increases. The Company has options to renew certain of the facilities leases for a period of 2 years.

Approximate annual future minimum operating lease payments as of December 31, 1999 are as follows:

Year	Operating Leases
2000	\$ 1,296,000
2001	855,000
2002	858,000
2003	577,000
2004	538,000
<u>Total minimum lease payments</u>	<u>\$ 4,124,000</u>

Rent expense for the years ended December 31, 1997, 1998 and 1999 was approximately \$1,033,000, \$879,000 and \$1,076,000, respectively. Equipment under equipment financing notes was approximately \$8,510,000 and \$9,687,000 at December 31, 1998, and 1999, respectively. Accumulated depreciation of equipment under equipment financing at December 31, 1998 and 1999 was approximately \$3,607,000 and \$4,529,000, respectively.

7 Stockholders' Equity

Initial Public Offering

In February 1997, the Company completed its initial public offering of 2,760,000 shares of common stock (including an exercised underwriters' over-allotment option for

360,000 shares) at a price of \$12.00 per share, providing the Company with net proceeds of approximately \$29.8 million. Additionally, all outstanding shares of preferred stock were converted into 8,328,847 shares of common stock and an outstanding \$1.0 million convertible debenture and related accrued interest was converted into 92,575 common shares upon the completion of the IPO.

Stock Plans

The Company's 1989 Stock Plan provided for both the direct sale of common stock and for the grant of options to purchase common stock to employees, directors, consultants and advisors of the Company. As of December 31, 1999, 144,476 shares have been sold directly under the plan and no shares were available for future issuance of common stock or grant of options to purchase common stock under the 1989 Stock Plan.

In December 1996, the Company adopted the 1996 Stock Incentive Plan (the "1996 Stock Plan"). The 1996 Stock Plan replaced the Company's 1989 Stock Plan. Although all future awards will be made under the 1996 Stock Plan, awards made under the 1989 Stock Plan will continue to be administered in accordance with the 1989 Stock Plan. The 1996 Stock Plan provides for awards in the form of restricted shares, stock units, options or stock appreciation rights or any combination thereof. As of December 31, 1999, a pool of 2,400,000 shares has been reserved for issuance under the 1996 Stock Plan. Additionally, any unpurchased shares of common stock pursuant to unissued, expired or cancelled options under the 1989 Stock Plan become available for awards under the 1996 Stock Plan.

The options are generally subject to four year vesting and expire ten years from the date of grant. At December 31, 1999, 338,125 shares were available for future issuance of common stock or grant of options to purchase common stock under the 1996 Stock Plan.

notes to financial statements (continued)

Information with respect to the Company's 1989 Stock Plan and 1996 Stock Plan option activity is as follows:

	Shares	Weighted average exercise price
Balance at December 31, 1996	1,281,980	\$ 3.46
Granted at fair value	388,400	\$ 9.93
Exercised	(154,996)	\$ 1.27
Cancelled	(75,661)	\$ 5.65
Balance at December 31, 1997	1,439,723	\$ 5.33
Granted at fair value	956,025	\$ 12.35
Exercised	(71,391)	\$ 3.06
Cancelled	(64,777)	\$ 9.66
Balance at December 31, 1998	2,259,580	\$ 8.24
Granted at fair value	964,850	\$ 10.11
Exercised	(191,823)	\$ 4.23
Cancelled	(182,456)	\$ 10.98
Balance at December 31, 1999	2,850,151	\$ 8.97

notes to financial statements (continued)

The following is a further breakdown of the options outstanding under the 1989 Stock Plan and 1996 Stock Plan as of December 31, 1999:

Range of exercise price	Options outstanding	Weighted average remaining contractual life in years	Weighted average exercise price	Options exercisable	Weighted average exercise price of options exercisable
\$ 0.24 - \$ 5.50	845,466	5.77	\$ 3.78	728,012	\$ 3.57
\$ 6.38 - \$ 10.00	1,134,878	8.99	\$ 9.45	271,642	\$ 9.24
\$ 10.13 - \$ 13.75	279,742	8.33	\$ 11.87	105,625	\$ 11.93
\$ 13.88 - \$ 16.31	590,065	8.39	\$ 14.11	237,569	\$ 14.09
<u>\$ 0.24 - \$ 16.31</u>	<u>2,850,151</u>	<u>7.85</u>	<u>\$ 8.97</u>	<u>1,342,848</u>	<u>\$ 7.24</u>

Adjusted pro forma information regarding net income is required by SFAS 123, and has been determined as if the Company had accounted for its employee stock options under the fair value method of that Statement. The fair value for these options was estimated at the date of grant using the Black-Scholes method for option pricing with the following weighted-average assumptions for 1997, 1998, and 1999:

	1997	1998	1999
Risk-free interest rate	6%	5.25%	6.36%
Volatility	55%	83%	83%
Dividend yield	0%	0%	0%
Expected life of options	6 years	5 years	5 years

For purposes of adjusted pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's adjusted pro forma information follows:

	Year ended December 31,		
	1997	1998	1999
Adjusted pro forma net income (loss)	\$ 430,973	\$ (3,256,548)	\$ (2,248,997)
Adjusted pro forma diluted net income (loss) per share	\$ 0.03	\$ (0.25)	\$ (0.16)

The pro forma effects on net income for 1997, 1998, and 1999 are not likely to be representative of the effects on reported net income or loss in future years. In management's opinion, existing stock option valuation models do not provide a reliable single measure of the fair value of employee stock options that have vesting provisions and are not transferable. In addition, option valuation models require the input of highly subjective assumptions, including expected stock price volatility. Changes in such subjective input assumptions can materially affect the fair value estimate of employee stock options.

notes to financial statements (continued)

Employee Stock Purchase Plan

In December 1996, the Company adopted an Employee Stock Purchase Plan (“ESPP”) which provides employees the opportunity to purchase common stock at a discount and pay for such purchases through payroll deductions, subject to certain limitations. A pool of 350,000 shares of common stock has been reserved for issuance under the ESPP (subject to anti-dilution provisions). During the years ended December 31, 1997, 1998 and 1999, 54,754, 71,304, and 60,773 shares, respectively, were issued under the ESPP. As of December 31, 1999, 163,169 shares of common stock were available for issuance under the ESPP.

At December 31, 1999, a total of 3,351,445 shares of the Company’s common stock were reserved for future issuances under the Company’s stock plans and employee stock purchase plan.

Stock Repurchase Program

In September 1998, the Company initiated a common stock repurchase program, under which it may purchase up to one million shares of its common stock. The repurchase program was terminated in January 2000. Under the program, Biosite purchased shares of its common stock from time to time through open market transactions at prices deemed appropriate by its management. The Company repurchased 122,400 shares and 38,000 shares of its common stock, respectively, in 1998 and 1999 at a total cost of approximately \$842,000 and \$359,000, respectively.

Stockholder Rights Plan

In October 1997, the Board of Directors of the Company declared a dividend distribution of one preferred stock purchase right (a “Right”) for each outstanding share of common stock of Biosite held of record at the close of business on November 3, 1997. Each Right represents a contingent right to purchase, under certain circumstances, one-one-thousandth of a share of a new series of Biosite preferred stock at a price of \$50.00 per one one-thousandth of a share, subject to adjustment. The Rights would be traded independently from Biosite’s common stock and become exercisable under certain circumstances involving the acquisition or a tender or exchange offer by a person or group for 15% or more

of Biosite’s common stock. In December 1999, the agreement governing the Rights was amended to provide that Kopp Holding Company and related entities could acquire up to 20% of Biosite’s outstanding common stock without making the Rights exercisable. The Rights expire on October 22, 2007, unless redeemed by the Company’s Board of Directors. The Rights can be redeemed by the Board at a price of \$0.01 per Right at any time before the Rights become exercisable, and in limited circumstances thereafter.

8 Income Taxes

Significant components of the income tax benefit (provision) are as follows:

	Year Ended December 31,		
	1997	1998	1999
Current:			
Federal	\$ (555,000)	\$ 69,000	\$ (124,000)
State	(458,000)	1,000	(35,000)
	(1,013,000)	70,000	(159,000)
Deferred:			
Federal	499,000	1,053,000	229,000
State	432,000	325,000	96,000
	931,000	1,378,000	325,000
	<u>\$ (82,000)</u>	<u>\$ 1,448,000</u>	<u>\$ 166,000</u>

As of December 31, 1999, the Company had federal research and development, California research and development, and California manufacturers’ credit carry forwards of approximately \$1,990,000, \$940,000, and \$485,000, respectively. The federal research and development, California research and development, and California manufacturers’ credits will begin expiring in 2005, 2011 and 2004, respectively, unless previously utilized.

As of December 31, 1999, the Company had federal and California tax net operating loss carry forwards of approximately \$643,000 and \$518,000, respectively. The federal and California tax net operating loss carry forwards will begin expiring in 2019, unless previously utilized.

Significant components of the Company’s deferred tax assets as of December 31, 1998 and 1999 are shown below.

notes to financial statements (continued)

	December 31,	
	1998	1999
Deferred tax assets:		
Research and development credit	\$ 1,997,000	\$ 2,601,000
Federal and California Alternative Minimum Tax credit	277,000	287,000
California Manufacturers' credit	276,000	315,000
Capitalized research expenses	21,000	2,000
Other	1,476,000	1,254,000
Total deferred tax assets	4,047,000	4,459,000
Deferred tax liability:		
Tax over book depreciation	(21,000)	(108,000)
Net deferred tax assets	\$ 4,026,000	\$ 4,351,000

No valuation allowance has been recorded to offset the deferred tax assets as the Company has determined that it is more likely than not that such assets will be realized. As of December 31, 1999, the Company has approximately \$4.4 million of net deferred tax assets, with no offsetting valuation allowance. The realization of the deferred tax assets is dependent upon the generation of future taxable income of approximately \$10.9 million. The Company will continue to assess the likelihood of realization of such assets; however, if future events occur which do not make the realization of such assets more likely than not, the Company will record a valuation allowance against all or a portion of the net deferred tax assets.

The reconciliation of income tax computed at the federal statutory tax rate to the benefit (provision) for income taxes is as follows:

	December 31,		
	1997	1998	1999
Tax at federal statutory rate	35%	35%	35%
Permanent tax differences	(2)	(5)	14
Decrease in valuation allowance for deferred tax assets —			
Tax credits	(30)	31	(70)
Other	3	(4)	3
Effective rate	6%	57%	(18)%

Pursuant to Internal Revenue Code Section 382, use of the Company's tax credit carry forwards may be limited if a cumulative change in ownership of more than 50% occurs within any three year period. However, any annual limitation is not expected to have a material adverse effect on the Company's ability to utilize its tax credit carry forwards.

9 Employee Savings Plan

In 1991, the Company implemented a 401(k) program which allows all qualifying employees to contribute up to a maximum of 20% of their annual salary, subject to annual limits. The Board of Directors may, at its sole discretion, approve Company contributions. No such contributions have been approved or made.

10 Defense of Patent Matters

In September 1997, Behring Diagnostics, Inc. and Behring Diagnostics, GmbH filed a patent infringement action against the Company in the U.S. District Court for the District of Delaware. The patent infringement action alleged that the Company's Triage DOA Panel products infringed a patent held by the plaintiffs, which expires in August 2000. The plaintiffs sought to recover damages of an unspecified amount and to enjoin future sales of the Triage DOA Panel products by the Company. Biosite answered the complaint, denying infringement and asserting affirmative defenses that the patent is invalid and unenforceable. Because of a merger, the identity of the plaintiffs changed to Dade Behring Inc., Dade Behring Marburg GmbH and Syva Company (collectively "Dade Behring"). To avoid protracted litigation and continued significant legal defense costs, the Company and Dade Behring executed a settlement agreement in March 1999 that resolved all disputes outstanding between the companies. Under the terms of the settlement agreement, the Company obtained a license to the patent and will provide Dade Behring the option to evaluate certain proprietary antibodies, resulting in a net payment of \$1,050,000 to Dade Behring by Biosite. In 1998, the Company charged to defense of patent matters \$604,000 which represented the applicable license costs for years prior to 1998. The Company continues to amortize the applicable license costs until the expiration of the related patent.

notes to financial statements (continued)

1 Quarterly Information (Unaudited)

The following quarterly information includes all adjustments which management considers necessary for a fair statement of such information. For interim quarterly financial statements, the provision for income taxes is estimated using the best available information for projected results for the entire year.

	1998			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
Net sales	\$ 7,884	\$ 8,711	\$ 8,752	\$ 9,077
Gross profit	6,129	6,368	5,715	5,699
Income (loss) before income taxes	(724)	(310)	219	(1,745)
Net income (loss)	(500)	(374)	455	(693)
Net income (loss) per share				
- Basic	\$ (0.04)	\$ (0.03)	\$ 0.04	\$ (0.05)
- Diluted	\$ (0.04)	\$ (0.03)	\$ 0.03	\$ (0.05)
Shares used in calculating per share amounts				
- Basic	12,906	12,938	12,986	12,923
- Diluted	12,906	12,938	13,514	12,923

notes to financial statements (continued)

		1999			
		First Quarter	Second Quarter	Third Quarter	Fourth Quarter
		(in thousands, except per share data)			
Net sales	\$ 9,448	\$10,594	\$11,317	\$11,652	
Gross profit	5,706	7,331	8,137	8,201	
Income (loss) before income taxes	(1,786)	193	1,394	1,137	
Net income (loss)	(1,057)	97	840	1,224	
Net income (loss) per share					
- Basic	\$ (0.08)	\$ 0.01	\$ 0.06	\$ 0.09	
- Diluted	\$ (0.08)	\$ 0.01	\$ 0.06	\$ 0.09	
Shares used in calculating per share amounts					
- Basic	12,973	13,015	13,056	13,083	
- Diluted	12,973	13,624	13,593	13,909	

The benefit for income taxes recognized in the fourth quarter of 1999 included \$112,000 of benefit resulting from the recognition of research and development credits generated during the first three quarters of 1999. Recognition of these credits had been deferred until management determined that their realization had become more likely than not.

financial highlights:

	1999	1998	1997	1996	1995
Statement of Operations Data:					
Net sales	\$ 43,011	\$ 34,424	\$ 31,677	\$ 28,206	\$ 25,147
Income (loss) from operations	(1,553)	(7,586)	1,209	1,964	4,594
Net income (loss)	1,104	(1,113)	1,198	3,549	7,908
Diluted net income (loss) per share	\$.08	\$ (.09)	\$.09	\$.34	\$.79
Common and common equivalent shares used in computing fully diluted per share amount					
	13,728	12,939	13,081	10,392	10,004
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 32,272	\$ 34,229	\$ 39,257	\$ 9,916	\$ 13,979
Working capital	39,978	41,214	46,611	14,305	14,428
Total assets	68,148	65,809	63,313	30,089	27,935
Long-term obligations	4,069	4,038	3,797	3,253	2,739
Stockholders' equity	56,885	54,683	55,090	22,153	18,526

corporate officers

Kim D. Blickenstaff

President and Chief Executive Officer

Gunars E. Valkirs, Ph.D.

Vice President, Research and Development and Chief Technical Officer

Thomas M. Watlington

Senior Vice President, Commercial Operations

Kenneth F. Buechler, Ph.D.

Vice President, Research

James E. Douglas

Vice President, Marketing

Christopher R. Hibberd

Vice President, Strategic Planning and Business Development

Charles W. Patrick

Vice President, Sales

Christopher J. Twomey

Vice President, Finance and Chief Financial Officer

Peter Witerzens, Ph.D.

Vice President, Operations

board of directors

Timothy J. Wollaeger

Chairman of the Board
General Partner
Kingsbury Associates, L.P.

Kim D. Blickenstaff

President and Chief Executive Officer
Biosite Diagnostics Incorporated

Anthony DeMaria, M.D.

Chief of Cardiovascular Medicine
UCSD Medical Center

Howard E. Greene, Jr.

Biotechnology Entrepreneur

Lonnie Smith

President and Chief Executive Officer
Intuitive Surgical, Incorporated

Gunars E. Valkirs, Ph.D.

Vice President, Research and Development and Chief Technical Officer
Biosite Diagnostics Incorporated

corporate offices

Biosite Diagnostics Incorporated
11030 Roselle Street
San Diego, CA 92121

legal counsel

Pillsbury Madison & Sutro LLP
San Francisco, CA

independent auditors

Ernst & Young LLP
San Diego, CA

transfer agent

American Stock Transfer & Trust Company
40 Wall Street, 46th Floor
New York, NY 10005
(718) 921-8248
www.AMSTOCK.com

NASDAQ listing

Biosite common stock is traded on the Nasdaq National Market under the symbol "BSTE"

form 10-K and form 10-Q

A copy of the Company's Annual Report to the Securities and Exchange Commission on Form 10-K and Quarterly Reports on Form 10-Q are available without charge upon written request to the Director, Investor Relations and Corporate Communications

investor relations and corporate communications department

Nadine Padilla
Director, Investor Relations and Corporate Communications
(800) 745-8026, x3187

Biosite's press releases are available by fax via PR Newswire's Company News On-Call service (800) 758-5804 Code # 116737, or are located on Biosite's web site: www.biosite.com

Quarterly updates are available only upon request. Please contact Investor Relations to have your name added to our mailing list.

Biosite®, Triage®, Immediate Response Diagnostics®, Omniclonal™, ExpressTest®, and the Company's logo are registered trademarks of Biosite Diagnostics Incorporated

Except for the historical information contained herein, the matters discussed in this Annual Report are forward-looking statements that involve risks and uncertainties, including the timely development, introduction and acceptance of new products, dependence on others, the impact of competitive products, patent issues, changing market conditions and the other risks detailed throughout this Annual Report. Actual results may differ materially from those projected. These forward-looking statements represent the Company's judgement as of the date of this Annual Report. The Company disclaims, however, any intent or obligation to update these forward-looking statements.



11030 Roselle Street

San Diego, CA 92121

1.800.745.8026

858.455.4808

Fax 858.455.4815

www.biosite.com