

Realizing the Value Within



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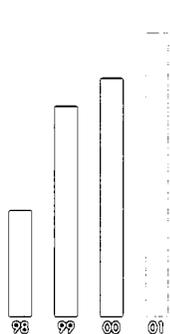
## About Embrex, Inc.

Embrex, Inc. is an international *in ovo* (in-the-egg) company specializing in the poultry industry. The Company is focused on realizing the value inside the avian egg. Our goal is to be the leading supplier of *in ovo* delivery systems, devices and novel *in ovo* biological products to the global poultry industry. We are achieving this goal by developing and commercializing patented biological and mechanical products that improve bird health, help reduce production costs and provide other economic benefits to the poultry industry. In addition to being named one of *Forbes* 200 Best Small Companies in America for 2001 and 2000, and *BusinessWeek's* Hot Growth 100 in 2000 (2001 has not been announced), Embrex also is listed on the North Carolina Technology Fast 50, which honors the fastest growing technology companies in the state.

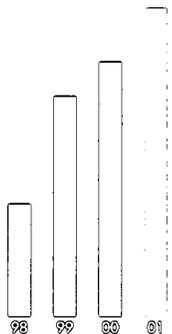
## Key Highlights

- Record revenues up 15%, net income up 20%
- EPS up 19% to all-time high
- Worldwide growth, product sales and Inovoject<sup>®</sup> system placements validate global growth strategy
- Placed 500th Inovoject<sup>®</sup> system
- Developed the first commercial-scale prototype of a gender sorting system that will begin field trials during the first half of 2002
- Launched the Egg Remover<sup>™</sup> system
- Began USDA application process for novel *in ovo* coccidiosis vaccine
- Filed USDA application for approval of Newplex<sup>™</sup> vaccine for Newcastle disease
- Received seven new U.S. patents, bringing current total to 36 U.S. patents and 96 foreign patents that further strengthen intellectual property portfolio and competitive advantage

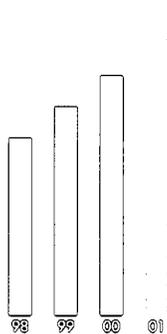
Earnings Per Share



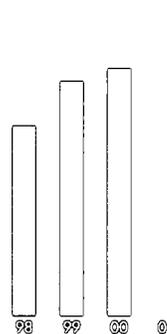
Net Income



Revenue

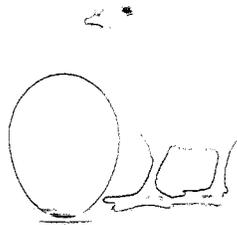


EBITDA



## Financial Highlights (in millions except per share data)

Year Ended	1998	1999	2000	2001	% Increase '00-'01
Earnings per share	\$0.34	\$0.68	\$0.77	\$0.92	+19%
Net income	2.9	5.7	6.6	8.0	+20%
Revenues	28.6	33.8	38.8	44.7	+15%
EBITDA	8.8	10.9	11.5	13.4	+17%



## Realizing the Value Within

What is Embrex? Some have called us a machine company; some have called us an agricultural biotech company; a few have named Embrex a delivery or injection company, while others have said we are a vaccine company. The truth is we are all these things, and therein lies our opportunity. Typical categories do not fit Embrex. This inability to label us is not surprising due to our unique integration of engineering, biology and avian embryology, as well as our machine and vaccine product offerings. But it is, we believe, one of our greatest strengths. In this

report, you will see how we define Embrex. More importantly, we will clarify for you the future of Embrex so that you may better determine how the Company might fit your investment strategy.

Regardless of our varied product offering, all our efforts are based on the fact that Embrex is The *In Ovo* Company<sup>SM</sup>. As The *In Ovo* Company<sup>SM</sup> we are able to converge many scientific disciplines with this single focus. After more than 15 years, we remain the leader of this new scientific discipline that is changing poultry science and production.

THE INOVOJECT® SYSTEM IS THE STANDARD FOR  
IN OVO VACCINE DELIVERY. RELIABLE, PRECISE, SAFE  
AND EFFECTIVE—THE SYSTEM IS SUPPORTED BY  
EMBREX'S PROVEN CUSTOMER SERVICE TEAM.

With 15 years of experience, we believe Embrex knows more about what occurs inside a chicken egg during its 21-day incubation period than any other organization in the world. The Company's *in ovo* platform began with one idea developed in the labs of the U.S. Department of Agriculture in the 1980s. Embrex exclusively licensed that technology and invented the Inovoject® system, an automated egg injection device that could vaccinate chicks while they were still in the egg. This has largely replaced a manual vaccination method done on the day of hatch.

What Embrex now has is a powerful and experienced *in ovo*-based knowledge infrastructure across the key disciplines of engineering, biology and avian embryology that allows us to develop novel, innovative value-based solutions to the challenges faced by the global poultry industry.

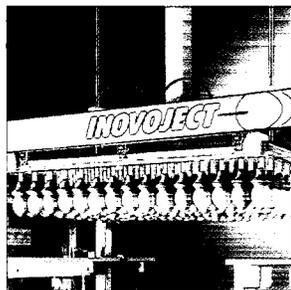
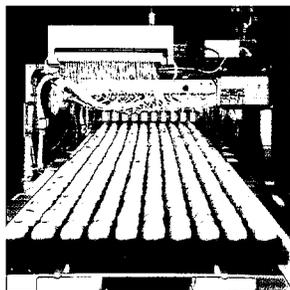
**The Inovoject® system**

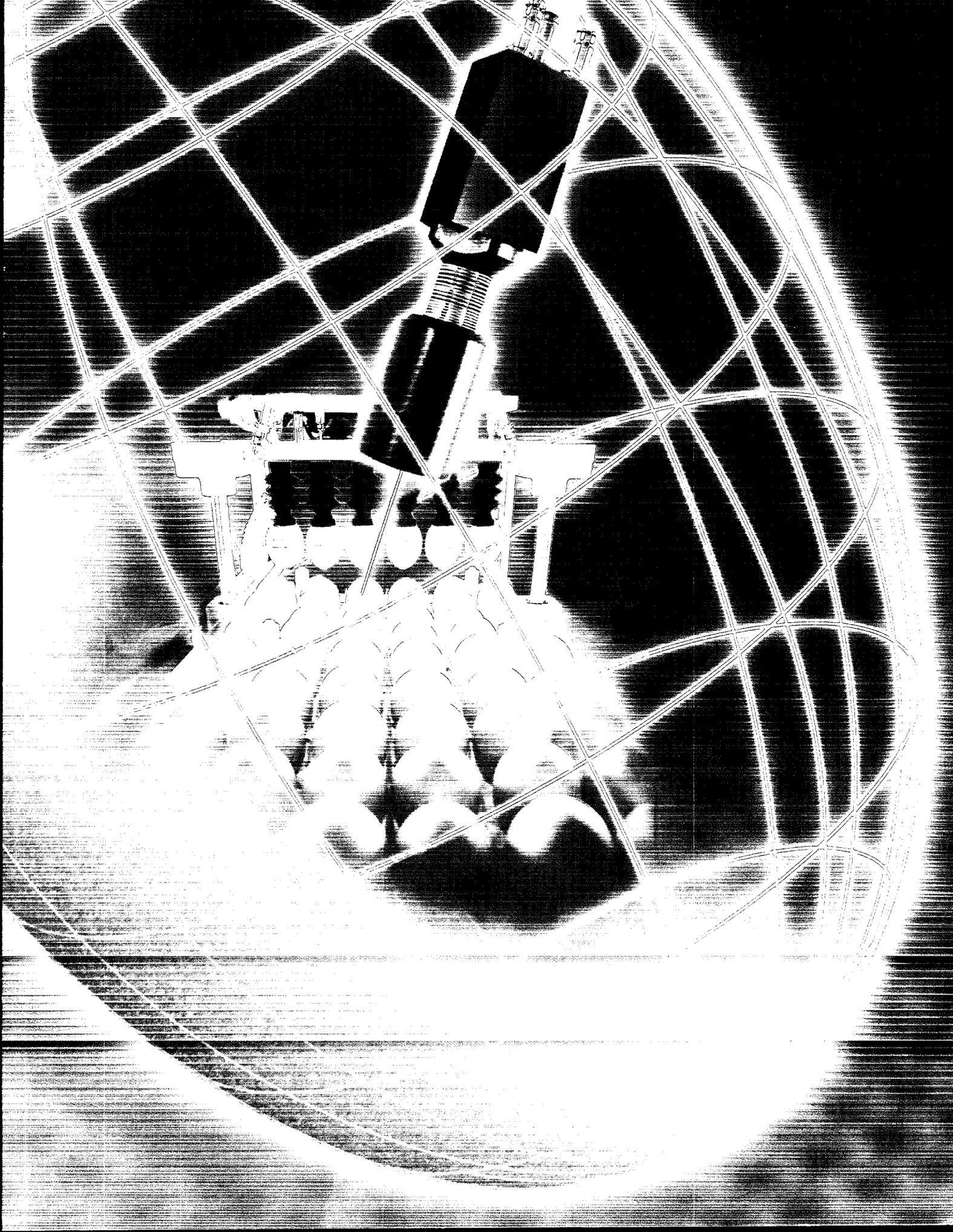
Worldwide, approximately one-third of all broiler chickens are vaccinated via Embrex's proprietary Inovoject® system each year—with more than 80% vaccinated in the United States. This number continues to grow every year as

more and more systems are installed in hatcheries around the world. More than two-thirds of the newly placed Inovoject® systems in 2001 were installed outside of the United States. The Company's growth strategy is to continue to bolster international placements with an emphasis on the largest markets and largest producers within those regions. Our long-term goal is to vaccinate two-thirds of the world's broilers.

**Egg Remover™ Option**

The Egg Remover™ device, a new product option for the Inovoject® system in





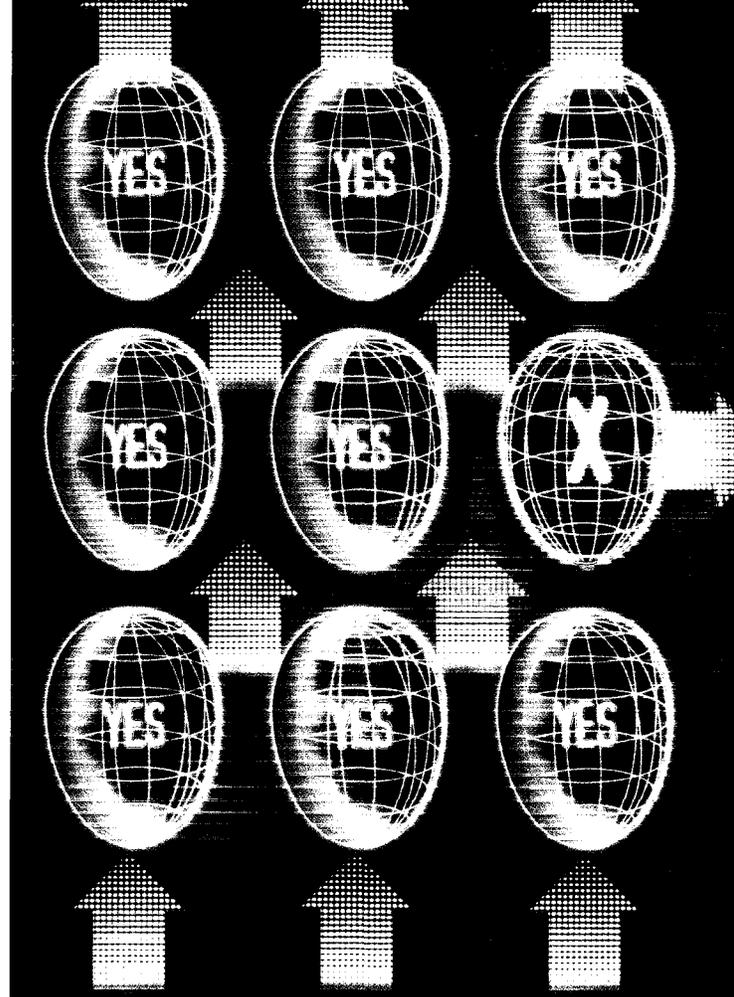
Embrex's line, identifies nonviable eggs at day 18 of the bird's 21-day incubation period. The Egg Remover™ removes these eggs before injection by the Inovoject® system. The benefits of removing what are often referred to as "clear eggs" at day 18 contribute to more chicks of better quality at lower costs to the producer. Trials in North America involving 270,000 eggs and the Egg Remover™ device show an increase in hatch when nonviable eggs are removed prior to hatch. It was launched in 2001 and initial systems are operating in Japan and the United States.

#### Vaccine Saver® Option

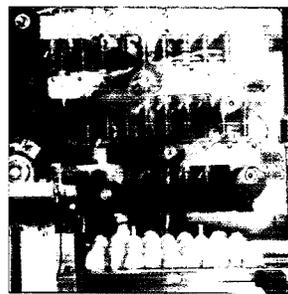
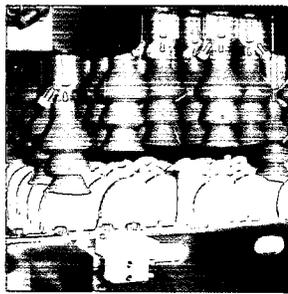
The Vaccine Saver® option for the Inovoject® system combines Embrex's proprietary identification technology with its novel *in ovo* vaccination technology. It identifies clear eggs, then selectively vaccinates fertilized eggs only. This option enables producers to reduce vaccine costs and has been accepted in markets where vaccines are expensive.

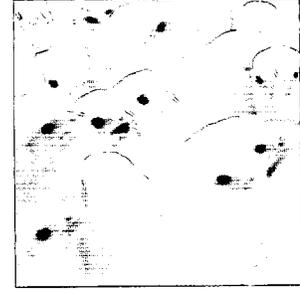
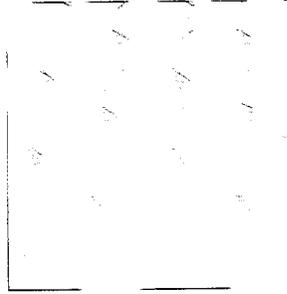
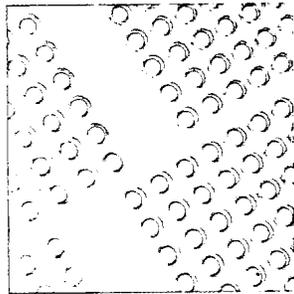
#### Gender Sorting

The *in ovo* gender sorting device segregates eggs by sex by testing a sample of fluid withdrawn from each egg by Embrex's proprietary technology. This

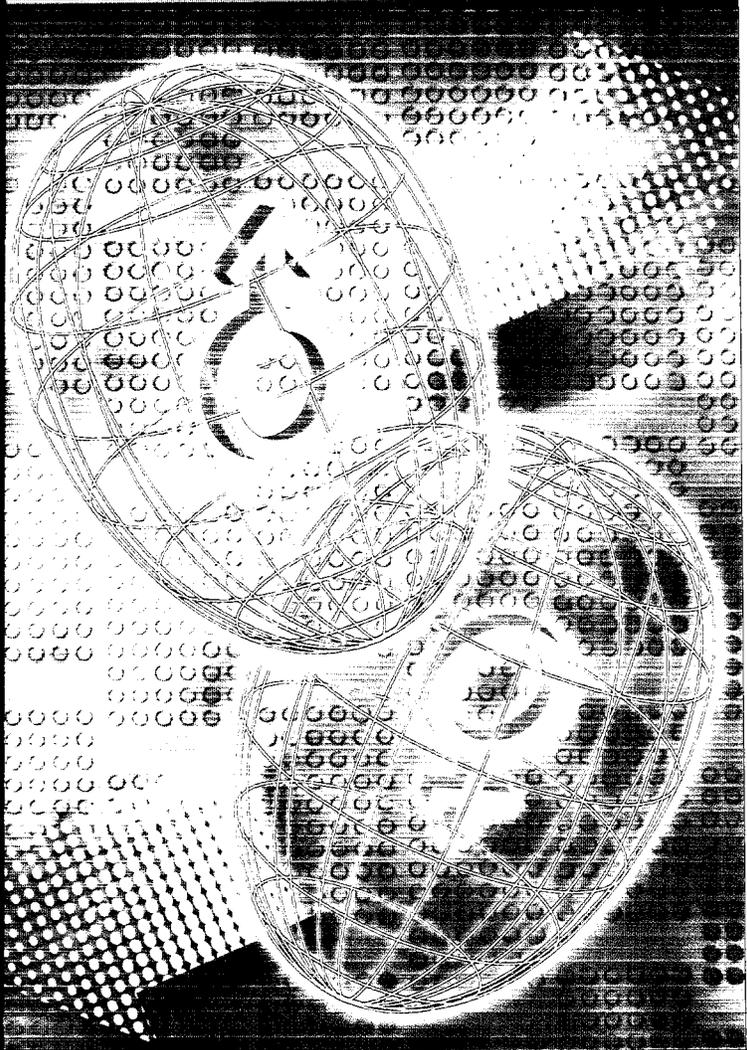


THE BENEFITS OF REMOVING CLEAR EGGS CONTRIBUTE TO MORE CHICKS OF BETTER QUALITY AT LOWER COSTS.





AN AUTOMATED DEVICE TO IDENTIFY  
A CHICK'S GENDER BEFORE HATCH  
HAS GENERATED STRONG INTEREST  
FROM POULTRY PRODUCERS.



system has evolved out of Embrex's core *in ovo* technology and builds upon the expertise gained from our existing *in ovo* devices. The first automated system of its kind, the gender sort device has the potential to replace a manual process that is now performed on a limited basis due to its high cost. We believe sex-separate rearing has many benefits, including improved processing and production efficiencies and more cost effective flock management. Our commercial-scale prototype will be placed in a hatchery owned by Cobb-Vantress Inc., the world leader in broiler breeding and a key collaborator on

this project. We estimate the total market opportunity at greater than \$300 million per year.

#### Viral Neutralizing Factor

An equally important component of Embrex's mission is to develop proprietary products that are administered through the Inovoject® system. This includes our VNF® (Viral Neutralizing Factor) line of avian biological products and an *in ovo* coccidiosis vaccine. Bursaplex®, our first USDA-approved VNF® product, is used to prevent infectious bursal disease. Sales of this product rose 45% in 2001, primarily due to expanded use in



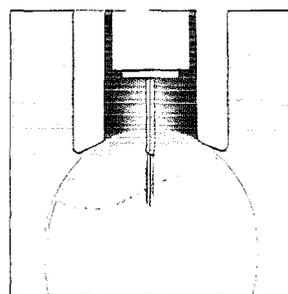
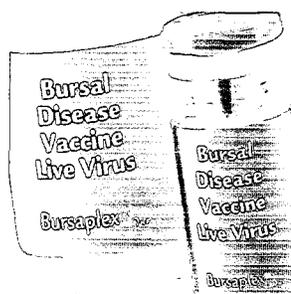
BURSAPLEX® BURSAL DISEASE VACCINE USES PROPRIETARY VNF® TECHNOLOGY, WHICH ENABLES SAFE VACCINE DELIVERY BEFORE CHICKS HATCH, ELIMINATING POST-HATCH VACCINATION.

Asia and Latin America. This product is now approved for use in 21 countries. We await approvals in 12 countries, including China, which we believe will be a very important market for Bursaplex®. Our second VNF® product, Newplex™ for Newcastle disease, is now being reviewed by the USDA. A third VNF® product under early development is designed to prevent infectious bronchitis in poultry. We believe these three products combined address a \$150 million annual global market.

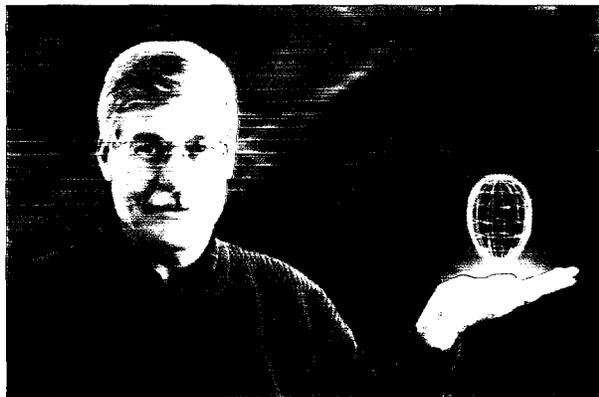
**Coccidiosis Vaccine**

2001 was a milestone year for our *in ovo* coccidiosis vaccine project. Large-scale field trial results demonstrated safety and efficacy, enabling us to move forward with our USDA application for approval. This product addresses a global market estimated to be in excess of \$350 million per year. We believe our vaccine, due to its effectiveness, ease-of-use and ability to be delivered *in ovo* with other vaccines, will be eagerly accepted by poultry producers worldwide. Currently, coccidiosis is managed by

coccidiostats, chemical compounds delivered through the feed to prevent this parasitic disease. Poultry develop resistance to these coccidiostats, requiring poultry producers to rotate usage. We believe administering our *in ovo* coccidiosis vaccine prior to hatch will significantly reduce the need for rotation and be more precise and accurate. In 2002, we will determine our manufacturing strategy and continue to pursue USDA registration of this product.



## To Our Shareholders



In the early days of Embrex, we had to invent a way to access the value that we knew existed in the egg. Our resolve to pioneer a business based on an entirely new scientific discipline has paid off. We continue to realize the value within the egg each and every day.

The strategy driving our growth is to develop and commercialize *in ovo* technology and products that help poultry producers produce better and more economical poultry. Our goal as The *In Ovo* Company<sup>SM</sup> is to be the leading supplier of products focused on our growing and unexcelled *in ovo* expertise. We are achieving that goal by placing Inovoject<sup>®</sup> systems and related *in ovo*-based devices with the world's largest poultry producers. We have aggressively demonstrated that we will remain at the forefront through innovation as we develop and commercialize patented biological, detection and delivery products to optimize bird health, production and processing economics.

### Performance

The performance of Embrex is gratifying. Our 2001 financial results tell a story of steady and disciplined progress. This solid, consistent performance was achieved by executing our business strategy to expand internationally and to develop new *in ovo* products. In 2001, Asian revenue was up 79%, led by Japan where Bursaplex<sup>®</sup> and Inovoject<sup>®</sup> system sales increased dramatically. Latin America saw solid progress with revenue growth of 63% over 2000. In 2002, we will strive for further progress in Asian and Latin American markets, particularly in China, the world's second largest poultry producing nation as well as Brazil, the world's third largest producer.

### Product Pipeline

Our product development pipeline is strong and builds on our expertise, experience and growing global presence. We estimate that the total market size addressed by our existing products and our product pipeline is approximately \$800 million per year. This pipeline, combined

with our growing customer presence, our unparalleled technology position, the delivery and detection capability of our devices, and our knowledge of things *in ovo* truly gives Embrex the opportunity to realize the value within.

### The Value of Our Vision

External resources have recognized the value of our vision. Financial support for a number of these projects has come from partnerships, customers and grants, as well as internal resources. Funding for our gender sort program came from internal resources and through our collaborator Cobb-Vantress, a breeding company with a vested interest in automating the gender sorting process. In conjunction with Origen Therapeutics, we also received a \$4.7 million Advanced Technology Program grant from the National Institute of Science and Technology to determine the feasibility of an early delivery project. If successful, this project may positively impact breeding science in the next decade. We are proud of our success in obtaining grant monies as a way of leveraging support for these projects and will continue to seek such funding in the future.

### Intellectual Property

Likewise, we have had excellent success in developing technology that can be patented. Our unique focus on being The *In Ovo* Company<sup>SM</sup> has driven our intellectual property strategy. Due to our multi-disciplined approach, we now have 36 U.S. patents and 96 foreign patents covering methods-of-use, composition of matter, extraction methods, vaccine preparation and specific design features of our devices. Eighty-five more patent applications are pending.

### Our Commitment

In today's business climate, Embrex remains committed to what has served the Company and shareholders well over the last 10 years. As The *In Ovo* Company<sup>SM</sup>, we will remain focused on poultry and expand the expertise and business offerings derived from our unequalled knowledge of what goes on inside an egg. We will strive to realize value for our customers, employees and shareholders as we enhance the performance of the poultry industry by using our knowledge to build new, better and novel products based on our core platform: *in ovo* technology.

Sincerely,

Randall L. Marcuson  
President and Chief Executive Officer  
March 16, 2002

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
Form 10-K

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

For the fiscal year ended December 31, 2001  
Commission file number 000-19495

Embrex, Inc.  
(Exact name of registrant as specified in its charter)

North Carolina  
(State or other jurisdiction  
of incorporation or organization)

56-1469825  
(I.R.S. Employer  
Identification Number)

1040 Swabia Court, Durham, North Carolina  
(Address of principal executive offices)

27703  
(Zip Code)

(919) 941-5185  
(Registrant's telephone number, including area code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:  
Common Stock, \$0.01 Par Value Per Share (and Rights Attached Thereto)  
(Title of class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

As of February 28, 2002, the aggregate market value of the voting stock held by non-affiliates was \$143.7 million, based on a price per common share of \$17.90 at the close of business on that date.

As of February 28, 2002, there were 8,030,726 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	Where Incorporated
Proxy Statement with respect to the Annual Meeting of Shareholders to be held on May 16, 2002, to be filed with the Securities and Exchange Commission	Part III

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## PART I

### ITEM 1. BUSINESS

#### GENERAL

Embrex, Inc. ("Embrex" or the "Company") is an international agricultural biotechnology company specializing in the poultry industry. Embrex is focused on developing patented biological and mechanical products that improve bird health, help reduce production costs and provide other economic benefits to the poultry industry. The Company was incorporated in 1985 in North Carolina.

Embrex has developed and commercialized the Inovoject® system, a proprietary, automated in-the-egg injection system which can inoculate 20,000 to 50,000 eggs per hour and eliminates the need for manual, post-hatch injection of certain vaccines. The Inovoject® system is designed to inject vaccines and other compounds in precisely calibrated volumes into targeted compartments within the egg. Embrex markets the Inovoject® system to commercial poultry producers, charging a fee for each egg injected. The Company has also introduced the Vaccine Saver® and Egg Remover™ modules to provide additional automation benefits to the poultry hatchery.

In addition to the Inovoject® system, Embrex has developed and is marketing its Viral Neutralizing Factor ("VNF®") technology, useful in the development of certain avian vaccines. The Company also has developed and is marketing Bursaplex®, a VNF®-based vaccine for protection against avian infectious bursal disease ("IBD"). Embrex also is developing various other proprietary mechanical and biological products to improve bird health, reduce bird production costs and provide other economic benefits to the poultry industry. These products are in various stages of development, and some are being developed in collaboration with major animal health companies, the United States Department of Agriculture (the "USDA"), major poultry producers and several leading universities in the field of avian science. These products are being designed to be delivered through the Inovoject® system, and some may also be administered prior to incubation as well as after hatching.

#### EXISTING PRODUCTS

##### Inovoject® Egg Injection System

Embrex has developed and commercialized a proprietary, automated in-the-egg injection system, which can inoculate 20,000 to 50,000 eggs per hour and eliminates the need for manual, post-hatch injection of certain vaccines. This proprietary system, called Inovoject®, is designed to inject vaccines and other compounds in precisely calibrated volumes into targeted compartments within the egg. Embrex markets the Inovoject® system to commercial poultry producers, charging a fee for each egg injected.

In 2001, the Company converted a number of hatcheries to the Inovoject® system and continued operating Inovoject® systems in hatcheries converted prior to 2001. The Company estimates that its Inovoject® system inoculates in excess of 80% of all eggs produced for the North American broiler poultry market and, therefore, expects diminished growth in the number of system installations and only modest Inovoject® system revenue growth in this market. Therefore, the Company must expand its Inovoject® system installations and product sales in markets outside North America in order to realize sustainable overall revenue growth. The Company estimates that approximately 70% or more of the world broiler production occurs outside the United States and Canada. Accordingly, the Company is continuing its strategy to further market its Inovoject® system outside North America.

During 2001, the Company placed a number of Inovoject® systems for trial and on contract at locations outside the United States and Canada. The Company's expansion outside the United States and Canada was focused initially on Europe, the Middle East, and Africa. In the second half of 1997, the Company began expansion efforts in Asia and, in 1998, in Latin America. Currently, the Company has Inovoject® systems either operating on contract or on trial in 30 countries. Overall, the placement of Inovoject® systems outside the United States and Canada is dependent on market acceptance of various *in ovo* ("in the egg") vaccines and obtaining regulatory approval of these vaccines in numerous countries.

Embrex has developed and introduced the Vaccine Saver® option for the Inovoject® system, which identifies infertile and early-dead eggs and selectively prevents vaccination to these eggs. It is designed for use in select markets where vaccine prices are high. The Vaccine Saver® option was introduced in Europe in the fourth quarter of 1999. Embrex has also developed a related system, the Egg Remover™ that works in conjunction with the Inovoject® system to remove infertile and early-dead eggs from incubator trays. This product has been launched commercially and is involved in ongoing hatchery field trials.

Certain poultry diseases are more prevalent in some geographic regions than in others. For example, Marek's disease, for which the Inovoject® system primarily is used in the United States, is not as widespread in Europe as in North America. Infectious Bursal Disease (also known as Gumboro disease) is prevalent in Northern Europe, Asia, parts of Latin America and, to a lesser extent, in the United States. The Company expects that the primary usage of its Inovoject® systems will vary by geographic region according to the prevailing diseases as well as regulatory approval and market acceptance of vaccines for *in ovo* delivery. There are a number of poultry vaccines marketed by various animal health companies in the United States and other markets, which can be used with the Inovoject® system.

#### VNF® (Viral Neutralizing Factor)

Embrex has developed, patented and commercialized a Viral Neutralizing Factor technology, which permits single-dose immunization of the avian embryo effective for the life of the bird. By using the VNF® technology to form an antibody-vaccine virus complex, immunization is provided in a single step, reducing or eliminating many of the multiple vaccinations carried out in the industry. VNF® can temporarily neutralize a virulent vaccine virus without impairing the virus' ability to stimulate an immune response. By using VNF® in this manner, the certain virulent vaccine virus can be made into a safe and effective vaccine, which can be used *in ovo* or after hatch.

The VNF® technology is the subject of four issued U.S. patents, a pending U.S. patent application, and several foreign patents and foreign patent applications. The U.S. patents are owned by the University of Arkansas and exclusively licensed to Embrex for avian use on a royalty basis for the life of the patents. VNF® is a component in the Company's Infectious Bursal Disease vaccine, Bursaplex®, described below. Embrex also is researching application of VNF® technology for other avian disease vaccines, including Newcastle disease, but there is no assurance that the Company's research will result in product opportunities.

#### Infectious Bursal Disease (IBD) Vaccines

VNF® technology is especially useful in vaccines against avian IBD, which weakens a bird's immune system. Birds infected by IBD typically exhibit poor growth or can succumb to other diseases because of a compromised immune system. This disease is currently widespread in Northern Europe, Asia, parts of Latin America and, to a lesser extent, in the United States. To date, IBD has been treated post-hatch via manually delivered vaccines or in drinking water. Existing vaccines are associated with certain limitations, and some vaccines cannot be used safely or effectively *in ovo*. The Company estimates the worldwide market for IBD vaccines is approximately \$60 million annually.

Embrex currently is seeking regulatory approval in selected Latin American and Asian markets for *in ovo* and post-hatch use of Bursaplex® and in December 2000 Shionogi & Co., LTD, Embrex's Japanese distributor, received regulatory approval of the product in Japan. While Embrex has received regulatory approval in some of these markets, there is no assurance that the remaining approvals will be obtained. The placement of Inovoject® systems outside the United States and Canada depends, in part, on market acceptance of various *in ovo* vaccines as well as regulatory approval. To date, regulatory approval for Bursaplex® has been received in 20 countries besides the United States, and regulatory approval is pending in 12 countries. Currently, Bursaplex® is being marketed in most of these countries where regulatory approval has been obtained.

The Company's VNF® technology is also used in an IBD vaccine produced by Cyanamid Webster, a unit of Fort Dodge Animal Health, a division of American Home Products Corp., which has been marketed by Fort Dodge in certain European countries under Fort Dodge's trade name Bursamune®. To date, Bursamune® has received regulatory approval in South Africa, Spain, Italy, Poland and the United Kingdom. During the second quarter of

2001, Fort Dodge advised its distributors that certain other Fort Dodge products, which compete with Bursamune®, could potentially be used *in ovo* in place of Bursamune®. Also, Fort Dodge has indicated to Embrex that it does not intend to continue marketing Bursamune® after existing inventories are used and does not intend to seek further regulatory approvals. Embrex believes Fort Dodge remains obligated under its agreements with Embrex. The Company is considering all of its alternatives and is in discussions with Fort Dodge to reach a resolution of this matter. Pending resolution, marketing and regulatory approval plans for Bursamune® will be delayed and Embrex does not expect to generate significant revenues from either the sales of VNF® to Fort Dodge or the royalties generated from Fort Dodge's Bursamune® sales.

## PRODUCTS UNDER DEVELOPMENT

Embrex is developing individually, and in collaboration with others, additional products and devices which address poultry health and performance needs *in ovo* and, in some cases, after hatch. These additional products are in various stages of development. There can be no assurance that Embrex will successfully develop or market any of these products. Marketing products developed jointly with others may require royalty or other payments by Embrex to its co-developers. There is no assurance regulatory approval will be obtained.

### *In Ovo* Products for Control of Coccidiosis and Newcastle Disease

The Company is developing a novel *in ovo* biological control method for coccidiosis. Coccidiosis is caused by a protozoan parasite, which attacks the gut of the chicken, causing significant problems with the intake and digestion of feed and, therefore, the physical and economic performance of the bird. Currently, virtually all broiler chickens, and most poultry in general, receive anti-coccidiosis compounds called coccidiostats incorporated into poultry feed. Over the years, coccidia have developed levels of resistance to these coccidiostats and thus effectiveness has been somewhat reduced. A limited number of live vaccines have also been developed and are administered orally soon after hatch. However, due to difficulties in providing a precise oral dose to each bird, growth depression can occur in broiler flocks. Therefore, such live vaccines are used primarily in parent stock. Using its Inovoject® system technology and its knowledge of avian embryology, the Company is developing a novel, efficacious and cost-effective means of preventing coccidiosis in broiler chickens. This program is aimed at overcoming many of the problems associated with current practices. The Company estimates that the worldwide market for products that control coccidiosis is in excess of \$350 million per year.

In 1997, the Company established the feasibility of an *in ovo* biological control method for coccidiosis. In 1999, Embrex entered into a collaborative research and development agreement with Pfizer Inc. to research and develop a live coccidiosis vaccine for *in ovo* delivery to poultry. During 2000 and 2001, Embrex conducted large-scale field trials, coordinated with two major U.S. poultry producers, that demonstrated that the *in ovo* coccidiosis vaccine under development is safe and efficacious, with performance equivalent to the commonly used coccidiostats. Although these field trials have been positive, there is no assurance that ongoing research and development will result in a marketable product. In June of 2001, the Company announced that it had acquired an exclusive worldwide license from Pfizer Inc. to all pending patents relating to *in ovo* poultry coccidiosis vaccines. Under the license agreement, Pfizer will receive milestone payments from Embrex and a royalty on future sales of the vaccine. Continued development of this project will involve further extensive clinical and field trials. There can be no assurances that any of these development efforts will be successful. Embrex has initiated the regulatory approval process with respect to these development efforts, but does not expect any coccidiosis product developed by the Company to reach the market in the near future.

The registration application for Newplex™, Embrex's Newcastle disease *in ovo* vaccine which like Bursaplex® is based on VNF® technology, was submitted to the USDA during July 2001. Following an initial positive response, the USDA allowed the manufacture of pre-licensing serials (vaccine lots), which will be used in the field trials required for product registration. Although this product has been submitted for registration there is no assurance that the USDA approval will be obtained.

### Gender Sorting Device

During 2001, Embrex continued its efforts to automate avian gender sorting. The Company believes that the economical and efficient *in ovo* determination of a bird's gender before it hatches will lead to an increase in the

practice of raising birds separately by gender. In a number of independent studies, gender separate rearing has been shown to increase the efficiency of feed utilization, improve processing plant operations and ultimately provide consumers with more uniform and economic poultry. In 1999, Embrex received a small business research grant to support the development of an automated device to sort poultry eggs by gender and, in October 2000, Embrex was awarded a \$270,000 follow-on Phase II Small Business Innovation Research (SBIR) grant to support development of an automated device for sorting poultry eggs by gender. The U.S. Department of Agriculture's Cooperative State Research, Education and Extension Service (CSREES) supported the grant.

Embrex has made substantial progress in developing a gender sorting prototype and in laboratory trials has determined gender in a series of eggs with 100% accuracy. In April 2001, Embrex entered into a Credit Agreement with Advanced Automation, Inc. under which Embrex agreed to loan Advanced Automation up to \$3.4 million in connection with development and construction of a gender sorting automation module for the Inovoject® system. In July 2001, Embrex entered into a Research, Development and Marketing Agreement with LifeSensors, Inc. under which Embrex and LifeSensors will collaborate in the development and production of a gender sorting biosensor module for the Inovoject® system.

In July 2001, Embrex entered into an agreement with Cobb-Vantress, the world leader in broiler breeding, under which Cobb-Vantress agreed to provide funds for Embrex's ongoing development of patented technology and a device to determine the gender of poultry *in ovo*. Embrex subsequently received initial funding from Cobb-Vantress. Upon the achievement of certain milestones in the development and commercialization of Embrex's gender sort device technology, to the mutual satisfaction of the parties, Embrex anticipates receiving additional nonrefundable payments from Cobb-Vantress. In return, Cobb-Vantress will receive favorable commercial terms upon adopting the gender sort device, if and when the device is ultimately commercialized. Embrex estimates that the worldwide market potential for the new gender sorting technology is in excess of \$300 million annually. Embrex has budgeted between \$5 million and \$7 million for its efforts to commercialize gender sort technology. Although the Company believes that this arrangement is a positive step forward, no assurances can be made that Embrex's development work will lead to a commercial device.

#### Other Products Under Development

During 2001, Embrex continued to evaluate technologies which, when coupled with Embrex's proprietary *in ovo* enabling delivery know-how, might have the potential to yield improvements in the areas of feed conversion, muscle mass and leanness within broiler chickens. These technologies may be applied at egg transfer or prior to incubation in order to have the desired effect. While the Company plans to continue its research efforts in these areas in 2002, there is no assurance that these efforts will yield product opportunities.

Embrex is also evaluating technologies and developing capabilities for characterizing and sorting eggs before or after injection by the Inovoject® system. Two of these evaluation programs have resulted in the development and introduction of the Vaccine Saver® option for the Inovoject® system and a related system, the Egg Remover™.

In June 2000, Embrex announced that it had embarked on a research collaboration with Origen Therapeutics, Inc., a privately held biotechnology company based in Burlingame, California, aimed at combining Origen's avian embryonic stem (ES) cell technology with Embrex's *in ovo* technology. The goal of the collaboration is to develop methods that enhance poultry production economics through intervention early in embryonic development. In July of 2001, Embrex along with Origen Therapeutics, Inc. was awarded an Advanced Technology Program (ATP) grant totaling \$4.7 million from the National Institute of Science and Technology (NIST), a division of the U.S. Department of Commerce. The four-year grant will help fund a project, with a proposed budget of \$9.7 million, for development of technology aimed at the large-scale production of poultry utilizing avian embryonic stem (ES) cells and *in ovo* technology. Although the Company believes that this arrangement and this grant is a positive step forward, no assurances can be made that Embrex's development work will lead to a commercial technology.

Embrex routinely enters into collaborative agreements with various animal health companies, pharmaceutical companies and research and academic institutions to evaluate the utility of certain of their compounds or devices when delivered or applied *in ovo*. Depending upon the outcome of these evaluations, Embrex may or may not proceed with these collaborations for further development. There is no assurance that these efforts will yield products or further collaborations.

## PATENTS AND PROPRIETARY RIGHTS

Embrex controls (either through direct ownership or exclusive license) 36 issued U.S. patents, 13 pending U.S. patent applications, 96 issued foreign patents and 72 pending foreign patent applications. In addition, Embrex has executed confidentiality agreements with its collaborators, subcontractors, employees and directors.

The Inovoject® system utilizes a process of injecting viral, bacterial or fungal vaccines into avian eggs that was patented in the United States by the USDA in 1984. Embrex holds the exclusive license to this patent through its expiration in June 2002. There can be no assurances that a competitive system will not be introduced when the patent expires. However, Embrex has supplemented the USDA patent with seven additional issued U.S. patents (and numerous foreign patents and patent applications) covering specific design features of the Inovoject® system. See Item 3, "Legal Proceedings", below.

Embrex also owns or licenses method-of-use patents for the *in ovo* administration of VNF® vaccines and other compounds to elicit various beneficial responses in poultry. Two U.S. patents for methods of treating IBD virus infections using VNF® vaccines, including *in ovo* administration, were issued to Embrex in 1995. A U.S. patent claiming the use of VNF® viral vaccines in all non-primate animals was allowed in 1997 and issued in February 1999. These patents and additional patent applications encompass the use of VNF® vaccine compounds regardless of the source of the VNF®. These VNF® patents additionally include composition-of-matter claims to VNF® vaccines against IBD virus disease and composition-of-matter claims to VNF® vaccines for combating viral diseases in non-primate animals. These patent claims cover the vaccine preparation, regardless of the manner in which the preparation is used. The Company filed three new U.S. patent applications in 1998, 10 new U.S. patent applications in 1999, six new U.S. patent applications in 2000 and six new U.S. patent applications in 2001. During 2000, Embrex also filed two new foreign patent applications. Each application covered various aspects of *in ovo* technology.

Embrex continues its efforts to patent methods of delivering compounds *in ovo*, including early intervention methods and devices. During the years 1998 through 2001, 21 U.S. patents were issued or allowed, further expanding Embrex's proprietary position with respect to *in ovo* technology.

Additionally, Embrex has federally registered the trademarks Embrex®, Inovoject®, VNF®, Bursaplex® and Vaccine Saver® in the United States, and has applied for federal and foreign registration of other various trademarks including Egg Remover™ and Newplex™.

## COMPETITION

The competition for the Inovoject® system is presently the manual, post-hatch administration of biological products. Since most of Embrex's products and potential products are being designed to be administered through the Inovoject® system, the Inovoject® system must continue to be accepted within the poultry industry and operated as intended under long-term commercial conditions for these potential products to be marketed successfully.

The Company holds the exclusive license to the U.S. patent for injecting vaccines into an avian embryo, which expires in June 2002. Embrex has supplemented this patent with seven additional U.S. patents covering specific design features of the Inovoject® system. In addition, Embrex relies on numerous foreign patents to protect its intellectual properties and to afford a competitive advantage. See "Patents and Proprietary Rights," above. There can be no assurance, however, that a competitive delivery method, either within or outside the United States, will not gain commercial acceptance, particularly once the patent has expired. Embrex continues to monitor for the presence of any competitive *in ovo* administration systems worldwide. See Item 3, "Legal Proceedings," below.

Competitive success for Embrex will be based primarily on the current comprehensive customer service and commercial acceptance of third-party and in-house *in ovo* products, achieving and retaining scientific expertise and technological superiority, identifying and pursuing scientifically feasible and commercially viable opportunities, obtaining proprietary protection for its research achievements, obtaining adequate funding and timely regulatory approvals, and attracting corporate sponsors or partners in developing, testing, producing, and marketing products, none of which can be assured. In addition, a primary competitive factor affecting Embrex is its ability to conduct

research and development. Embrex's ability to successfully compete also is dependent on its ability to attract and retain key personnel. Maintaining financial and human resources, therefore, are important factors for success.

## **PRODUCTION, MARKETING AND DISTRIBUTION**

### **Production**

Embrex currently subcontracts the production of all of its mechanical and biological products and expects to continue to do so for the foreseeable future. The Company believes that alternative sources of manufacture and supply generally exist.

See "Risk Factors" filed as Exhibit 99 to this report.

### **Inovoject® System, Vaccine Saver® option and Egg Remover™**

Embrex's in-house engineering staff designs the Inovoject® system, Vaccine Saver® option and Egg Remover™, which incorporates proprietary mechanical, pneumatic and electronic sub-systems and concepts. The Company uses one contract manufacturer to fabricate its Inovoject® systems and Egg Removers™. While other machine fabricators exist and have constructed limited numbers of Inovoject® systems, a change in fabricators could cause a delay in manufacturing and a possible delay in the timing of future Inovoject® system and Egg Removers™ installations and revenues from those installations. The Vaccine Saver® option is assembled in our manufacturing area at the Company's corporate headquarters and the components are sourced from multiple vendors.

### **VNF® (Viral Neutralizing Factor) Vaccines**

In 1993, Embrex signed multi-year agreements with SPAFAS, Inc. ("SPAFAS"), a subsidiary of Charles River Laboratories, Inc., under which SPAFAS supplies the VNF® component for the bursal vaccines Bursaplex® and Bursamune®. In connection with this agreement, Embrex maintains appropriate inventory levels and places orders with SPAFAS to allow Embrex to satisfy anticipated customer demand for VNF®. The regulatory approval granted by the USDA for Bursaplex® in January 1997 specifically covers vaccines produced with SPAFAS-manufactured VNF®. Additional agreements covering the Company's needs for the next four years is in negotiation and is expected to be finalized during 2002.

The Company has granted Merial Select, Inc. ("Select") (a Merck and Aventis company) exclusive rights to manufacture, in the United States, an IBD vaccine containing Embrex's VNF® product, known as Bursaplex®, for Embrex to market in North America, Latin America and Asia. Embrex has also granted Fort Dodge (a unit of American Home Products Corp.) non-exclusive rights to manufacture IBD vaccines containing the Company's VNF® product, known as Bursamune®, to be marketed in Europe, the Middle East and Africa. However, these rights are not being exercised pending resolution of the matter mentioned above. Abic Ltd. has been granted similar rights to manufacture and market an IBD vaccine, known as GuMBryo(TM), in Israel. The manufacture of the IBD vaccines being produced by Select, Fort Dodge and Abic, and the Company's VNF® product, generally must be performed in licensed facilities or under approved regulatory methods. Although there are other manufacturers who are capable of manufacturing IBD products and producing products such as VNF®, a change of supplier for the Company could adversely affect Embrex's future operating results due to the time it would take a new supplier to obtain regulatory approval of its production process or manufacturing facilities. The Company seeks to minimize this exposure through multi-year supply agreements and the maintenance of adequate inventories.

### **Marketing and Distribution**

Because of the geographical and industrial concentration of the poultry industry in the United States and other global markets, Embrex markets its products and provides ongoing service directly to the industry. Embrex's marketing is focused principally on the broiler chicken segment of the poultry industry, but the Company also has adapted its products for use by, and initiated trials and entered into commercial contracts with, broiler breeder companies and a limited number of turkey producers.

In order to encourage proper use of the Inovoject® system technology within an appropriate production environment, Embrex leases and licenses Inovoject® systems to hatcheries. The lease agreements cover the use of the mechanical equipment and ongoing field service, maintenance and technical support provided by Embrex. The agreements also include a license with royalty fees for use of Embrex's proprietary injection process. Also, in a very limited number of markets, under specific circumstances Embrex may sell the Inovoject® system to a third party distributor or a human flu vaccine manufacturer. Products, which are delivered *in ovo*, are sold separately by Embrex and others and may generate some royalty revenue for the Company.

The Company has initiated arrangements for international distribution of Bursaplex®, subject in each case to the availability of required regulatory approvals. The Company has agreements with other parties to distribute Bursaplex® in Peru, Pakistan, Poland, Egypt and South Africa. Of these countries, regulatory approval has been granted in Peru, Pakistan and Poland. An agreement for Israel also entitles a distributor, Abic Ltd., to manufacture and market a VNF®-based IBD vaccine mentioned above. Subject to these agreements, the Company also will conduct international marketing directly.

Other significant poultry markets exist in Asia and Latin America. In 1997 and 1998, the Company entered into agreements with other parties to distribute Bursaplex® in Venezuela, Colombia, South Korea, Malaysia, Taiwan, Japan and Vietnam, subject to regulatory approvals. To date, regulatory approval for Bursaplex® has been granted in 20 countries besides the United States, and regulatory approval is temporary or pending in 12 countries. Embrex also added staff for selected Asian and Latin American markets and installed Inovoject® systems on a commercial or trial basis in certain Asian markets. In 1998, Embrex established Embrex BioTech Trade (Shanghai) Co., Ltd. in China, which will focus on marketing and distribution of Embrex products in China. Also in 1998, Embrex established Embrex Inc. Sucursal Argentina, a branch office in Argentina, responsible for commercial development and customer service and support. Initially, this office will serve only Argentina, but may extend to other regional markets such as Chile, Paraguay or Uruguay. In 1999, Embrex established a subsidiary in Brazil, Inovoject do Brasil Ltda. In January 2001, Embrex established subsidiaries in France and Spain to market and service Inovoject® systems in those countries.

In Japan, Embrex has a distribution agreement with Ishii Company, Ltd. ("Ishii"), a leading chick producer and the dominant supplier of hatchery equipment in Japan. The Japanese Ministry of Agriculture, Fisheries and Forestry granted veterinary medical device regulatory approval for the Inovoject® system in 1999. Ishii is marketing the Inovoject® egg injection system to poultry producers throughout Japan. In December 2000, Shionogi & Co., LTD, Embrex's exclusive distributor in Japan for Bursa-BDA [NP], the Japanese product name for Bursaplex®, successfully gained the necessary regulatory registration of the product Bursa-BDA [NP] for the Japanese market.

The Company's revenues attributable to international operations in 2001, 2000, and 1999 were 31%, 29%, and 23% of the Company's consolidated revenues, respectively. The Company's identifiable assets attributable to international operations in 2001, 2000, and 1999 were 32%, 36%, and 30% of the Company's consolidated assets, respectively.

The Company's gross profit attributable to international operations in 2001, 2000, and 1999 were 19%, 16%, and 19% of the Company's consolidated gross profit respectively. See "Notes to Consolidated Financial Statements."

#### RESEARCH AND DEVELOPMENT EXPENDITURES

Research and development expense was \$5.9 million in 1999, \$6.7 million in 2000 and \$8.1 million in 2001. The increase in research and development expense from 1999 to 2001 largely reflects additional research activities in several areas, increases in outside contract research, supplies consumption and Inovoject® system design and development and global technical support activity. Research and development is principally Company sponsored and funded primarily from internal sources and supplemented by grant and other sources of funds as appropriate.

#### GOVERNMENTAL REGULATION

Regulation by governmental authorities in the United States and other countries is a significant factor in the production and marketing of Embrex's products and in its on-going research and development activities. Although the use of the Inovoject® system is not subject to regulatory approval in the United States, animal health products

being developed by Embrex and other companies must receive approval for marketing from either the USDA or the Food and Drug Administration (the "FDA") and from similar agencies in foreign countries where the Company has begun or contemplates doing business. These countries may also require approval of the Inovoject® system. Regulatory agencies require that products be tested and demonstrate appropriate levels of safety and efficacy. Generally, with respect to animal health products in the U.S., the USDA has regulatory authority over products which are biological in origin or which stimulate or affect an animal's immune system, and the FDA has authority over all other products. The time and cost of USDA approvals are generally less than those for FDA approvals. FDA approval generally requires more extensive animal and toxicology testing than USDA approvals and may take five or more years to obtain, whereas USDA approvals generally take one to three years to obtain. The Company's products also are subject to regulatory approval in other countries.

Management believes that compliance with environmental regulations currently has no material adverse effect on the Company's capital expenditures, earnings or competitive position.

## EMPLOYEES

At December 31, 2001, Embrex employed 221 persons, 220 of whom were full-time employees, an increase of 22 persons from the 198 full-time employees at December 31, 2000.

## SIGNIFICANT CUSTOMERS

Tyson Foods, Inc. ("Tyson") accounted for approximately 20% of Embrex's consolidated 2001 revenues. Based on millions of pounds of ready-to-cook poultry meat produced in 2001, Tyson accounted for approximately 23% of the broilers grown in the United States. During 1997, Tyson extended its contract with Embrex through 2004. There are no customers besides Tyson that represent 10% or greater of total revenues. However, Embrex's three largest customers, including Tyson, accounted for approximately 32% of consolidated 2001 revenues, down from 34% in 2000. The decrease in 2001 is largely the result of the expansion of the Company's customer base.

See "Risk Factors" filed as Exhibit 99 to this report.

## ITEM 2. PROPERTIES

Embrex leases its corporate headquarters and research and development facilities, which occupy approximately 48,000 square feet and are located adjacent to Research Triangle Park, North Carolina. About one-third of the space is devoted to research and development. The lease has an initial six-year term and with annual increases of approximately 3% and 4% during an additional six-year renewal term. Embrex paid an annual rent of approximately \$0.4 million during 2001. In addition to research and development activities conducted at its corporate headquarters, Embrex has a 12,800 square-foot research facility near its headquarters. The lease is a ten-year term expiring November 14, 2007, with a five-year renewal option. The annual rent paid in 2001 was approximately \$0.2 million, with annual increases of approximately 3% through the first ten years and approximately 4% during the five-year renewal term.

In addition to the Company's facilities in North Carolina, Embrex has leased office and warehouse space in some of its offsite and international operations.

## ITEM 3. LEGAL PROCEEDINGS

In September 1996, Embrex filed a patent infringement suit in the U.S. District Court for the Eastern District of North Carolina against Service Engineering Corporation, a Maryland corporation, and Edward G. Bounds, Jr., a Maryland resident and officer of Service Engineering Corporation. The suit alleged that each of the defendants' development of an *in ovo* injection device, designed to compete with Embrex's patented Inovoject® system injection method, infringes at least one claim of U.S. Patent No. 4,458,630 exclusively licensed to Embrex for the *in ovo* injection of vaccines into an avian embryo (the "Sharma Patent"). Further, Embrex claimed that the defendants had violated the terms of a Consent Judgment and Settlement Agreement entered into with Embrex in November 1995 in which prior litigation was concluded with Service Engineering Corporation and Edward G. Bounds, Jr. agreeing not to engage in future activities violating the Sharma Patent. Embrex sought injunctive relief to prevent infringement

of the Sharma Patent as well as monetary damages. In November 1996, Service Engineering Corporation and Edward G. Bounds, Jr., responded to Embrex's patent infringement suit by asserting various affirmative defenses and denying the substantive allegations in Embrex's complaint. This suit concluded on July 30, 1998 with a jury verdict in favor of Embrex. The verdict fully upheld the validity of all claims of the Sharma Patent, finding that the defendants had willingly infringed all asserted claims of the patent. The jury also found that Service Engineering Corporation and Edward G. Bounds, Jr., had breached the 1995 Consent Judgment and Settlement Agreement and that such breach was not in good faith. The jury awarded Embrex damages of \$500,000 plus litigation expenses and court costs. The U.S. District Court for the Eastern District of North Carolina entered a Judgment in favor of Embrex on September 28, 1998, which included a monetary award of \$2,612,885 and an injunction prohibiting Service Engineering Corporation and Edward G. Bounds, Jr., from practicing methods claimed in, or otherwise infringing, the Sharma Patent. This injunction will expire with the expiration of the Sharma Patent in June of 2002. Following an appeal by Service Engineering Corporation and Edward G. Bounds, Jr. to the U.S. Court of Appeals for the Federal Circuit seeking a reversal of the Judgment, in July 2000, the United States Court of Appeals for the Federal Circuit affirmed the district court's decision to award to Embrex litigation expenses plus interest valued at approximately \$1.5 million. In addition, the appeals court upheld the finding that Service Engineering Corporation and Edward G. Bounds, Jr. had willfully infringed all asserted claims of the Sharma Patent. However, the appeals court vacated the award of direct infringement damages finding that the district court erroneously awarded direct damages without proper evidence to support the award. Therefore, the appeals court remanded that award (\$500,000 which was trebled) to the district court for further proceedings for determination of a reasonable royalty for the infringement of the patented method by Service Engineering Corporation and Edward G. Bounds, Jr. These proceedings were opened on August 28, 2000, but were stayed early in 2001 pending the conclusion of a bankruptcy proceeding initiated by Edward G. Bounds, Jr.

On April 15, 1999, Machining Technologies, Inc. of Hebron, Maryland served on Embrex a Complaint for Declaratory Judgment against Embrex in the U.S. District Court for the District of Maryland. Machining Technologies, Inc. sought a declaration that the Sharma Patent is not infringed, invalid and/or not enforceable. Machining Technologies, Inc. was a manufacturer of egg injection machine parts to Edward G. Bounds, Jr. and Service Engineering Corporation. Embrex believed the action was without legal basis and, on June 4, 1999, filed a motion to dismiss the action. On March 7, 2000, the U.S. District Court for the District of Maryland granted Embrex's motion to dismiss this action and ordered this case closed.

See "Risk Factors" filed as Exhibit 99 to this report.

#### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2001.

### PART II

#### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

The Company's Common Stock trades on the Nasdaq National Market under the symbol EMBX. The quarterly trading ranges of the sales prices of the Company's Common Stock for the last two fiscal years were as shown in the table below:

Quarter Ended	Common Stock Price Per Share	
	High	Low
March 31, 2000	\$ 20.00	\$ 10.75
June 30, 2000	\$ 19.88	\$ 11.63
September 30, 2000	\$ 15.75	\$ 10.88
December 31, 2000	\$ 17.75	\$ 12.19

<u>Quarter Ended</u>	<u>High</u>	<u>Low</u>
March 31, 2001	\$ 16.75	\$ 11.06
June 30, 2001	\$ 15.90	\$ 11.87
September 30, 2001	\$ 18.55	\$ 13.98
December 31, 2001	\$ 18.30	\$ 14.77

At February 28, 2002, there were 390 holders of record of the Common Stock. The Company has paid no dividends on any stock since inception and has no plans to pay dividends on its Common Stock in the foreseeable future.

#### ITEM 6. SELECTED FINANCIAL DATA

##### SUMMARY OF OPERATIONS BY QUARTERS (UNAUDITED)

The selected financial data below should be read in conjunction with the Company's consolidated financial statements and related notes appearing elsewhere in this report.

(In Thousands, Except Per Share Amounts)

	<u>2001</u>				<u>2000</u>			
	<u>1st Qtr</u>	<u>2nd Qtr</u>	<u>3rd Qtr</u>	<u>4th Qtr</u>	<u>1st Qtr</u>	<u>2nd Qtr</u>	<u>3rd Qtr</u>	<u>4th Qtr</u>
Revenues	\$10,801	\$10,759	\$11,471	\$11,629	\$9,291	\$9,674	\$9,727	\$10,104
Operating Expenses	4,187	4,098	4,540	\$4,977	3,511	3,581	3,526	4,448
Net income	2,066	1,914	2,105	\$1,882	1,541	1,615	1,660	1,815

	<u>2001</u>				<u>2000</u>			
	<u>1st Qtr</u>	<u>2nd Qtr</u>	<u>3rd Qtr</u>	<u>4th Qtr</u>	<u>1st Qtr</u>	<u>2nd Qtr</u>	<u>3rd Qtr</u>	<u>4th Qtr</u>
Net income (per share of Common Stock)								
Basic	\$0.26	\$0.24	\$0.26	\$0.24	\$0.19	\$0.21	\$0.21	\$0.23
Diluted	\$0.24	\$0.22	\$0.24	\$0.22	\$0.18	\$0.19	\$0.19	\$0.21
Number of Shares Used in Per Share Calculation								
Basic	7,927	8,057	8,077	7,967	7,945	7,870	7,910	7,880
Diluted	8,576	8,673	8,728	8,597	8,733	8,701	8,554	8,569

##### 5-YEAR SUMMARY OF SELECTED FINANCIAL DATA

(In Thousands, Except Per Share Amounts)

##### CONSOLIDATED STATEMENTS OF OPERATIONS DATA

	<u>2001</u>	<u>2000</u>	<u>1999</u>	<u>1998</u>	<u>1997</u>
Revenues	\$44,660	\$38,796	\$33,750	\$28,615	\$24,789
Research and development expenses	8,120	6,725	5,857	4,995	4,188
Other operating expenses	9,681	8,341	8,181	6,837	5,607
Net income	7,967	6,631	5,744	2,861	1,760

	<u>2001</u>	<u>2000</u>	<u>1999</u>	<u>1998</u>	<u>1997</u>
Net income per share of Common Stock					
Basic	\$1.00	\$0.84	\$0.70	\$0.35	\$0.21
Diluted	\$0.92	\$0.77	\$0.68	\$0.34	\$0.21
Number of Shares Used in Per Share Calculation					
Basic	8,007	7,901	8,151	8,255	8,184
Diluted	8,644	8,639	8,488	8,339	8,339

#### CONSOLIDATED BALANCE SHEET DATA

Working capital	\$9,670	\$7,695	\$7,858	\$8,299	\$7,585
Total assets	34,058	26,770	26,233	24,990	25,161
Long-term liabilities	43	37	20	644	3,278
Accumulated deficit	(15,730)	(23,697)	(30,328)	(36,072)	(38,933)
Shareholders' equity	29,314	22,661	21,035	18,805	15,741

### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the Company's consolidated financial statements and related notes appearing elsewhere in this report.

Consolidated net income for 2001 increased to \$8.0 million, representing an increase of 20% over 2000 net income of \$6.6 million, which was 15.8% higher than 1999 net income of \$5.7 million. Diluted earnings per share increased from \$0.68 in 1999 and \$0.77 in 2000 to \$0.92 in 2001. For the year ended 2001, shares outstanding on a diluted basis were 8.6 million, approximately the same as 2000 and up from the 8.5 million for the year ended 1999. The increase in diluted average shares outstanding from 1999 to 2001 is attributable primarily to the increase in the number of in-the-money stock options included in the diluted average shares outstanding calculation. This occurred due to an appreciation in the price of the Company's Common Stock, which began in the second half of 1999 and continued into 2001. The increase relating to stock options was offset in part by stock repurchases under the Company's share repurchase program described below.

#### REVENUES

Consolidated revenues in 2001 totaled \$44.7 million, representing an increase of 15% over 2000 revenues of \$38.8 million, which were 15% over 1999 revenues of \$33.8 million. Inovoject® system revenues totaled \$39.7 million in 2001 compared to \$36.2 million in 2000 and \$32.3 million in 1999, representing increases of 10% from 2000 to 2001, and 12% from 1999 to 2000, with the 2001 increase coming principally from additional Inovoject® systems and injection activity in North America, Asia and Latin America, and Inovoject® system sales in Japan and Europe. During 2001, the US Dollar strengthened against selected currencies compared to the same period during 2000. If average exchange rates during 2001 had remained the same as the average exchange rates for these currencies during 2000, then the Company's revenues would have been \$45.0 million or 7% higher than the actual increase of \$5.9 million.

The 2001 revenues include Inovoject® system lease fees derived from multi-year contracts and paid trials in the United States and foreign countries, and the sale of Inovoject® systems to distributors and human flu vaccine companies. The sale of Inovoject® systems to distributors may cause variability in revenue and gross profit on an annual and quarterly basis. Embrex estimates that as of December 31, 2001, it was vaccinating in excess of 80% of the estimated 9.0 billion broiler birds grown in the United States in 2001. Given its market penetration, the Company expects only moderate Inovoject® systems revenue and earnings growth in this market.

Management anticipates moderate revenue and earnings growth in 2002 from existing Inovoject® system operations in the United States and Canada, higher revenue and earnings growth from new Inovoject® system leases in other

countries, and sales of Bursaplex® product to poultry producers worldwide. However, the rate at which the marketplace will accept the Inovoject® system technology outside the United States and Canada, possible competition within the United States once the patent expires, the timing of regulatory approvals of third-party vaccines for *in ovo* use outside the United States and Canada, start-up costs in new markets, possible variability in United States hatchery bird production as a result of grain price fluctuations, and variability in the demand for, and pricing of, U.S. poultry and poultry products both inside and outside the United States, will impact the pace of revenue growth, if any, and the sustaining of profitability from the installation and operational throughputs of Inovoject® systems.

Sales of Bursaplex®, the Company's proprietary vaccine for the treatment of avian infectious bursal disease, were the principal source of \$3.4 million of product revenues in 2001 as compared to \$2.3 million of product revenues in 2000 and \$1.3 million of product revenues in 1999, representing revenue increases of 45% for 2001 over 2000 and 86% for 2000 over 1999. Bursaplex® sales alone and excluding sales of VNF® to Fort Dodge for the manufacture of Bursamune® increased 70% in 2001 over 2000 sales as continued demand in the United States, Asian and Latin American markets out paced 2000 and the North American region sold Bursaplex® to its Japanese distributor for the entire year 2001 (such sales had begun during the third quarter of 2000). During the second quarter of 2001, Fort Dodge notified Embrex that it does not intend to continue marketing Bursamune® after existing inventories are used (see "Existing Products—Infectious Bursal Disease (IBD) Vaccines", above).

#### COST OF PRODUCT SALES AND INOVOJECT® REVENUES

Cost of revenues accounted for 41% of total revenues in 2001 as compared to 43% and 39% of total revenues in 2000 and 1999, respectively. The improved gross margin in 2001 as compared to 2000 is due in part to operating efficiencies gained in the management of Inovoject® systems, a change in revenue mix that includes increased sales of the Inovoject® system and Bursaplex® as well as the non-operating other revenue mentioned above that has no associated cost of revenue. The increased cost of revenues as a percentage of total revenues in 2000 as compared 1999 was primarily attributable to the \$619,000 audit adjustment charge taken in 2000 due to misappropriation at the Company's Embrex Europe subsidiary (see Note 12 of "Notes to Consolidated Financial Statements" below). These adjustments included changes to accounts receivable and prepaid expenses, which flowed through to cost of revenue. In addition, various international start-up-operating expenses were reclassified as cost of revenue, beginning in January 2000. Operating income was not affected by the operating expense classification change.

#### OPERATING EXPENSES

Operating expenses totaled \$17.8 million compared to \$15.1 million in 2000, and \$14.0 million in 1999.

General and administrative ("G&A") expenses were \$7.1 million in 2001, up 9% from \$6.5 million in 2000 which was down 12% from \$7.4 million in 1999. The 2001 increase from 2000 was primarily due to expenses related to investment in information system infrastructure to support the Company's ERP information system, facility lease payments and related operating expenses and the Embrex Europe investigation, while the 2000 decrease from 1999 was primarily due to the previously mentioned reclassification of international start-up expenses from G&A to sales and marketing and cost of revenue.

Sales and marketing expenses totaled \$2.6 million in 2001 compared to \$1.9 million in 2000 and \$0.8 million in 1999. Increases during these periods resulted from expenses related to increased new business activity, support infrastructure for new markets and training programs for customer support personnel and the annualization of additional infrastructure implemented during 2000. The reclassification of international start-up expenses from G&A to sales and marketing also contributed to the 2000 increase over 1999.

Research and development ("R&D") expenses were \$8.1 million in 2001 compared to \$6.7 million in 2000 and \$5.9 million in 1999. The increase in R&D expense from 2000 to 2001 is principally due to additional development work on the Gender Sort project, and the Coccidiosis and Newcastle disease *in ovo* vaccines. The increase in R&D expense from 1999 to 2000 largely reflects additional research activity in several areas, an increase in outside contract research, supplies consumption and Inovoject® system design and development and global technical support activity. The Company continues to manage its research and development effort to leverage its know-how, patent position, market presence and expenditures.

## OTHER INCOME AND EXPENSE

Interest income totaled \$206,000, \$180,000, and \$315,000 in years 2001, 2000, and 1999, respectively. The decreasing interest income from 1999 to 2001 resulted primarily from lower cash balances, which were primarily attributable to the common stock repurchase program (described below), and secondarily from lower prevailing interest rates.

Interest expense totaled \$21,000 in 2001 compared to \$80,000 in 2000 and \$311,000 in 1999. In 2001, the decrease from 2000 was primarily due to not utilizing the Company's line of credit and the reduction in outstanding capital equipment leases. These leases were fully paid during 2001 and the Company currently has no capital leases on its balance sheet. In 2000, the decrease in interest expense reflected the repayment of approximately \$565,000 of capital equipment leases. Management expects to continue to rely on the use of internally generated funds to finance the cost of additional Inovoject® systems in 2002, as was the case in 2001.

## VALUATION AND QUALIFYING ACCOUNTS

To date, the Company has not experienced any material accounts receivable collection issues. However, based on a review of cumulative balances, industry experience and the current economic environment, the Company currently reserves from 2% to 4%, depending on whether the receivable is denominated in U.S. dollars or a foreign currency, of our outstanding trade accounts receivable balance as an allowance for uncollectable accounts. The consolidated balance for uncollectable accounts as of December 31, 2001 was \$171,000.

To date, the Company has not experienced nor does expect to experience any material Inovoject® system or product warranty issues. However, based on sales of Inovoject® systems and products the Company has established a reserve for future claims. The consolidated balance for warranties as of December 31, 2001 was \$218,000.

To date, the Company has not experienced any material inventory obsolescence. However, based on a percentage of the current product and Inovoject® part inventory levels the Company has established a reserve against future Inovoject® parts obsolescence due to technological improvements and limited shelf life of product inventories. The consolidated balance for product and parts obsolescence as of December 31, 2001 was \$222,000.

## EFFECT OF INFLATION

Management expects cost of product sales and Inovoject® systems revenues, operating expenses and capital equipment costs to change in line with periodic inflationary changes in price levels. While management generally believes that the Company will be able to offset the effect of price level changes by adjusting selling/lease prices and effecting operating efficiencies, any material unfavorable changes in price levels could have a material adverse affect on its results of operations.

## LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2001, the Company's cash and cash equivalents balances totaled \$3.9 million compared to \$3.0 million and \$4.8 million at December 31, 2000 and 1999, respectively. The increase from 2000 to 2001 reflects a change in the amount of the Company's stock repurchases during 2001. The decrease from 1999 to 2000 reflected the ability of the Company to fund capital expenditures with internal cash instead of equipment lease financing. Working capital increased to \$9.7 million in 2001 from \$7.7 million in 2000.

During 2001, operating activities generated \$11.6 million in cash, primarily due to non-cash depreciation and net income. Within investing activities, Inovoject® systems purchases and other capital expenditures required \$7.2 million of cash and \$2.2 million was used for the investment in Embrex Iberica, Embrex's subsidiary in Spain, and the financing of Advanced Automation, Inc. for work on the Gender Sort device under a Credit Agreement signed during the third quarter of 2001. Financing activities used \$1.0 million, due primarily to common stock repurchases (see below), which was partially offset by \$2.2 million received for issuance of common stock, substantially all of which was issued in connection with the exercise of stock options during 2001.

In October 1998, the Company announced that the Board of Directors authorized a share repurchase program (the "1998 Repurchase Program") to purchase up to 10% of outstanding shares of Common Stock, or up to approximately 830,000 shares over 18 months, in open market or privately negotiated transactions. During the second quarter of 2000, Management was authorized by the Board of Directors to extend the stock repurchase program (the "2000 Repurchase Program"). This extension allowed for the purchase up to 6% of outstanding shares, or up to approximately 500,000 shares over 18 months in open market or privately negotiated transactions. During 2001, the Company repurchased 201,216 shares of its Common Stock for \$3.2 million at an average price of \$16.00 per share under the 2000 Repurchase Program, which ended during the fourth quarter of 2001. During the entire term of the 1998 Repurchase Program, the Company repurchased 830,000 shares of its Common Stock for \$9.0 million at an average price of \$10.80 per share. During the entire term of the 2000 Repurchase Program, the Company repurchased 345,216 shares of its Common Stock for \$5.2 million at an average price of \$15.08 per share. See "Notes to Consolidated Financial Statements."

In April 1999, the Company obtained a \$6.0 million secured revolving line of credit from its bank, Branch Banking and Trust Company. This line of credit may be used for working capital purposes and was extended in October 2000 for an additional 18 months and will now expire in April 2002. The Company intends to renew this facility. At December 31, 2001, there were no outstanding borrowings under this credit facility.

As of December 31, 2001, the Company had outstanding commitments for expenditures of approximately \$1.5 million related to ordered Inovoject® systems, obtaining proprietary rights for Embrex's current development project portfolio, as well as construction costs for the Company's new facility.

Based on its current operations, management believes that the Company's available cash and cash equivalents, together with cash flow from operations, external funds for R&D projects and its bank line of credit, will be sufficient to meet its cash requirements as these currently exist, but may continue to explore additional alternative funding opportunities with respect to collaborative ventures and new product development.

#### **FORWARD-LOOKING STATEMENTS**

Information set forth in this Annual Report on Form 10-K contains various "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements represent the Company's judgment concerning the future and are subject to risks and uncertainties that could cause the Company's actual operating results and financial position to differ materially. Such forward looking statements can be identified by the use of forward looking terminology such as "may," "will," "expect," "plan," "intend," "target," "anticipate," "estimate," "believe," or "continue," or the negative thereof or other variations thereof or comparable terminology.

The Company cautions that any such forward-looking statements include statements with respect to future products, services, markets and financial results. These statements involve risks and uncertainties that could cause actual results to differ materially, including without limitation the ability of the Company to penetrate new markets, the ability to develop new products and technology, the degree of market acceptance of new products, the outcome of the Company's patent litigation appeal, the potential to lose protection of proprietary rights and patents through expiration, invalidity, or otherwise, the complete commercial development of potential future products or the ability to obtain regulatory approval of products. Such approval is dependent upon a number of factors, such as results of trials, the discretion of regulatory officials, and potential changes in regulations. These statements are also contingent upon continued growth and production levels of the global poultry industry and the economic viability of certain markets. Additional information on these risks and other factors which could affect the Company's consolidated financial results are included in the Risk Factors described in Exhibit 99 to this report and in the Company's other filings with the Securities and Exchange Commission, including the Company's Forms 10-Q, 10-K and 8-K.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Market risk is the risk of potential loss arising from adverse changes in market rates and prices. The Company's primary market risk exposure is in changes in foreign currency exchange rates. Approximately 31%, 29% and 23% of our revenues for the years ended 2001, 2000, and 1999, respectively, were derived from our operations outside

the United States. Our consolidated financial statements are denominated in U.S. Dollars and, accordingly, changes in the exchange rates between foreign currencies and the U.S. Dollar will affect the translation of our subsidiaries' financial results into U.S. Dollars for purposes of reporting our consolidated financial results.

Accumulated currency translation adjustments recorded as a separate component (reduction) of shareholders' equity were (\$329,000) at December 31, 2001 as compared with (\$484,000) at December 31, 2000. Our most significant foreign currency exchange rate exposure is in the British pound. To date, the Company has not utilized any derivatives or other hedging instruments to affect this exposure.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Shareholders Embrex Inc.

We have audited the accompanying consolidated balance sheets of Embrex, Inc. and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. Our audits also included the financial statement schedule listed in the Index at Item 14(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of Embrex, Inc. and subsidiaries at December 31, 2001 and 2000, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

Raleigh, North Carolina  
February 22, 2002

*Ernst & Young LLP*

## CONSOLIDATED BALANCE SHEETS

(Dollars in thousands)

	<u>December 31,</u>	
	2001	2000
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$3,907	\$2,966
Restricted cash (Note 2)	275	275
Inventories:		
Materials and supplies	1,361	1,516
Product	900	833
Accounts receivable – trade (net of allowance of \$171 and \$196 in 2001 and 2000, respectively)	7,128	5,226
Other current assets	800	951
Total Current Assets	<u>14,371</u>	<u>11,767</u>
Inovoject® Systems under construction	1,560	1,325
Inovoject® Systems	32,555	31,023
Less accumulated depreciation	<u>(24,754)</u>	<u>(22,471)</u>
	7,801	8,552
Equipment, furniture and fixtures	12,123	8,541
Less accumulated depreciation	<u>(4,172)</u>	<u>(3,682)</u>
	7,951	4,859
Other Assets:		
Patents, goodwill and exclusive licenses of patentable technology (net of accumulated amortization of \$144 in 2001 and \$94 in 2000)	752	267
Other long-term assets (Note 1)	<u>1,623</u>	<u>0</u>
Total Other Assets	2,375	267
<b>TOTAL ASSETS</b>	<u><u>\$34,058</u></u>	<u><u>\$26,770</u></u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities		
Accounts payable	\$1,210	\$ 677
Accrued expenses	3,245	3,059
Deferred revenue	28	200
Product warranty accrual	218	113
Current portion of capital lease obligations	<u>0</u>	<u>23</u>
Total Current Liabilities	4,701	4,072
Long-term debt, less current portion (Note 4)	43	37
Shareholders' Equity (Notes 5, 6 and 7)		
Common Stock, \$.01 par value per share Authorized 30,000,000 shares issued and outstanding – 7,998,168 net of 1,175,216 treasury shares and 7,879,525 net of 974,000 treasury shares at December 31, 2001 and 2000, respectively	90	88
Additional paid-in capital	59,932	57,700
Accumulated other comprehensive income	(776)	(447)
Accumulated deficit	(15,730)	(23,697)
Treasury stock	<u>(14,202)</u>	<u>(10,983)</u>
Total Shareholders' Equity	<u>29,314</u>	<u>22,661</u>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<u><u>\$34,058</u></u>	<u><u>\$26,770</u></u>

See accompanying notes.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	<u>Year ended December 31,</u>		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
<b>REVENUES</b>			
Inovoject® revenue	\$39,719	\$36,189	\$32,314
Product revenue	3,379	2,332	1,252
Other revenue	<u>1,562</u>	<u>275</u>	<u>184</u>
Total Revenues	44,660	38,796	33,750
Cost of Product Sales and Inovoject® Revenues	<u>18,124</u>	<u>16,770</u>	<u>13,119</u>
	26,536	22,026	20,631
<b>OPERATING EXPENSES</b>			
General and administrative	7,053	6,474	7,386
Sales and marketing	2,628	1,867	795
Research and development	<u>8,120</u>	<u>6,725</u>	<u>5,857</u>
Total Operating Expenses	<u>17,801</u>	<u>15,066</u>	<u>14,038</u>
Operating Income	8,735	6,960	6,593
Other Income (Expense)			
Interest income	206	180	315
Interest expense	(21)	(80)	(311)
Other	<u>21</u>	<u>78</u>	<u>(12)</u>
Total Other Income (Expense)	<u>206</u>	<u>178</u>	<u>(8)</u>
Income Before Taxes	8,941	7,138	6,585
Income Taxes (Note 9)	<u>974</u>	<u>507</u>	<u>841</u>
Net Income	<u>\$7,967</u>	<u>\$6,631</u>	<u>\$5,744</u>
<b>Net Income per share of Common Stock (Note 11)</b>			
Basic	\$1.00	\$0.84	\$0.70
Diluted	\$0.92	\$0.77	\$0.68
<b>Number of Shares Used in Per Share Calculation (Note 11)</b>			
Basic	8,007	7,901	8,151
Diluted	8,644	8,639	8,488

See accompanying notes.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(Dollars in thousands)

	<u>Year ended December 31,</u>		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
<b>Operating Activities</b>			
Net income	\$7,967	\$6,631	\$5,744
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	4,448	4,289	4,096
Loss on fixed asset disposal	238	-0-	-0-
Changes in operating assets and liabilities:			
Accounts receivable, inventories and other current assets	(1,663)	(564)	(1,564)
Accounts payable, accrued expenses and other current liabilities	652	(205)	1,331
<b>NET CASH PROVIDED BY OPERATING ACTIVITIES</b>	<u>11,642</u>	<u>10,151</u>	<u>9,607</u>
<b>Investing Activities</b>			
Purchases of Inovoject® systems, equipment, furniture and fixtures	(7,211)	(6,167)	(5,903)
(Additions)/reductions to patents and other noncurrent assets	<u>(2,159)</u>	<u>72</u>	<u>(240)</u>
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<u>(9,370)</u>	<u>(6,095)</u>	<u>(6,143)</u>
<b>Financing Activities</b>			
Issuance of Common Stock	2,234	2,473	338
Net changes in line of credit	-0-	(356)	356
Repayment of long-term debt	6	-0-	(10)
Proceeds from long-term debt	-0-	37	-0-
Payments on capital lease obligations	(23)	(565)	(2,664)
Repurchase of Common Stock	<u>(3,219)</u>	<u>(6,994)</u>	<u>(3,776)</u>
<b>NET CASH USED IN FINANCING ACTIVITIES</b>	<u>(1,002)</u>	<u>(5,405)</u>	<u>(5,756)</u>
<b>INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS</b>	1,270	(1,349)	(2,292)
<b>CURRENCY TRANSLATION ADJUSTMENTS</b>	(329)	(484)	(76)
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<u>2,966</u>	<u>4,799</u>	<u>7,167</u>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<u>\$3,907</u>	<u>\$2,966</u>	<u>\$4,799</u>

### SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:

Total interest paid was \$21,000, \$80,000 and \$311,000 for the years ended December 31, 2001, 2000, and 1999, respectively.

Total income taxes paid were \$955,000, \$582,000 and \$618,000 for the years ended December 31, 2001, 2000, and 1999, respectively.

See accompanying notes.

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(Dollars in thousands)

	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock	Total
BALANCE AT JANUARY 1, 1999	\$83	\$54,894	\$113	(\$36,072)	(\$213)	\$18,805
Stock repurchased					(3,776)	(3,776)
Stock issued:						
Upon exercise of options and issuance of bonus Stock	1	401				402
Under employee stock purchase plan		87				87
Upon exercise of warrants		(151)				(151)
Other comprehensive income, net of tax (note 1):						
Currency translation adjustments			(76)			(76)
Net income				5,744		5,744
Comprehensive income						<u>5,668</u>
BALANCE AT DECEMBER 31, 1999	84	55,231	37	(30,328)	(3,989)	21,035
Stock repurchased					(6,994)	(6,994)
Stock issued:						
Upon exercise of options	3	1,912				1,915
Under employee stock purchase plan		198				198
Upon exercise of warrants	1	99				100
Employee compensation		260				260
Other Comprehensive income, net of tax (note 1):						
Currency translation adjustments			(484)			(484)
Net income				6,631		6,631
Comprehensive income						<u>6,147</u>
BALANCE AT DECEMBER 31, 2000	88	57,700	(447)	(23,697)	(10,983)	22,661
Stock repurchased					(3,219)	(3,219)
Stock issued:						
Upon exercise of options	2	1,640				1,642
Under employee stock purchase plan		162				162
Upon exercise of warrants		108				108
Employee compensation		322				322
Other comprehensive income, net of tax (note 1):						
Currency translation adjustments			(329)			(329)
Net income				7,967		7,967
Comprehensive income						<u>7,638</u>
BALANCE AT DECEMBER 31, 2001	<u>\$90</u>	<u>\$59,932</u>	<u>(\$776)</u>	<u>(\$15,730)</u>	<u>(\$14,202)</u>	<u>\$29,314</u>

See accompanying notes.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### 1. SIGNIFICANT ACCOUNTING POLICIES

#### NATURE OF BUSINESS

Embrex, Inc. is an international agricultural biotechnology company specializing in the poultry industry. Embrex is focused on developing patented biological and mechanical products that improve bird health, help reduce production costs and provide other economic benefits to the poultry industry. Embrex has developed and commercialized the Inovoject® system, a proprietary, automated in-the-egg injection system which can inoculate 20,000 to 50,000 eggs per hour and eliminates the need for manual, post-hatch injection of certain vaccines. The Company has also introduced the Vaccine Saver® and Egg Remover™ modules to provide additional automation benefits to the poultry hatchery. In addition, Embrex has developed and is marketing its VNF® technology, useful in the development of certain avian vaccines. The Company also has developed and is marketing Bursaplex®, a VNF®-based vaccine for protection against avian infectious bursal disease ("IBD").

#### PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the accounts of Embrex, Inc. and its wholly owned subsidiaries, Embrex Europe Limited, Embrex France s.a.s., Embrex Iberica, Embrex BioTech Trade (Shanghai) Co., Ltd. and Inovoject do Brasil Ltda. (the "Company"). All significant intercompany transactions and accounts have been eliminated. Currently, non-U.S. operations account for approximately 31% of the Company's revenues.

#### CASH AND CASH EQUIVALENTS

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

#### INVENTORIES

Items recorded as inventory are generally purchased from others and recorded at the lower of cost or market using the average cost method. Materials and supplies inventories include spare parts for the Inovoject® systems as well as laboratory and general supplies. Product inventories are comprised of biological compounds, principally the Company's Viral Neutralizing Factor product (VNF®).

#### INOVOJECT® SYSTEMS

Inovoject® systems are comprised of egg injection and related equipment available for lease to customers. The equipment is recorded at the lower of cost or estimated net realizable value. Depreciation is computed principally by using accelerated and straight-line methods over the estimated useful life of the equipment and commences after construction is complete and the equipment is placed in service.

#### EQUIPMENT, FURNITURE AND FIXTURES

Equipment, furniture and fixtures are recorded at cost. Depreciation is computed principally by using accelerated and straight-line methods over the estimated useful lives of the assets placed in service, generally three-to-five years.

#### PATENTS AND EXCLUSIVE LICENSES OF PATENTABLE TECHNOLOGY

Costs incurred to acquire exclusive licenses of U.S. patentable technology and to apply for and obtain U.S. patents on internally developed technology are capitalized and amortized using the straight-line method. Exclusive license agreements are amortized over the period of the license. Patents are amortized over the shorter of the useful or legal life of the patent.

## **OTHER LONG-TERM ASSETS**

This asset includes a loan asset with Advanced Automation, Inc. This loan will grow in accordance with expenses incurred in pursuit of the Development Program established between Embrex and Advanced Automation. Simple interest accrues on the loan and is included in the loan balance.

## **FOREIGN CURRENCY TRANSLATION**

All assets and liabilities in the balance sheets of the Company's foreign subsidiaries, Embrex Europe Limited, Embrex France s.a.s., Embrex Iberica, Embrex BioTech Trade (Shanghai) Co., Ltd. and Inovoject do Brasil Ltda, are translated at year-end exchange rates except shareholders' equity which is translated at historical rates. Revenues, costs and expenses are recorded at average rates of exchange during the year. Translation gains and losses are accumulated as a component of shareholders' equity. Foreign currency transaction gains and losses are included in determining net income.

## **REVENUE RECOGNITION**

Inovoject® system fees are recognized based on eggs processed during the period. Product sales are recognized when the products are shipped. Contract research revenue is recognized as services are performed over the term of the contract. Revenue received, but not yet earned, is classified as deferred revenue.

## **RESEARCH AND DEVELOPMENT COSTS**

Research and development costs, including costs incurred to complete contract research, are charged to operations when incurred and are included in operating expenses.

## **INCOME TAXES**

The Company accounts for income taxes under the provisions of Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" (SFAS 109). SFAS 109 requires recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary basis differences that have arisen between financial statement and income tax reporting.

## **NET INCOME PER SHARE**

Basic net income per share was determined by dividing net income available for common shareholders by the weighted average number of common shares outstanding during each year. Diluted net income per share reflects the potential dilution that could occur assuming conversion or exercise of all convertible securities and issued and unexercised stock options. A reconciliation of the net income available for common shareholders and number of shares used in computing basic and diluted net income per share is in Note 11.

## **USE OF ESTIMATES**

The presentation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from these estimates.

## **PRINCIPAL CUSTOMERS**

Tyson Foods, Inc. ("Tyson") accounted for approximately 20%, 21% and 24% of consolidated 2001, 2000, and 1999 revenues, respectively. Based on the millions of pounds of ready-to-eat poultry meat produced in 2001, Tyson accounted for approximately 23% of the broilers grown in the United States. In 2001, Tyson was the only customer that represented greater than 10% of total revenues.

## CONCENTRATION OF CREDIT RISK

The Company's principal financial instrument, subject to potential concentration of credit risk, is accounts receivable which are unsecured. As of December 31, 2001, Tyson Foods, Inc. accounted for approximately 10% of consolidated accounts receivable, and substantially all of the Company's accounts receivable are due from companies in the poultry industry.

## SOURCES OF SUPPLY

The Company has developed a strategic relationship with one contract manufacturer to fabricate its Inovoject® systems. While other machine fabricators exist and have constructed limited numbers of Inovoject® systems, a change in fabricators could cause a delay in manufacturing and a possible delay in the timing of future Inovoject® installations and revenues from those installations.

The Company has granted Merial Select, Inc. ("Select") (a Merck and Aventis company) exclusive rights to manufacture, in the United States, IBD vaccines containing Embrex's proprietary VNF® product for Embrex to market in North America, Latin America and Asia under the trade name Bursaplex®. Embrex granted Cyanamid Websters, a unit of Fort Dodge Animal Health, which is a division of American Home Products Corp. ("Fort Dodge"), rights to manufacture and market bursal disease vaccines containing the Company's VNF® product to be marketed in Europe, the Middle East and Africa under the trade name Bursamune®. However in 2001, Fort Dodge indicated to Embrex that it does not intend to continue marketing Bursamune® after existing inventories are used and does not intend to seek further regulatory approvals. Abic Ltd. has been granted similar rights to manufacture and market an IBD vaccine, known as GuMBryo(TM), in Israel. Additionally, the Company has one contract supplier of its VNF® product. The manufacture of the bursal disease vaccines being produced by Select, Fort Dodge and Abic and the Company's VNF® product generally must be performed in licensed facilities and/or under methods approved by regulatory agencies. Although there are other manufacturers who are capable of manufacturing bursal disease products and producing products such as VNF®, a change of suppliers could adversely effect the Company's future operating results due to the time it would take a new supplier to obtain regulatory approval of its production process and/or manufacturing facilities. The Company seeks to minimize this exposure through multi-year supply agreements and the maintenance of adequate inventories.

## COMPREHENSIVE INCOME

In June 1997, the FASB issued Statement No. 130, Reporting Comprehensive Income (SFAS 130). This Statement establishes standards for reporting and display of comprehensive income and its components in the consolidated financial statements. In accordance with SFAS 130, the Company has determined total comprehensive income, net of tax, to be \$ 7.6 million, \$6.1 million and \$5.7 million for the years ended December 31, 2001, 2000, and 1999, respectively. Embrex's total comprehensive income represents net income plus the after-tax effect of foreign currency translation adjustments for the years presented.

## SEGMENTS

The Company operates in a single segment. The table below presents the Company's operations by geographic area:

	2001	2000	1999
Net Revenue:			
United States	\$30,959	\$27,591	\$26,038
International	13,701	11,205	7,712
Total Assets:			
United States	\$23,230	\$17,168	\$18,424
International	10,828	9,602	7,809

## IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS

### Derivative Instruments

Statement of Financial Accounting Standard (SFAS) No. 133, "Accounting for Derivative Instruments and for Hedging Activities", is effective for fiscal years beginning after June 15, 2000. SFAS 133 establishes reporting standards for derivative instruments, including derivative instruments embedded in other contracts, and for hedging activities. SFAS No. 133 requires that an entity recognize all derivatives as either assets or liabilities in the statement of financial position and measure those instruments at fair value. The Company adopted SFAS No. 133 for its fiscal year ended December 31, 2001. The adoption of this pronouncement did not have a material impact on the Company's results of operations or balance sheet.

### Recently Issued Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, "Business Combinations", and SFAS No. 142, "Goodwill and Other Intangible Assets". SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 requires that ratable amortization of goodwill be replaced with periodic tests of the goodwill's impairment and that intangible assets other than goodwill be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001 and for all business combinations accounted for by the purchase method for which the date of acquisition is after June 30, 2001. The provisions of SFAS No. 142 will be effective for fiscal years beginning after December 15, 2001, and will thus be adopted by the Company, as required, in fiscal year 2002. The Company does not expect the adoption of SFAS No. 141 and SFAS No. 142 to have a material impact on the Company's results of operations or balance sheet.

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations". SFAS No. 143 requires an entity to record a liability for an obligation associated with the retirement of an asset at the time that the liability is incurred by capitalizing the cost as part of the carrying value of the related asset and depreciating it over the remaining useful life of that asset. The standard is effective for the Company beginning January 1, 2003. The Company does not expect the adoption of SFAS No. 143 to have a material impact on the Company's results of operations or balance sheet.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be disposed of". SFAS No. 144 addresses how and when to measure impairment on long-lived assets and how to account for long-lived assets that an entity plans to dispose of either through sale, abandonment, exchange or distribution to owners. The new provisions supersede SFAS No. 121, which addressed asset impairment and certain provisions of APB Opinion 30 related to reporting the effects of the disposal of a business segment and requires expected future operating losses from discontinued operations to be recorded in the period in which the losses are incurred rather than the measurement date. Under SFAS No. 144, more dispositions may qualify for discontinued operations treatment in the income statement. The provisions of SFAS No. 144 became effective for the Company on January 1, 2002. The Company does not expect the adoption of SFAS No. 144 to have material impact on the Company's results of operations or balance sheet.

### 2. RESTRICTED CASH

On October 13, 1997, the Company executed a ten-year collateralized lease relative to the facilities housing the Company's research facility. Such collateral exists in the form of a certificate of deposit, which is required to be maintained at least through the end of the seventh year of the lease.

### 3. LEASES

At December 31, 2001 and 2000, the Company had assets totaling \$0 and \$23,000, respectively, financed by capital lease agreements which expired and were paid off during 2001. Accumulated depreciation and amortization includes \$0 and \$9,000 of amortization related to these assets at December 31, 2001 and 2000, respectively. Amortization of assets financed by capital leases is included with depreciation expense.

The Company leases its facilities under a number of operating leases extending through November 2007. The Company has the option to cancel one of its operating lease agreements with the payment of a \$180,000 penalty. Total rent expense was \$955,000, \$791,000 and \$483,000 for the years ended December 31, 2001, 2000, and 1999, respectively.

At December 31, 2001, the Company's minimum future commitments under operating leases were as follows:

	Operating Leases
2002	\$ 779,000
2003	725,000
2004	750,000
2005	757,000
Thereafter	<u>2,186,000</u>
Total	<u>\$5,197,000</u>

#### 4. DEBT

In April 1999, the Company obtained a \$6.0 million secured revolving line of credit facility from its bank, Branch Banking and Trust Company. This facility may be used for working capital purposes and was extended in October 2000 for an additional 18 months and will now expire in April 2002. The Company anticipates that this line of credit will be renewed when it expires in April 2002. The entire unpaid balance of the line of credit then-outstanding plus accrued interest is due in full at maturity. Borrowings drawn down under this facility bear interest at a rate over LIBOR and are collateralized by a security interest in the Company's inventory and accounts receivable. At December 31, 2001, there were no outstanding borrowings under this credit facility.

#### 5. SHAREHOLDERS' EQUITY

At December 31, 2001, the Company had reserved a total of 2,022,138 shares of its Common Stock for future issuance as follows:

For exercise of Common Stock options and Bonus Stock .....	1,950,317
For possible future issuance to employees and others under employee stock purchase plans. ....	<u>71,821</u>
Total reserved .....	<u>2,022,138</u>

At December 31, 2001, the Company had no issued and outstanding warrants to purchase Common Stock.

In October 1998, the Company announced that the Board of Directors authorized a share repurchase program (the "1998 Repurchase Program") to purchase up to 10% of outstanding shares of Common Stock, or up to approximately 830,000 shares over 18 months, in open market or privately negotiated transactions. During the second quarter of 2000, Management was authorized by the Board of Directors to extend the stock repurchase program (the "2000 Repurchase Program"). This extension allowed for the purchase up to 6% of outstanding shares, or up to approximately 500,000 shares over 18 months in open market or privately negotiated transactions. During 2001, the Company repurchased 201,216 shares of its Common Stock for \$3.2 million at an average price of \$16.00 per share under the 2000 Repurchase Program, which ended during the fourth quarter of 2001. During the entire term of the 1998 Repurchase Program, the Company repurchased 830,000 shares of its Common Stock for \$9.0 million at an average price of \$10.80 per share. During the entire term of the 2000 Repurchase Program, the Company repurchased 345,216 shares of its Common Stock for \$5.2 million at an average price of \$15.08 per share.

## 6. STOCK OPTION PLANS

The Company has elected to follow Accounting Principles Board Option No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related Interpretations in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under FASB Statement No. 123, "Accounting for Stock-Based Compensation," requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized.

The Company's stock option plans provide for option grants designated as either non-qualified or incentive stock options. The options generally vest over a four-year period and expire ten years from the date of grant. In general, the exercise price of stock options is the closing price of the Company's Common Stock on the date of grant.

Most U.S. employees and certain employees outside the United States are eligible to receive a grant of stock options periodically with the number of shares generally determined by the employee's salary grade and performance level. In addition, certain management and professional level employees may receive a stock option grant upon hire. Non-employee directors of the Company receive annual grants of stock options in amounts specified in the applicable plan.

Stock option information with respect to all of the Company's stock option plans follows:

	<u>Number of Shares</u>	<u>Option Price Range per Share</u>	<u>Expiration Date</u>
Balance at December 31, 1998, outstanding options	1,294,539	\$2.00 to \$8.75	1999-2008
Granted	340,416	\$4.625 to \$6.125	
Exercised	(159,513)	\$2.00 to \$7.00	
Canceled	(75,412)	\$5.125 to \$7.125	
Balance at December 31, 1999, outstanding options	1,400,030	\$2.00 to \$8.75	2000-2009
Granted	407,328	\$10.50 to \$17.25	
Exercised	(354,692)	\$2.00 to \$10.50	
Canceled	(80,996)	\$5.00 to \$10.50	
Balance at December 31, 2000, outstanding options	1,371,670	\$ 2.00 to \$17.25	2001-2010
Granted	399,058	\$14.56 to \$15.94	
Exercised	(277,027)	\$ 2.00 to \$15.63	
Canceled	(15,947)	\$ 2.00 to \$17.25	
Balance at December 31, 2001, outstanding options	1,477,754	\$ 2.00 to \$17.25	2002-2011

An amendment in May 2000 to the Company's Incentive Stock Option and Nonstatutory Stock Option Plan increased the authorized grant of options to company personnel from 1.9 million shares of common stock up to 2.6 million shares. All options granted have ten-year terms and a four-year vesting schedule.

Pro forma information regarding net income and income per share is required by SFAS 123, and has been determined as if the Company accounted for its employee stock options granted subsequent to December 31, 1994 under the fair value method of SFAS 123. The fair value for these options was estimated at the date of grant using a Black-Scholes option-pricing model with the following weighted average assumptions:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Risk free interest rate	5.00%	6.62%	4.76%
Dividends	----	----	----
Volatility factor	0.420	0.500	0.500

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

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

For the year ended December 31

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Pro forma net income (in thousands)	\$6,473	\$5,464	\$5,017
Pro forma basic income per share.	\$0.81	\$0.69	\$0.62

At December 31, 2001, 2000, and 1999, exercisable options for 748,560, 727,789 and 857,962 shares, respectively were outstanding.

The exercise prices for options outstanding as December 31, 2001 ranged from \$4.63 to \$17.25 per share.

Exercise Price	Options Outstanding			Options Currently Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (yrs.)	Weighted Average Price	Number Exercisable	Weighted Average Exercise Price
\$4.63 – 6.89	765,666	5.49	\$5.83	600,522	\$6.01
\$7.00 – 14.56	327,104	7.79	11.34	109,613	10.97
\$14.67 – \$17.25	384,984	9.13	15.66	38,425	15.61
	1,477,754	6.95	9.40	748,560	7.14

The weighted average grant date fair value of options granted during 2001 was \$15.51.

## 7. EMPLOYEE STOCK PURCHASE PLAN

The Company maintains an Employee Stock Purchase Plan for its U.S.-based employees (the "U.S. Purchase Plan") and a similar plan for its employees outside the U.S. (the "Non-U.S. Purchase Plan") to provide an additional opportunity for the Company's employees to share in the ownership of the Company. Under terms of both plans, all regular full-time employees of the Company (or the Company's subsidiaries) may make voluntary payroll contributions thereby enabling them to purchase Common Stock. Contributions are limited to 20% of an employee's compensation. An amendment in May 2000 to the Company's Purchase Plans increased the maximum number of shares of Common Stock that may be purchased under the U.S. Purchase Plan from 100,000 to 200,000. Shares issued under the Non-U.S. Purchase Plan decrease the number of shares that may be issued under the U.S. Purchase Plan by a corresponding amount. Thus, the maximum number of shares that may be issued under both Purchase Plans together shall not exceed 200,000. The purchase price of the stock is the lesser of 85% of the Fair Market Value on the first business day of the Purchase Period or 85% of the Fair Market Value on the date of exercise which can be at any time during the Plan year.

Under the Purchase Plans, during 2001, 2000, and 1999, 16,811, 23,418 and 21,074 shares of Common Stock, respectively, were purchased. To date, 128,179 shares of Common Stock have been purchased.

## 8. 401(K) RETIREMENT SAVINGS PLAN

The Company has a 401(k) plan which is available to all employees upon employment who are at least 18 years of age. Employer contributions are voluntary at the discretion of the Company. The Company does not match any employee contributions with stock.

Company contributions amounted to \$274,361, \$178,436 and \$74,542 for the years ended December 31, 2001, 2000, and 1999, respectively.

## 9. INCOME TAXES

The components of income tax expense for the years ended December 31 are as follows:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Current:			
Federal	\$601,000	\$154,000	\$348,000
State	90,000	77,000	169,000
Foreign	<u>283,000</u>	<u>276,000</u>	<u>324,000</u>
	<u>\$974,000</u>	<u>507,000</u>	<u>\$841,000</u>

The Company's consolidated effective tax rate differed from the statutory rate as set forth below for the years ended December 31:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Federal taxes at statutory rate	\$3,047,000	\$2,427,000	\$2,178,000
State and local income taxes, net of Federal benefit	448,000	286,000	321,000
Non-deductible expenses	199,000	(138,000)	488,000
Foreign losses for which no benefit has been recognized	156,000	203,000	(67,000)
Change in valuation allowance	(3,159,000)	(2,547,000)	(2,403,000)
Alternative minimum and foreign withholding taxes	<u>283,000</u>	<u>276,000</u>	<u>324,000</u>
	<u>\$974,000</u>	<u>\$507,000</u>	<u>\$841,000</u>

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has no deferred tax liabilities. Significant components of the Company's deferred tax assets are as follows:

	<u>At December 31,</u>	
	<u>2001</u>	<u>2000</u>
Deferred tax assets:		
Book (under)/over tax depreciation and amortization	(\$921,000)	\$486,000
Net operating loss carryforwards	2,431,000	4,230,000
Research and experimental tax credit carryforwards	2,952,000	2,754,000
Charitable contributions carryforward	2,000	31,000
Accrued liabilities and reserves	(23,000)	99,000
Alternative Minimum Tax credit carryforward	<u>350,000</u>	<u>350,000</u>
Total deferred tax assets	\$4,791,000	\$ 7,950,000
Valuation allowance for deferred tax assets	(4,791,000)	(7,950,000)
Net deferred tax assets	-	-

During 2001 and 2000, the valuation allowance decreased by \$3,159,000 and \$2,547,000, respectively.

At December 31, 2001, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$6.4 million which are available to offset future taxable income. These net operating loss carryforwards expire during the years 2002 through 2006. Any loss carryforward amounts exceeding the limitation can be carried forward to future years within the carryforward period.

In addition, the Company has Research and Experimental Tax Credit carryforwards totaling approximately \$3.3 million which are available to offset future federal income taxes. These credits expire during the years 2002 through 2014.

#### 10. COMMITMENTS AND CONTINGENCIES

The Company is engaged in certain legal and administrative proceedings incidental to its normal business activities. While it is not possible to determine the ultimate outcome of those actions, in the opinion of management after discussion with legal counsel, it is unlikely that the outcome of such litigation and other proceedings will have a material adverse effect on the results of the Company's operations or its financial position.

#### 11. NET INCOME PER SHARE

The following table sets forth the computation of basic and diluted net income per share (in thousands, except per share amounts):

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Numerator:			
Net Income Available To Common Stockholders	\$7,967	\$6,631	\$5,744
Effect of dilutive securities:			
Numerator for diluted earnings per share-income available to common stockholders after assumed conversions	<u>\$7,967</u>	<u>\$6,631</u>	<u>\$5,744</u>
Denominator:			
Denominator for basic net income per share—weighted-average	8,007	7,901	8,151
Effect of Dilutive Securities:			
Employee Stock Options	636	714	336
Warrants	<u>1</u>	<u>24</u>	<u>1</u>
Dilutive Potential Shares	637	738	337
Denominator for diluted net income per share—adjusted weighted-average shares and assumed conversions	<u>8,644</u>	<u>8,639</u>	<u>8,488</u>
Basic net income per share	<u>\$1.00</u>	<u>\$0.84</u>	<u>\$0.70</u>
Diluted net income per share	<u>\$0.92</u>	<u>\$0.77</u>	<u>\$0.68</u>

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

**PART III**

**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

Information on the executive officers and directors is incorporated by reference from the Company's Proxy Statement (under the headings "Management" and "Proposal 1: Election of Directors," respectively), with respect to the Annual Meeting of Shareholders to be held on May 16, 2002, to be filed with the Securities and Exchange Commission.

**ITEM 11. EXECUTIVE COMPENSATION**

This information is incorporated by reference from the Company's Proxy Statement (under the heading "Executive Compensation"), with respect to the Annual Meeting of Shareholders to be held on May 16, 2002, to be filed with the Securities and Exchange Commission.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

This information is incorporated by reference from the Company's Proxy Statement (under the heading "Share Ownership of Management and Certain Beneficial Owners"), with respect to the Annual Meeting of Shareholders to be held on May 16, 2002, to be filed with the Securities and Exchange Commission.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Not applicable.

**PART IV**

**ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K**

(a)(1). The consolidated financial statements listed below are included in Item 8 of this report.

Report of Independent Auditors

Consolidated Financial Statements

Consolidated Balance Sheets at December 31, 2001 and 2000

Consolidated Statements of Operations for each of the three years ended December 31, 2001, 2000, and 1999

Consolidated Statements of Cash Flows for each of the three years ended December 31, 2001, 2000, and 1999

Consolidated Statements of Shareholders' Equity for each of the three years ended December 31, 2001, 2000, and 1999

Notes to Consolidated Financial Statements

(a)(2). Financial Statement Schedule

Schedule II - Valuation and Qualifying Accounts

(a)(3) The exhibits listed below are filed as part of this report. Executive compensation plans and arrangements are listed in Exhibits 10.14 through 10.42.

Exhibits	Description
3.1(1)	Restated Articles of Incorporation
3.2(2)	Articles of Amendment to Restated Articles of Incorporation, effective March 21, 1996
3.3(3)	Articles of Amendment to Restated Articles of Incorporation, effective May 28, 1996
3.4(4)	Amended and Restated Bylaws, effective September 21, 2000
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4
4.2(5)	Specimen of Common Stock Certificate
4.3(6)	Rights Agreement dated as of March 21, 1996 between Embrex and Branch Banking and Trust Company, as Rights Agent
10.1(7)	License Agreement dated December 11, 1991, between Embrex and the National Technical Information Service, a Primary operating unit of the United States Department of Commerce
10.2(7)	Collaborative Research Agreement dated January 17, 1989 between Embrex and the University of Arkansas
10.3(7)	License Agreement dated October 1, 1998 between Embrex and the National Technical Information Service, a Primary operating unit of the United States Department of Commerce
10.4(7)	Lease Agreement dated December 9, 1986 between Embrex, as tenant, and Imperial Center Partnership and Petula Associates, Ltd., as landlord, as amended by First Amendment dated June 11, 1987, Second Amendment dated December 1, 1988, and Third Amendment dated May 2, 1989
10.5(5)	Fourth Amendment of Lease dated October 1, 1994 between the Company and Glaxo Inc. (as successor in interest to Imperial Center Partnership and Petula Associates, Ltd.)
10.6(5)	Fifth Amendment of Lease dated December 13, 1996 between the Company and Glaxo Wellcome Inc. (as successor in interest to Glaxo Inc.)
10.7(8)	Lease for Royal Center II dated October 13, 1997 between the Company and Petula Associates, Ltd.
10.8(16)	Sublease Agreement dated October 1, 1999, between Embrex, as subtenant, and Wandel & Goltermann Technologies, Inc., as sublandlord
10.9(16)	First Amendment to Sublease Agreement dated February 29, 2000, among Wandel & Goltermann Technologies, Inc., Embrex and W & G Associates
10.10(7)	Facility Agreement dated March 1, 1991, between Embrex and Mississippi Agriculture and Forestry Experiment Station, Mississippi State University
10.11(7)	Unrestricted Grant Agreement dated April 1, 1988, between Embrex and North Carolina State University, as Amended by Amendment dated September 15, 1989 and Amendment dated April 22, 1991
10.12(7)	Unrestricted Grant Agreement dated November 1, 1986, between Embrex and North Carolina State University, as Amended by Amendment dated May 3, 1989, Amendment dated September 15, 1989, and Amendment dated April 22, 1991
10.13(7)	Basic Research Agreement dated October 24, 1989, between Embrex and University of Arkansas, as amended on October 23, 1990, February 1, 1991 and July 22, 1991
10.14(7)	1988 Incentive Stock Option Plan and form of Incentive Stock Option Agreement
10.15(7)	1989 Nonstatutory Stock Option Plan and form of Nonstatutory Stock Option Agreement
10.16(7)	1991 Nonstatutory Stock Option Plan and form of Nonstatutory Stock Option Agreement

- 10.17(9) Incentive Stock Option and Nonstatutory Stock Option Plan and forms of Stock Option Agreements - June 1993
- 10.18(3) Amendment dated May 16, 1996 to Incentive Stock Option and Nonstatutory Stock Option Plan - June 1993
- 10.19(10) Amended and Restated Incentive Stock Option and Nonstatutory Stock Option Plan - May 1998
- 10.20(13) Amended and Restated Incentive Stock Option and Nonstatutory Stock Option Plan - January 1999 and form Of Stock Option Agreement
- 10.21(11) Amended and Restated Incentive Stock Option and Nonstatutory Stock Option Plan - July 2000
- 10.22(5) Amended and Restated Employee Stock Purchase Plan - November 1996
- 10.23(11) Amended and Restated Employee Stock Purchase Plan - July 2000
- 10.24(11) Amended and Restated Employee Stock Purchase Plan for Non-U.S. Employees - July 2000
- 10.25(7) Employment Agreement dated November 15, 1989, between Embrex and Randall L. Marcuson
- 10.26(5) Amendment to Employment Agreement dated May 21, 1996 between Embrex and Randall L. Marcuson
- 10.27(5) Change In Control Severance Agreement dated May 21, 1996 between Embrex and Randall L. Marcuson
- 10.28(12) Amendment to Change in Control Severance Agreement dated October 1, 1998 between Embrex and Randall L. Marcuson
- 10.29(7) Employment Agreement dated October 16, 1989, between Embrex and Catherine A. Ricks
- 10.30(5) Change In Control Severance Agreement dated May 21, 1996 between Embrex and Catherine A. Ricks
- 10.31(12) Amendment to Change in Control Severance Agreement dated October 1, 1998 between Embrex and Catherine A. Ricks
- 10.32(2) General Provisions to Employment Agreement between Embrex and Brian V. Cosgriff dated August 18, 1995
- 10.33(5) Change In Control Severance Agreement dated May 21, 1996 between Embrex and Brian V. Cosgriff
- 10.34(12) Amendment to Change in Control Severance Agreement dated October 1, 1998 between Embrex and Brian V. Cosgriff
- 10.35(2) Terms and Conditions of Employment between Embrex Europe Limited and David M. Baines dated May 12, 1994
- 10.36(5) Change In Control Severance Agreement dated June 9, 1996 between Embrex and David M. Baines
- 10.37(12) Amendment to Change in Control Severance Agreement dated October 1, 1998 between Embrex and David M. Baines
- 10.38(5) Letter Agreement and General Provisions to Employment Agreement dated August 20, 1996 between Embrex and Don T. Seaquist and Amendment to Employment Agreement dated September 9, 1996 between Embrex and Don T. Seaquist
- 10.39(5) Change In Control Severance Agreement dated September 9, 1996 between Embrex and Don T. Seaquist
- 10.40(12) Amendment to Change in Control Severance Agreement dated October 1, 1998 between Embrex and Don T. Seaquist
- 10.41(12) Letter Agreement and General Provisions to Employment Agreement dated February 3, 1999 between Embrex and Brian C. Hrudka

10.42(12)	Change In Control Severance Agreement dated March 24, 1999 between Embrex and Brian C. Hrudka
10.43(13)	Agreement among Embrex, Micro Cap Partners, L.P., Palo Alto Investors, Inc., Walter Smiley and William L. Edwards dated as of April 18, 1999
10.44(13)	Indemnification Agreement among Embrex, Randall L. Marcuson, Charles E. Austin, C. Daniel Blackshear, Lester M. Crawford, Peter J. Holzer, Kenneth N. May, and Arthur M. Pappas dated as of April 1, 1999
10.45	Amendment to Indemnification Agreement among Embrex, John E. Klein and Walter V. Smiley dated as of May 17, 2001
10.46	Amendment to Indemnification Agreement between Embrex and Dr. Ganesh M. Kishore, Ph.D., dated as of February 14, 2002
10.47(15)	Letter Agreement among Embrex, Micro Cap Partners, L.P., Palo Alto Investors, Inc., and William L. Edwards dated as of February 11, 2000
10.48(8)	Inovoject® Egg Injection System Lease, Limited License, Supply and Service Agreement dated September 1, 1994 between Embrex and Tyson Foods, Inc. (asterisks located within the exhibit denote information which has been deleted pursuant to a request for confidential treatment filed with the Securities and Exchange Commission)
10.49(8)	Amendment dated March 26, 1997 to the Inovoject® Egg Injection System Lease, Limited License, Supply and Service Agreement dated September 1, 1994 between Embrex and Tyson Foods, Inc. (asterisks located within the exhibit denote information which has been deleted pursuant to a request for confidential treatment filed with the Securities and Exchange Commission)
10.50(2)	Limited License and Supply Agreement dated as of July 20, 1995 between Embrex and Webster
10.51(5)	Amendments dated August 1, 1996 and November 11, 1996 to Limited License and Supply Agreement dated as of July 20, 1995 between Embrex and Webster
10.52(2)	Agreement dated as of January 22, 1996 between Embrex and Select
10.53(2)	Letter Agreement dated as of January 22, 1996 between Select and Embrex
10.54(2)	License dated as of January 22, 1996 granted by Select to Embrex
10.55(14)	Loan Agreement between Embrex and Branch Banking and Trust Company dated as of April 7, 1999
10.56(17)	License and Royalty Agreement between Embrex and Pfizer, Inc. and its Affiliates dated as of June 22, 2001 (asterisks located within the exhibit denote information which has been deleted pursuant to a request for confidential treatment filed with the Securities and Exchange Commission)
10.57(18)	Credit Agreement between Embrex and Advanced Automation, Inc. dated as of April 1, 2001
10.58(18)	Amended and Restated Research, Development and Marketing Agreement between Embrex and LifeSensors, Inc. dated as of July 20, 2001 (asterisks located within the exhibit denote information which has been deleted pursuant to a request for confidential treatment filed with the Securities and Exchange Commission)
21	Subsidiaries
23	Consent of Ernst & Young LLP to the incorporation of their report dated February 22, 2001 with respect to the consolidated financial statements and schedule of Embrex, Inc. and subsidiaries included in this Form 10-K in the Registration Statements on Form S-3 (Registration Nos. 333-18231 and 333-31811), as filed with the Securities and Exchange Commission on December 19, 1996 and July 22, 1997, respectively, and into the Registration on Form S-8 (Registration Nos. 33-51582, 33-63318, 333-04109, 333-56279, and 333-42676), as filed with the Securities and Exchange Commission on September 1, 1992, May 25, 1993, May 20, 1996, June 8, 1998, and July 31, 2000, respectively.
24	Powers of Attorney (included in the signature page for this report)
99	Risk Factors relating to the Company

- (1) Exhibit to the Company's Form 10-K as filed with the Securities and Exchange Commission for fiscal year ending December 31, 1991 and incorporated herein by reference
  - (2) Exhibit to the Company's Form 10-K as filed with the Securities and Exchange Commission for the fiscal year ending December 31, 1995 and incorporated herein by reference
  - (3) Exhibit to the Company's Form 10-Q as filed with the Securities and Exchange Commission for the three months ended June 30, 1996 and incorporated herein by reference
  - (4) Exhibit to the Company's Form 10-Q as filed with the Securities and Exchange Commission for the three months ended September 30, 2000 and incorporated herein by reference
  - (5) Exhibit to the Company's Form 10-K as filed with the Securities and Exchange Commission for the fiscal year ending December 31, 1996 and incorporated herein by reference
  - (6) Exhibit to the Company's Registration Statement on Form 8-A as filed with the Securities and Exchange Commission on March 22, 1996 and incorporated herein by reference
  - (7) Exhibit to the Company's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission (Registration No. 33-42482) effective November 7, 1991 and incorporated herein by reference
  - (8) Exhibit to the Company's Form 10-K as filed with the Securities and Exchange Commission for the fiscal year ending December 31, 1997 and incorporated herein by reference
  - (9) Exhibit to the Company's Form 10-K as filed with the Securities and Exchange Commission for the fiscal year ending December 31, 1992 and incorporated herein by reference
  - (10) Exhibit to the Company's Registration Statement on Form S-8 as filed with the Securities and Exchange Commission (Registration No. 333-56279) effective June 8, 1998 and incorporated herein by reference
  - (11) Exhibit to the Company's Form S-8 as filed with the Securities and Exchange Commission on July 31, 2000 and incorporated herein by reference
  - (12) Exhibit to the Company's Form 10-K as filed with the Securities and Exchange Commission for the fiscal year ending December 31, 1998 and incorporated herein by reference
  - (13) Exhibit to the Company's Form 10-Q as filed with the Securities and Exchange Commission for the three months ended March 31, 1999 and incorporated herein by reference
  - (14) Exhibit to the Company's Form 10-Q as filed with the Securities and Exchange Commission for the three months ended June 30, 1999 and incorporated herein by reference
  - (15) Exhibit to the Company's Form 8-K as filed with the Securities and Exchange Commission on February 22, 2000 and incorporated herein by reference
  - (16) Exhibit to the Company's Form 10-K as filed with the Securities and Exchange Commission for the fiscal year ending December 31, 1999 and incorporated herein by reference
  - (17) Exhibit to the Company's Form 10-Q as filed with the Securities and Exchange Commission for the three months ended June 30, 2001 and incorporated herein by reference
  - (18) Exhibit to the Company's Form 10-Q as filed with the Securities and Exchange Commission for the three months ended September 30, 2001 and incorporated herein by reference
- (b). No reports on Form 8-K were filed during the last quarter of the fiscal year ended December 31, 2001.

## SIGNATURES AND POWER OF ATTORNEY

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

EMBREX, INC.

Date : March 22, 2002

By: /s/ Randall L. Marcuson  
Randall L. Marcuson  
President and Chief Executive  
Officer

We, the undersigned directors and officers of Embrex, Inc. (the "Company"), do hereby constitute and appoint Randall L. Marcuson and Don T. Seaquist or either of them, our true and lawful attorneys-in-fact and agents, with full power of substitution, to execute and deliver an Annual Report on Form 10-K pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Act"), with respect to the year ended December 31, 2001, to be filed with the Securities and Exchange Commission, and to do any and all acts and things and to execute any and all instruments for us and in our names in the capacities indicated below, which said attorneys-in-fact and agents, or either of them, may deem necessary or advisable to enable the Company to comply with the Act and any rules, regulations, and requirements of the Securities and Exchange Commission in connection with such Report, including without limitation the power and authority to execute and deliver for us or any of us in our names and in the capacities indicated below any and all amendments to such Report; and we do hereby ratify and confirm all that the said attorneys-in-fact and agents, or either of them, shall do or cause to be done by virtue of this power of attorney.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Randall L. Marcuson</u> Randall L. Marcuson	President, Chief Executive Officer and Director	March 22, 2002
<u>/s/ Don T. Seaquist</u> Don T. Seaquist	Vice President, Finance and Administration (Principal Financial and Accounting Officer)	March 22, 2002
<u>/s/ C. Daniel Blackshear</u> C. Daniel Blackshear	Director	March 22, 2002
<u>/s/ Peter J. Holzer</u> Peter J. Holzer	Director	March 22, 2002
<u>/s/ Ganesh M. Kishore, Ph.D.</u> Ganesh M. Kishore, Ph.D.	Director	March 22, 2002
<u>/s/ John E. Klein</u> John E. Klein	Director	March 22, 2002
<u>/s/ Arthur M. Pappas</u> Arthur M. Pappas	Director	March 22, 2002
<u>/s/ Walter V. Smiley</u> Walter V. Smiley	Director	March 22, 2002

## RISK FACTORS

IN ADDITION TO THE OTHER INFORMATION CONTAINED OR INCORPORATED BY REFERENCE IN THIS REPORT, YOU SHOULD CONSIDER THE FOLLOWING FACTORS CAREFULLY IN EVALUATING US AND OUR BUSINESS BEFORE MAKING AN INVESTMENT DECISION. IF ANY OF THE FOLLOWING RISKS OCCUR, OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS COULD BE MATERIALLY ADVERSELY AFFECTED.

**OUR FUTURE GROWTH DEPENDS ON EXPANSION OF INTERNATIONAL REVENUES AND WE WILL BE SUBJECT TO INCREASED RISKS IN THE INTERNATIONAL MARKETPLACE**

We estimate that our Inovoject® system inoculates more than 80% of all eggs produced for the North American broiler poultry market. Given this market penetration, we expect diminished growth in the number of system installations and only modest system revenue growth in this market. For this reason, we must expand our Inovoject® system installations and product sales in markets outside the United States and Canada in order to realize significant overall revenue growth. In 2001, sales outside of the United States accounted for 31% of our consolidated revenues, up from 29% in 2000 and 23% in 1999. Lack of market acceptance of our Inovoject® system and *in ovo* (“in the egg”) products in these markets would adversely affect our revenue growth. Revenue growth outside the United States and Canada depends on gaining market acceptance of the Inovoject® system and *in ovo* administration of biological products in markets outside the United States and Canada to treat prevailing poultry diseases in those markets.

International sales are also subject to a variety of risks, including risks arising from the following:

- currency fluctuations, trading restrictions, tariffs, trade barriers and taxes;
- adverse changes in local investment or exchange control regulations, potential restrictions on the flow of international capital, and the possibility of expropriation or confiscatory taxation or price controls; and
- economic and political conditions beyond our control, including country-specific conditions such as political instability, government corruption and civil unrest.

**OUR FUTURE GROWTH ALSO DEPENDS ON THE DEVELOPMENT AND MARKET ACCEPTANCE OF NEW PRODUCTS**

In addition to international expansion, we need to develop and market new products in order to continue to generate increased revenues and growth of our business. We currently are developing, both independently and in collaboration with others, various products which address poultry health and performance needs. Some of these products are being designed to be delivered *in ovo* through the Inovoject® system, and some may also be administered via injection after hatching. These products are in various stages of development. There is no guarantee that any new products will be successfully developed and marketed. In addition, we have not initiated the regulatory approval process for some of these potential products, and we cannot assure you that regulatory approval will be obtained. Our inability to develop new products or any delay in our development of them may adversely affect our revenue growth. Because of a number of factors, a new product may not reach the market without lengthy delays, if at all. Some of the factors which may affect our development and marketing of new products include the following:

- our research and evaluations of compounds and new technologies may not yield product opportunities;
- potential products may involve extensive and time-consuming clinical trials to demonstrate safety and effectiveness and the results of such trials are uncertain;

--potential products may require collaborative partners and we may be unable to identify partners or enter into arrangements on terms acceptable to us;

--we may not be able to contract for the manufacture of new products at a cost or in quantities necessary to make them commercially viable;

--regulatory approval of these products may not be obtained or may be obtained only with lengthy delays;

--we may not be able to secure additional financing that may be needed to bring a potential product to market;

--we may experience unexpected safety or efficacy concerns with respect to marketed products, whether or not scientifically justified, leading to adverse public reaction, product recalls, withdrawals or declining sales;

--marketing products developed jointly with other parties may require royalty payments or other payments by us to our co-developers, which may adversely affect our profitability;

--we may be unable to accurately predict market requirements and evolving standards; and

--we may not be able to attract and retain sufficient numbers of qualified development personnel.

We have developed and commercialized a technology using our proprietary viral neutralizing factor (VNF®). Our Bursaplex® product uses this technology. However, Bursaplex® has only been sold in commercial quantities during the past two years, and there is no assurance that the product will continue to be sold in commercial quantities.

As of July, 2001 we have submitted a registration application to the United States Department of Agriculture (USDA) for Newplex™, our *in ovo* Newcastle disease vaccine which like Bursaplex® is based on VNF® technology. Although this product has been submitted for registration there is no assurance that USDA approval will be obtained.

There can be no assurance that we will successfully complete the development and commercialization of any new products or that such products, if commercialized, will meet revenue and profit expectations.

#### WE FACE RISKS OF RAPIDLY CHANGING TECHNOLOGY AND COMPETITION

We are involved in areas of technology, which are subject to rapid and significant technological change. Competitors include independent companies that specialize in biotechnology as well as major chemical and pharmaceutical companies, universities, and public and private research organizations. Many of our competitors are well established and have substantially greater marketing, financial, technological and other resources than us. Competitive *in ovo* delivery methods, either within or outside the United States, are under development and may gain commercial acceptance. The poultry biological business is especially competitive and dominated by a few very large companies with an established global presence. Also, competitors may succeed in developing technologies and products that are more effective than any which have been or are being developed by us or which would render our technology and products obsolete or non-competitive. We may not be successful in establishing or maintaining technological competitiveness. Increased competition could mean lower prices for our products, reduced demand for our products and a corresponding reduction in our ability to recover development, engineering and manufacturing costs. Any of these developments could have an adverse effect on our business, results of operations and financial condition.

**WE DO NOT MANUFACTURE ANY OF OUR PRODUCTS AND ARE CURRENTLY  
DEPENDENT ON A SINGLE CONTRACT MANUFACTURER FOR INOVOJECT® SYSTEMS,  
FOR VNF® PRODUCTION, AND FOR BURSAPLEX® PRODUCTION**

We currently do not have large-scale facilities for the production of our Inovoject® system and biological products and do not plan to develop these facilities in the foreseeable future. Therefore, we will rely principally upon relationships with contract manufacturers. There can be no assurance that we can maintain manufacture and supply agreements on terms and at costs acceptable to us. We have various relationships with manufacturers and suppliers, including those described below. The loss of any of these relationships could adversely affect our operating results. There are a number of risks associated with our dependence on third-party manufacturers including:

- reduced control over delivery schedules;
- quality assurance;
- manufacturing yields and costs;
- the potential lack of adequate capacity during periods of excess demand;
- limited warranties on products supplied to us;
- increases in prices and the potential misappropriation of our intellectual property; and
- catastrophic loss of production capacity due to property damage, man made or by nature.

If our third-party manufacturers fail to provide us with an adequate supply of finished products, our business would be harmed. Except for our contract with SPAFAS for production of VNF®, we have no long-term contracts or arrangements with any of our vendors that guarantee product availability or the continuation of particular payment terms. In addition, we are currently dependent on a single contract manufacturer for several of our key products as described below. Although we believe our relationship with each of the manufacturers is sound, we cannot assure you that we will continue to maintain relationships with them or that they will continue to exist.

#### **Inovoject® System**

We rely on one contract manufacturer to fabricate all of our Inovoject® systems. While other machine fabricators exist and have constructed limited numbers of Inovoject® systems, we do not currently have alternative sources for production of the Inovoject® system. If our current fabricator is unable to carry out its manufacturing obligations to our satisfaction, we may be unable to obtain alternative manufacturing, or to obtain such manufacturing on commercially reasonable terms or on a timely basis. Any delays in the manufacturing process may adversely impact our ability to meet commercial demands for Inovoject® system installations and delay receipt of revenues from those installations.

#### **Biological Products**

We obtain all of our requirements for the active ingredient in VNF® (Viral Neutralizing Factor) from SPAFAS, Inc. (SPAFAS), a subsidiary of Charles River Laboratories, Inc. Under our agreement with SPAFAS, we maintain appropriate inventory levels and place orders with SPAFAS to allow us to satisfy anticipated customer demand for VNF®. The manufacture of our VNF® product generally must be performed in licensed facilities or under approved regulatory methods. The regulatory approval granted by the USDA for Bursaplex® in January 1997 specifically cover vaccines produced with SPAFAS-manufactured VNF®. Although there are other manufacturers who are capable of manufacturing VNF®, we do not currently have alternative sources for production of VNF®.

We obtain all of our requirements for Bursaplex® from Merial Select, Inc. (Select), a Merck and Aventis company. The manufacture of Bursaplex® must be performed in licensed facilities or under approved regulatory methods. Although there are other manufacturers who are capable of manufacturing IBD products, we do not currently have alternative sources for production of Bursaplex®.

If either SPAFAS or Select is unable to carry out its manufacturing obligations (described immediately above) to our satisfaction, we may be unable to obtain alternative manufacturing, or to obtain such manufacturing on commercially reasonable terms or on a timely basis. A change of supplier for the Company could adversely affect our future operating results due to the time it would take a new supplier to obtain regulatory approval by the USDA of its production process or manufacturing facilities. We could also be sued for breach under various contracts under which we are obligated to supply VNF® or Bursaplex® to third parties. If the terms of regulatory approvals in any foreign countries are only effective as to a product manufactured with SPAFAS VNF® or Bursaplex® as manufactured by Select, a change of manufacturer may also result in the need to reapply for approval in those countries and in the need to suspend sales of a product in those countries until new approvals could be secured based on the replacement manufacturer. Any delays in securing new approvals would have an adverse effect on our revenues and growth prospects. We cannot guarantee that we would be able to secure new approvals in every country or that such approvals would be granted in a timely fashion.

#### **WE ARE DEPENDENT ON DISTRIBUTORS IN CERTAIN MARKETS**

We market and distribute our Inovoject® system principally by leasing and licensing the systems directly to hatcheries. In some markets, such as Japan, we instead rely upon distributors for the Inovoject® system. We also rely on third parties to market certain biological products, such as products containing VNF®, and we may enter into other arrangements in the future. There can be no assurance that we can maintain these relationships on terms acceptable to us. The loss of any of these relationships could adversely affect our operating results. There are a number of risks associated with our dependence on distributors and other third parties including:

--reduced control over marketing and sales efforts and in turn the extent of resulting market penetration or acceptance;

--reduced control over distribution and related customer satisfaction; and

--potential delays in distribution associated with securing new distributors, if current relationships are not maintained.

#### **ECONOMIC FACTORS AFFECTING OUR CUSTOMERS MAY ADVERSELY AFFECT OUR FINANCIAL RESULTS**

Our revenues come from purchases by the poultry producing industry. If there is a general economic decline in that industry, our operations and financial condition could be materially and adversely affected. Also, domestic and global economic factors beyond our control may adversely impact our customers and, as a result, our revenues and earnings. Examples of these factors include the following:

--fluctuations in the price of poultry feed;

--market demand for poultry products, including the supply and pricing of alternative proteins; and

--the extent to which our cost of products and operating expenses increase faster than contractual price adjustments with our customers.

For example, if rising poultry feed prices increase the production costs of commercial poultry producers, these producers may reduce production. This decreased production could adversely impact our revenues, since a principal component of our revenues is fees charged to customers for the number of eggs injected by the Inovoject® system.

**POULTRY HEALTH AND DISEASE FACTORS AFFECTING OUR CUSTOMERS MAY ADVERSELY AFFECT OUR FINANCIAL RESULTS**

Any widespread poultry health problem or disease outbreak could have a negative impact on global poultry production. Revenues and earnings derived from both the U.S. and international poultry industry could be materially and adversely affected. In addition, the emergence of new disease variants, serotypes and strains in the domestic and/or global markets may reduce the efficacy of our biological products and result in reduced revenues and earnings.

**THE LOSS OF KEY CUSTOMERS COULD ADVERSELY AFFECT OUR FINANCIAL RESULTS**

Historically, a significant portion of our revenues has come from a relatively small number of customers. Tyson Foods, Inc. (Tyson) accounted for approximately 20 % of our consolidated 2001 revenues. Our top three customers, including Tyson, accounted for approximately 32% of our consolidated 2001 revenues, which is down from 34% in 2000 and 38% in 1999. We expect a similar level of customer concentration to continue in future years. The poultry market is highly concentrated, with the largest poultry producers dominating the market. For example, in 2001, Tyson supplied approximately 23% of all broilers grown in the United States. The concentration of our revenues with these large customers makes us particularly dependent on factors affecting those customers. If we lose a large customer and fail to add new customers to replace lost revenues, our operating results will be materially and adversely affected. Also, if these customers reduce the number of eggs they produce at hatcheries, we will receive lower Inovoject® system revenues since our fees are based on the number of eggs injected.

**IF WE LOSE THE PROTECTION OF OUR PATENTS AND PROPRIETARY RIGHTS, OUR FINANCIAL RESULTS COULD SUFFER**

Some of our products and processes used to produce our products involve proprietary rights, including patents. We own some of the technologies employed in these processes, and some are owned by others and licensed to us. The Inovoject® system utilizes a process that was patented by the USDA in the United States. We hold an exclusive license to this primary patent which expires in 2002. We have supplemented the USDA patent with additional U.S. and foreign patents covering specific design features of the Inovoject® system. However, there is a risk that a competitive system will be introduced after the primary patent expires.

We believe that patent protection of materials or processes we develop and any products that may result from the research and development efforts of our licensors and us are important to the possible commercialization of our products. The loss of the protection of these patents and proprietary rights could adversely affect our business and our competitive position in the market. The patent position of companies such as ours generally is highly uncertain and involves complex legal and factual questions. Some of the reasons for this uncertainty include the following:

--To date no consistent regulatory policy has emerged regarding the breadth of claims allowed in biotechnology patents. So, there can be no assurance that patent applications relating to our products or technology will result in patents being issued or that, if issued, the patents will afford protection against competitors with similar technology;

--Patent applications in the United States are maintained in secrecy until patents issue so we may not be aware that technology we use or independently discover is covered by the pending patent application of a third party;

--Some patent licenses held by us may be terminated upon the occurrence of specified events or become non-exclusive after a specified period;

--Companies that obtain patents claiming products or processes that are necessary for or useful to the development of our products could bring legal actions against us claiming infringement (though we currently are not the subject of any patent infringement claim);

--Issuance of a valid patent does not prevent other companies from using alternative, non-infringing technology so we cannot be sure that any of our patents (or patents issued to others and licensed to us) will provide significant commercial protection;

--We may not have the financial resources necessary to obtain patent protection in some countries or to enforce any patent rights we may hold;

--The laws of some foreign countries may not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting their proprietary rights in these foreign countries;

--We may be required to obtain licenses from others to develop, manufacture or market our products. We may not be able to obtain these licenses on commercially reasonable terms, and the patents underlying the licenses may not be valid and enforceable; and

--We also rely upon unpatented, proprietary technology, which we may not be able to protect fully if others independently develop substantially equivalent proprietary information or techniques, improperly gain access to our proprietary technology, or disclose this technology to others.

We attempt to protect our proprietary materials and processes by relying on trade secret laws and non-disclosure and confidentiality agreements with our employees and other persons with access to our proprietary materials or processes or who have licensing or research arrangements with us. We plan to continue to use these protections in the future but we cannot be sure that these agreements will not be breached or that we would have adequate remedies for any breach. Even with these protections, others may independently develop or obtain access to these materials or processes which may adversely affect our competitive position.

If we are sued for infringing the patent or other proprietary rights of a third party, we could incur substantial costs and diversion of management and technical personnel, whether or not the litigation is ultimately determined in our favor.

We have been involved in the patent litigation summarized below:

*Embrex v. Service Engineering Corporation and Edward G. Bounds, Jr.*

In September 1996, we filed a patent infringement suit against Service Engineering Corporation and Edward G. Bounds, Jr. in the U.S. District Court for the Eastern District of North Carolina. We made the following claims against the defendants:

--Their development of an *in ovo* injection device, designed to compete with our patented Inovoject® injection method, infringes at least one claim of the U.S. Patent No. 4,458,630 exclusively licensed to us for the *in ovo* injection of vaccines into an avian embryo (the Sharma Patent); and

--They violated the terms of a Consent Judgment and Settlement Agreement entered into with us in November 1995 in which prior litigation was concluded with Service Engineering Corporation and Edward G. Bounds, Jr. agreeing not to engage in future activities violating the Sharma Patent.

--We sought injunctive relief to prevent infringement of the Sharma Patent as well as monetary damages.

In November 1996, Service Engineering Corporation and Edward G. Bounds, Jr. responded to our suit by asserting various affirmative defenses and denying the substantive claims in our complaint.

This suit concluded on July 30, 1998 with a jury verdict in favor of us, which verdict:

--fully upheld the validity of all asserted claims of the Sharma Patent, finding that the defendants had willingly infringed all asserted claims of the patent;

--found that the defendants had breached the 1995 Consent Judgment and Settlement Agreement and that the breach was not in good faith; and

--awarded us damages of \$500,000 plus litigation expenses and court costs.

The Court entered a Judgment in favor of us on September 28, 1998, which included a monetary award of \$2,612,885 and an injunction prohibiting the defendants from practicing methods claimed in, or otherwise infringing, the Sharma Patent. This injunction will expire with the expiration of the Sharma Patent in June of 2002.

On October 28, 1998, Service Engineering Corporation and Edward G. Bounds, Jr. filed a notice of appeal in the U.S. Court of Appeals for the Federal Circuit seeking a reversal of the Judgment. In July 2000, the U.S. Court of Appeals for the Federal Circuit affirmed the district court's decision to award to Embrex litigation expenses plus interest valued at approximately \$1.5 million. In addition, the appeals court upheld the finding that Service Engineering Corporation and Edward Bounds had willfully infringed all asserted claims of the Sharma Patent. However, the appeals court vacated the award of direct infringement damages finding that the district court erroneously awarded direct damages without proper evidence to support the award. Therefore, the appeals court remanded that award (\$500,000 which was trebled) to the district court for further proceedings for determination of a reasonable royalty for the infringement of the patented method by Service Engineering Corporation and Edward G. Bounds, Jr. These proceedings were opened on August 28, 2000, but were stayed early in 2001 pending the conclusion of a bankruptcy proceeding initiated by Edward G. Bounds, Jr.

#### **Machining Technologies, Inc. v. Embrex**

On April 15, 1999, Machining Technologies, Inc. of Hebron, Maryland served on us a Complaint for Declaratory Judgment against us in the U.S. District Court for the District of Maryland. Machining Technologies, Inc. sought a declaration that the Sharma Patent is not infringed, invalid and/or not enforceable. Machining Technologies, Inc. was a manufacturer of egg injection machine parts to Edward G. Bounds, Jr. and Service Engineering Corporation. We believed that this action was without legal basis and, on June 4, 1999, filed a motion to dismiss this action. On March 7, 2000, the U.S. District Court for the District of Maryland granted our motion to dismiss this action and ordered this case closed.

#### **THE LOSS OF KEY COLLABORATORS AND OTHER KEY PARTIES COULD ADVERSELY AFFECT OUR FINANCIAL RESULTS**

We currently conduct our operations with various third-party collaborators, licensors or licensees. We plan to continue developing these relationships and believe our present and future collaborators, licensors and licensees will perform their obligations under their agreements with us, based on an economic motivation to succeed. However, financial or other difficulties facing these parties may affect the amount and timing of funds and other resources devoted by the parties under these agreements. In addition, disagreements may arise with these third parties which could delay or lead to the termination of the development or commercialization of new products, or result in litigation or arbitration, which would be time consuming and expensive. Thus, there is no assurance that we will develop any new products or generate any revenues from these collaborative agreements.

#### **WE ARE SUBJECT TO AN INHERENT RISK OF PRODUCT LIABILITY**

The development, manufacture, distribution and marketing of our products involve an inherent risk of product liability claims and associated adverse publicity. These claims may be made even with respect to those products that are manufactured in licensed and approved facilities or that otherwise possess regulatory approval for commercial sale. These claims could expose us to significant liabilities that could prevent or interfere with the development and marketing of our products. Product liability claims could require us to spend significant time and money in litigation or pay significant damages. Although we currently maintain liability insurance, which we believe is adequate to cover the Company's potential exposure in this area, there can be no assurance that the coverage limits of our policies will be adequate. Such insurance is expensive, difficult to obtain and may not continue to be available on acceptable terms or at all.

## GOVERNMENT REGULATION AND THE NEED FOR REGULATORY APPROVAL MAY ADVERSELY AFFECT OUR BUSINESS

Regulatory approval required in various areas of our business may adversely affect our operations. The primary emphasis of these requirements is to assure the safety and effectiveness of our products. While the use of the Inovoject® system is not subject to regulatory approval in the United States, it may require regulatory approval by foreign agencies. Also, research and development activities and the investigation, manufacture and sale of poultry health and performance enhancement products are subject to regulatory approval in the United States by either the USDA or the United States Food & Drug Administration (FDA) and state agencies, as well as by foreign agencies. Obtaining regulatory approval is a lengthy, costly and uncertain process. Approval by the USDA generally takes 1 to 3 years, while approval by the FDA generally takes 5 or more years. Various problems may arise during the regulatory approval process and may have an adverse impact on our operations. Changes in the policies of U.S. and foreign regulatory bodies could increase the time required to obtain regulatory approval for each new product. Delays in obtaining approval may adversely affect the marketing of, and the ability to receive revenues and royalties from, products developed by us. There is no assurance that any future products developed by us or by our collaborative partners will receive regulatory approval without lengthy delays, if at all. Even when approved, regulators may impose limitations on the uses for which the product may be marketed and may continue to review a product after approving it for marketing. Regulators may impose restrictions and sanctions, including banning the continued sale of the product, if they discover problems with the product or its manufacturer.

Pursuant to some of our licensing or joint development agreements, the licensees or joint developers bear the costs associated with the regulatory approval process for some products. We plan to continue to enter into these types of agreements in the future. If we cannot generate sufficient funds from operations or enter into licensing or joint development agreements to develop products, we may not have the financial resources to complete the regulatory approval process with respect to all or any of the products currently under development. We must obtain approval from appropriate regulators before we can sell our products in a particular jurisdiction.

Other regulations apply or may apply to research and manufacturing activities, including federal, state and local laws, regulations and recommendations relating to the following:

- safe working conditions;
- laboratory and manufacturing practices; and
- use and disposal of hazardous substances used in conjunction with research activities.

It is difficult to predict the extent to which these or other government regulations may adversely impact the production and marketing of our products.

## OUR INABILITY TO ATTRACT AND RETAIN KEY PERSONNEL COULD ADVERSELY AFFECT OUR BUSINESS

We must continue to attract and retain experienced and highly educated scientific and management personnel and advisors to be able to develop marketable products and maintain a competitive research and technological position. Competition for qualified employees among biotechnology companies is intense. There can be no assurance that we will be able to continue to attract and retain qualified staff. The departure of any key executive or our inability to recruit and retain key scientific or management personnel could have an adverse affect on our business, results of operations or financial condition. Our ability to replace key individuals may be difficult and may take an extended period of time because of the limited number of individuals in the biotechnology industry with the breadth of skills and experience required to develop and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such individuals. We have obtained insurance in the amount of \$1,000,000 on the life of Randall L. Marcuson, our President and Chief Executive Officer, of which we are the sole beneficiary. This amount may not be sufficient to compensate us for the loss of his services.

**IF WE CANNOT CONTINUE TO PROVIDE TIMELY SUPPORT AND MAINTENANCE TO OUR CUSTOMERS, OUR BUSINESS MAY SUFFER**

We are required to supply, support, and maintain large numbers of Inovoject® systems at our customers' hatcheries on a timely basis at a reasonable cost to us. There can be no assurance that we will be able to continue to provide these services on a cost-effective basis. If we are unable to do so, our customers may reduce their use of our products, which could adversely affect our operating results.

**WE HAVE ANTI-TAKEOVER DEFENSES THAT COULD DISCOURAGE OR DELAY A TAKEOVER**

Provisions of our certificate of incorporation and bylaws could have the effect of discouraging or delaying an acquisition of our company. For example, the Board of Directors has the authority to issue up to 15,000,000 shares of Preferred Stock in one or more series and to determine the designations, preferences and relative rights and qualifications, limitations or restrictions of the shares constituting any series of Preferred Stock, without any further vote or action by the shareholders. The issuance of Preferred Stock by the Board of Directors could affect the rights of the holders of Common Stock. For example, an issuance could result in a class of securities outstanding that would have preferences with respect to voting rights and dividends and in liquidation over the Common Stock, and could (upon conversion or otherwise) enjoy all of the rights applicable to Common Stock. The authority of the Board of Directors to issue Preferred Stock potentially could be used to discourage attempts by others to obtain control of us through merger, tender offer, proxy contest or otherwise by making these attempts more difficult to achieve or more costly. The Board of Directors may issue the Preferred Stock without shareholder approval and with voting and conversion rights which could adversely affect the voting power of the holders of Common Stock. No agreements or understandings currently exist for the issuance of Preferred Stock, and the Board of Directors has no present intention to issue any Preferred Stock. We adopted a shareholder rights plan which could have the effect of discouraging a takeover of us. The rights plan, if triggered, would make it more difficult to acquire us by, among other things, allowing existing shareholders to acquire additional shares at a substantial discount, thus substantially inhibiting an acquiror's ability to obtain control of us.

## Corporate Information

### DIRECTORS

C. Daniel Blackshear<sup>2</sup>  
*President and  
Chief Executive Officer*  
Carolina Turkeys

Lester M. Crawford,  
DVM, Ph.D.  
(resigned  
February 22, 2002)  
*Deputy Commissioner*  
Food and Drug  
Administration

Peter J. Holzer<sup>1,2\*</sup>  
*Chairman of the Board*  
*Advisory Director*  
AMT Capital  
Management, LLC

Ganesh M. Kishore, Ph.D.  
(elected January 2002)  
*Principal and Chief  
Scientist*  
Auxyn Bioscience  
Ventures, LP

John E. Klein<sup>1,2</sup>  
*President*  
Bunge Corporation

Randall L. Marcuson  
*President and Chief  
Executive Officer*  
Embrex, Inc.

Arthur M. Pappas<sup>1</sup>  
*Chairman and  
Chief Executive Officer*  
A. M. Pappas &  
Associates, LLC

We would like to welcome Dr. Ganesh Kishore to our Board of Directors. He has an outstanding track record of scientific accomplishment and product commercialization and we look forward to his contribution to Embrex.

The Board of Directors would like to acknowledge the service of Lester Crawford and Arthur Pappas. Dr. Crawford has resigned to take a position with the Food and Drug Administration. He has contributed significantly with his regulatory insight and animal health industry knowledge. Mr. Pappas will not stand for re-election. He has been a valuable asset to Embrex with his broad knowledge of the human pharmaceutical and biotechnology industries as well as his venture experience. The Board wishes them much success.

1 Member, Compensation Committee (\*Chairman)

2 Member, Audit Committee (\*Chairman)

Walter V. Smiley<sup>1</sup>  
*President*  
Smiley Investment  
Company

### OFFICERS

David M. Baines, Ph.D.  
*Vice President, Global  
Marketing and Sales*

Brian V. Cosgriff  
*Vice President, Sales and  
Marketing, North  
America*

Brian C. Hrudka  
*Vice President, Global  
Product Development  
and Supply*

Randall L. Marcuson  
*President and Chief  
Executive Officer*

Catherine A. Ricks, Ph.D.  
*Vice President, Research  
and Development*

Don T. Seaquist  
*Vice President, Finance  
and Administration and  
Corporate Secretary*

### TRADEMARKS

Embrex<sup>®</sup>  
Inovoject<sup>®</sup>  
VNP<sup>®</sup>  
Bursaplex<sup>®</sup>  
Vaccine Saver<sup>®</sup>  
Egg Remover<sup>™</sup>  
Newplex<sup>™</sup>  
The In Ovo Company<sup>SM</sup>

### CORPORATE OFFICES

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Post Office Box 13989  
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Fax (919) 941-5186  
www.embrex.com

### REGISTRAR AND TRANSFER AGENT

Branch Banking and Trust Company  
Corporate Trust Department  
223 West Nash Street  
Wilson, North Carolina 27893  
Telephone (800) 213-4314  
Fax (252) 246-4890

### INDEPENDENT AUDITORS

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Highwoods Tower One, Suite 700  
3200 Beechleaf Court  
Raleigh, North Carolina 27604-1063

### CORPORATE COUNSEL

Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, LLP  
2500 First Union Capitol Center  
Raleigh, North Carolina 27601

### INVESTOR RELATIONS INQUIRIES

Ellen T. Corliss  
*Vice President, Investor Relations and  
Corporate Communications*  
Embrex, Inc.  
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Fax (919) 941-5186  
E-mail [ir@embrex.com](mailto:ir@embrex.com)  
NASDAQ Ticker Symbol: EMBX

### ANNUAL MEETING OF SHAREHOLDERS

The annual meeting of shareholders will be held at 9 a.m., May 16, 2002 at the North Carolina Biotechnology Center, 15 Alexander Drive, Research Triangle Park, North Carolina. Telephone (919) 541-9366. For directions, go to [www.ncbiotech.org](http://www.ncbiotech.org), click on About Us, then click on Directions.

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