

ESPERION THERAPEUTICS INC/MI

Form 10-K

March 26, 2003

**Table of Contents**

---

---

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

**For the fiscal year ended: December 31, 2002, OR**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number: 001-16033

**ESPERION THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State of incorporation)

**38-3419139**  
(I.R.S. Employer Identification No.)

**3621 South State Street**

**695 KMS Place**  
**Ann Arbor, Michigan 48108**  
**(734) 332-0506**

(Address of principal executive offices, including zip code, and telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class: **None**

Name of each exchange on which registered: **None**

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock, \$0.001 par value**  
(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

## Edgar Filing: ESPERION THERAPEUTICS INC/MI - Form 10-K

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.  Yes  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act).  Yes  No

The aggregate market value of the voting stock of the registrant held by non-affiliates of the registrant as of June 28, 2002, computed by reference to the closing price on The Nasdaq National Market® on such date, was approximately \$151,512,467.

The number of outstanding shares of the registrant's common stock, as of March 1, 2003, was 29,401,966.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2003 Annual Meeting of Stockholders are incorporated by reference into Part III and certain documents are incorporated by reference into Part IV.

---

---

---

**TABLE OF CONTENTS**

**PART I**

Item 1. Business

**PART II**

Item 6. Selected Consolidated Financial Data

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Item 8. Financial Statements and Supplementary Data

**INDEX TO FINANCIAL STATEMENTS**

**REPORT OF INDEPENDENT ACCOUNTANTS**

**CONSOLIDATED BALANCE SHEETS**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

**PART III**

Items 10, 11, 12 and 13. Directors and Executive Officers of the Registrant; Executive Compensation; Security Ownership of Certain Beneficial Owners and Management; Certain Relationships and Related Transactions

Item 14. Controls and Procedures

**PART IV**

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

**SIGNATURES**

**INDEX TO EXHIBITS**

Second Amendment to Commercial Sublease Agreement

Lease Extension - Third Renewal Term

Employment Arrangement Between Roger S. Newton

Employment Arrangement Between Timothy M. Mayleben

Employment Arrangement Between Brian R. Krause

Employment Arrangement Between Jean-Louis Dasseux

Employment Arrangement Between Frank Thomas

Subsidiaries

Consent of PricewaterhouseCoopers LLP

Certification Pursuant to Section 906

Certification Pursuant to Section 906

---

**Table of Contents**

**ESPERION THERAPEUTICS, INC.**

**FORM 10-K**

**TABLE OF CONTENTS**

	<b>Page</b>
	<b><u>        </u></b>
<b>PART I</b>	
Item 1. Business	1
Item 2. Properties	26
Item 3. Legal Proceedings	27
Item 4. Submission of Matters to a Vote of Security Holders	27
<b>PART II</b>	
Item 5. Market for Registrant's Common Equity and Related Stockholder Matters	28
Item 6. Selected Consolidated Financial Data	29
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	31
Item 7A. Quantitative and Qualitative Disclosures about Market Risk	38
Item 8. Financial Statements and Supplementary Data	39
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	63
<b>PART III</b>	
Item 10. Directors and Executive Officers of the Registrant	63
Item 11. Executive Compensation	63
Item 12. Security Ownership of Certain Beneficial Owners and Management	63
Item 13. Certain Relationships and Related Transactions	63
Item 14. Controls and Procedures	63
<b>PART IV</b>	
Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K	64
SIGNATURES	69

---

## **Table of Contents**

### **Forward-Looking Information is Subject to Risk and Uncertainty**

The information contained in this report includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, as enacted by the Private Securities Litigation Reform Act of 1995. These forward-looking statements are often identified by words such as hope, may, believe, anticipate, plan, expect, require, assume and similar expressions. We caution readers that forward-looking statements speak only as of the date of this filing, reflect management's current expectations, estimations and projections and involve certain factors, such as risks and uncertainties, that may cause our actual results, performance or achievements to be far different from those suggested by our forward-looking statements. These factors include, but are not limited to, risks associated with: our ability to successfully execute our business strategies, including entering into any strategic partnerships or other transactions; the progress and cost of development of our product candidates; the extent and timing of market acceptance of new products developed by us or by our competitors; dependence on third parties to conduct clinical trials for our product candidates; the extent and timing of regulatory approval, as desired or required, for our product candidates; dependence on licensing arrangements and other strategic relationships with third parties; clinical trials; manufacturing; dependence on patents and proprietary rights; procurement, maintenance, enforcement and defense of our patents and proprietary rights; competitive conditions in the industry; business cycles affecting the markets in which any of our future products may be sold; extraordinary events and transactions; seeking and consummating business acquisitions, including the diversion of management attention to the assimilation of the operations and personnel of any acquired business; the timing and extent of our financing needs and our access to funding, including through the equity market; fluctuations in foreign exchange rates; and economic conditions generally or in various geographic areas. All of the foregoing factors are difficult to forecast. These risks and uncertainties are discussed below in the section entitled Factors Affecting our Future Prospects. We do not intend to update any of these factors or to publicly announce the results of any revisions to any of these forward-looking statements other than as required under the federal securities laws.

## **PART I**

### **Item 1. Business**

#### **Overview**

Esperion Therapeutics, Inc. is a biopharmaceutical company dedicated to the discovery and development of HDL-targeted therapies for the treatment of cardiovascular disease. We have focused our initial drug discovery and development activities on a novel class of drugs to treat acute and chronic cardiovascular disease. We intend to commercialize a novel class of drugs that focus on a new treatment approach that we call HDL Therapy, which is based upon our understanding of high density lipoprotein, or HDL, function. Through HDL Therapy, we intend to exploit, with a portfolio of product candidates, the beneficial properties of HDL in cardiovascular disease.

We are currently developing four product candidates, including three biopharmaceuticals: ETC-588, or LUV; ETC-216, or AIM; and ETC-642, or RLT Peptide; and one oral small molecule, now designated ETC-1001 (previously designated ESP 31015). The biopharmaceuticals are currently being developed for the acute treatment of high-risk atherosclerosis, such as acute coronary syndromes, while the small molecule will target chronic treatment of risk factors associated with cardiovascular disease. Each of these product candidates, as explained in detail under

Our Products in Development, is designed to enhance the naturally occurring processes in the body that remove excess cholesterol from artery walls and other tissues. The current development status of our three biopharmaceutical product candidates, which are in the clinical phase of development, and our small molecule product candidate is as follows:

*ETC-588 (Phase II):* We continue to enroll patients in two Phase II clinical trials for ETC-588. These two trials were initiated in 2002: one trial in patients with carotid atherosclerosis and the other trial in patients with acute coronary syndromes.

**Table of Contents**

*ETC-216 (Phase II):* We completed enrollment in March 2003 for a Phase II clinical trial for ETC-216. This study was initiated in late 2001 in patients with acute coronary syndromes.

*ETC-642 (Phase I):* A Phase I clinical trial was completed for ETC-642 in 2002 in patients with stable cardiovascular disease. A second Phase I clinical trial for ETC-642 was initiated in 2002 in patients with stable cardiovascular disease.

*ETC-1001 (Pre-clinical):* We plan to initiate our first clinical trial for ETC-1001 in the second quarter of 2003, pending United States Food and Drug Administration, or FDA, acceptance of an Investigational New Drug, or IND, application for this product candidate. We expect to continue clinical testing of the three biopharmaceutical product candidates throughout 2003.

Our product development to date has used in vitro assays, testing procedures performed outside the body, animal models and human clinical testing. Clinical and pre-clinical studies suggest that our product candidates increase HDL-cholesterol, or HDL-C, or its function, and enhance the removal of excess cholesterol and other lipids from artery walls and other tissues. Preliminary results in early clinical trials indicate that ETC-588, ETC-642 and ETC-216 increase the mobilization of cholesterol, or the removal of cholesterol from arteries and other tissues and delivery of cholesterol to the liver, as evidenced by measurements of the amount of cholesterol in the blood both before and after administration. Third-party published reports of preliminary human clinical studies of compounds that are similar in function and composition to some of our product candidates suggest that these compounds may increase elimination of cholesterol from the body by enhancing the efficiency of the reverse lipid transport, or RLT, pathway. We believe that the therapies that we are developing could enhance the naturally occurring processes in the body for the removal of excess cholesterol and other lipids from artery walls. We believe that this removal of excess cholesterol from the body will lead to improvements in vascular structure by stabilizing vulnerable plaque, which could ultimately lead to a reduction in clinical events resulting from cardiovascular disease, including atherosclerosis. Our clinical development plans are focused on planning and conducting clinical trials to assess the benefit of treatment with our product candidates.

We are also pursuing the discovery and development of orally active organic small molecules designed to increase HDL-C levels and/or enhance the function of HDL to stimulate the RLT pathway, as well as decrease LDL cholesterol, or LDL-C, and triglycerides, another type of lipid, or fat. We believe that some of these small molecules may also possess anti-diabetic and anti-obesity properties. We have implemented several strategies to develop potential small molecule product candidates based on well-known mechanisms by which HDL is produced in the body. One strategy has yielded several classes of active molecules. We believe that our drug discovery technologies and scientific and drug development expertise have potential applicability to the discovery and development of therapies for a broad range of cardiovascular diseases, including treatments for coronary heart disease, peripheral arterial disease (atherosclerosis occurring in arteries near the body's extremities) and stroke.

We were incorporated in Delaware and commenced operations in July 1998. We became a public company in August 2000 and our common stock trades on The Nasdaq National Market under the symbol *ESPR*. Our executive offices and primary research facility are located at 3621 South State Street, 695 KMS Place, Ann Arbor, Michigan 48108, our telephone number is (734) 332-0506 and our website is [www.esperion.com](http://www.esperion.com).

**Background**

*General*

The cardiovascular system is comprised of the heart and blood vessels and delivers oxygen and other nutrients to the tissues and organs of the body, such as the brain, kidneys and lungs; in addition, it is able to remove waste products. The heart propels blood through a network of arteries and veins. The kidneys regulate the blood volume, and the lungs put oxygen in the blood and remove carbon dioxide. To accomplish these tasks, the cardiovascular system must maintain adequate blood flow, which can be dramatically reduced by the excessive deposit of a type of lipid, or fat, called cholesterol within artery walls in vulnerable plaque.

## **Table of Contents**

Cholesterol is essential for cells to function normally. Our bodies obtain cholesterol both through the foods we eat and by manufacturing cholesterol inside some of our cells and organs. Cholesterol either remains within the cell or is transported by the blood to various organs. The major carriers for cholesterol in the blood are lipoproteins, which are particles composed of fat and protein, including low density lipoprotein, or LDL, and high density lipoprotein, or HDL. LDL delivers cholesterol to organs where it can be used to produce hormones, maintain healthy cells or be transformed into natural products that assist in the digestion of other lipids. HDL removes excess cholesterol from arteries and tissues and transports it to the liver for elimination from the body.

The RLT pathway consists of a four-step process responsible for removing excess cholesterol and other lipids from artery walls and other tissues and transporting them to the liver for elimination from the body. The first step is the removal of cholesterol from artery walls and other tissues by HDL in a process called cholesterol removal. In the second step, cholesterol is converted to a new form that is more tightly associated with HDL as it is carried in the blood; this process is called cholesterol conversion. The third step is the transport and delivery of that converted cholesterol to the liver in a process known as cholesterol transport. The final step is the transformation and discarding of cholesterol by the liver in a process called cholesterol elimination. We believe our product candidates have the potential to enhance the effectiveness of these four steps in the RLT pathway in humans.

In a healthy human body, there is a balance between the delivery and removal of cholesterol. Over time, however, an imbalance can occur in our bodies in which there is too much cholesterol delivery by LDL and too little removal by HDL. When people have a high level of LDL-C, and a low level of HDL-C, the imbalance results in more cholesterol being deposited in artery walls than being removed. This imbalance can also be exaggerated by, among other factors, age, gender, high blood pressure, smoking, diabetes, obesity, genetic factors, physical inactivity and consumption of a high-fat diet. The excess cholesterol carried in the blood in LDL particles can be deposited throughout the body, but frequently ends up in artery walls, especially those in the heart. As a consequence, repeated deposits of cholesterol, called plaque, form and can narrow or block the arteries, possibly leading to a heart attack or stroke. The plaque can also accumulate in artery walls leaving them vulnerable to rupture, which could also lead to a heart attack.

### *Cardiovascular Disease*

According to the American Heart Association, cardiovascular disease is the number one killer of American men and women. It is estimated that in 2003, the direct and indirect annual cost of cardiovascular disease will be \$350 billion, of which an estimated \$37 billion will be spent on drug therapy. The most prominent form of cardiovascular disease is atherosclerosis, a systemic disease that includes the buildup of plaque in artery walls limiting blood flow to the heart, brain, other vital organs and extremities. Atherosclerosis can result in heart attacks, chest pain and a variety of other complications, and is responsible for over half of all deaths from cardiovascular disease.

### *Importance of HDL in Cardiovascular Disease*

Physicians recognize high LDL-C and low HDL-C levels as independent risk factors for cardiovascular disease. In addition, high HDL-C levels generally are associated with reduced risk of cardiovascular disease. Clinical studies have suggested that:

*Low levels of HDL-C are a risk factor for coronary heart disease.* The first study suggesting that people with low HDL-C had increased risk of atherosclerotic cardiovascular disease was reported in 1951. Since that time, a number of studies have confirmed that a low HDL-C level is an independent risk factor for coronary heart disease.

*Increasing HDL-C reduces risk of coronary heart disease.* The Helsinki Heart Study, completed in 1987, suggested that increasing HDL-C levels reduced the risk of coronary heart disease in individuals at risk due to low HDL-C, high LDL-C, and high triglycerides, another type of lipid.



## **Table of Contents**

*Increasing HDL-C levels reduces the risk of death from coronary artery disease, heart attack or stroke.* The Veterans Affairs Cooperative Studies Program High Density Lipoprotein Cholesterol Intervention Trial, completed in 1999, suggested that men with coronary artery disease who took a lipid regulating drug for five years experienced on average a 6% increase in HDL-C, resulting in a 24% risk reduction in death due to coronary artery disease, heart attack or stroke.

*Low levels of HDL-C translate to a low survival rate following coronary artery bypass surgery.* A 20-year study completed by The Cleveland Clinic Foundation in 1999 suggested that people with low HDL-C levels have a lower survival rate following coronary artery bypass surgery.

In addition, published pre-clinical studies by third parties suggest other protective properties of HDL, such as reducing inflammation in arteries and reducing cholesterol deposits in artery walls.

## **Current Treatments for Cardiovascular Disease**

Treatments are either short-term solutions, termed acute, or long-term solutions, termed chronic. Acute treatments are reserved for more life-threatening cardiovascular conditions, such as a heart attack, a condition where there is a shortage of oxygen-rich blood available to the heart. In contrast, chronic treatments are used to prevent cardiovascular disease from worsening and having to resort to acute treatments. Current acute treatments may include costly invasive procedures, while chronic treatments are usually in tablet or pill form. Chronic treatments have focused more on stable atherosclerosis and have been successful at showing clinical benefit over long periods of time (i.e., months or years). We believe that current trends indicate a growing interest in finding successful treatments for unstable acute coronary syndromes and that achieve clinical benefits in short periods of time (i.e., days or weeks) rather than months or years.

### *Acute Treatments*

Acute treatments are required when blood flow to the heart is severely restricted and the patient is at immediate risk for further complications. Two of the most common invasive procedures used to restore blood flow are coronary artery bypass surgery, or CABG, and percutaneous coronary intervention (PCI) (i.e., balloon angioplasty, with or without stents). In bypass surgery, a cardiovascular surgeon opens the patient's chest cavity to expose the heart and redirects blood flow around the blocked arteries by grafting a healthy vessel removed from another location in the patient. In PCI, a cardiovascular surgeon inserts a long, thin flexible tube with an inflatable balloon at its end through a leg artery and advances the tube to the heart to position it in the artery at the point of blockage. The balloon is then inflated and this pushes aside the plaque that caused the blockage, usually resulting in a reopening of the artery to allow greater blood flow. Frequently, a cardiologist reinforces the newly opened artery with a wire-mesh cylinder called a stent. More recently, drug-coated stents have been introduced to prevent restenosis (re-closure of the artery). In addition, patients with acute coronary syndromes may be prescribed agents, as recommended in the American College of Cardiology and American Heart Association guidelines for the treatment of acute coronary syndromes, including aspirin, clopidogrel, heparin, nitrates, gpIIb/IIIa inhibitors, beta-blockers, fibrinolytic therapy, statins and ACE inhibitors. Despite these many treatments and/or procedures, a short-term risk for recurrent clinical events still exists.

The primary benefit of successful acute treatments is the immediate restoration of oxygen-rich blood flow to the heart. However, the major drawbacks are that:

These invasive procedures, by their nature, involve a risk of complications, including death.

There is significant recovery time after coronary artery bypass surgery.

These invasive procedures are very costly. According to the American Heart Association, it is estimated that in 2000, 519,000 coronary artery bypass surgeries were performed on 314,000 patients in the United States with an average cost of about \$45,000. In 2000, approximately 561,000 PCI procedures were performed in the United States. The average cost of a PCI is \$20,000 and more when a stent is used.

## **Table of Contents**

Many patients are not eligible for these invasive procedures due to their medical and/or treatment history and physical condition.

These invasive procedures are localized and treat only one segment of a diseased artery at a time, and, since atherosclerosis affects the entire cardiovascular system, many additional vulnerable arteries are left untreated after using these procedures.

### *Chronic Treatments*

The initial recommendation for a patient with elevated LDL-C, a well-known risk factor for cardiovascular disease, is frequently a change in lifestyle involving exercise combined with a low-fat, low-cholesterol diet. If a patient's cholesterol level does not improve, then the patient's physician moves to the next step of treatment to achieve acceptable levels of cholesterol in the blood.

Chronic treatments for cardiovascular disease have the goal of preventing or limiting progression of the disease to reduce risk of heart disease, disability or death. Physicians frequently will prescribe a statin that lowers the level of LDL-C in the blood by inhibiting cholesterol production in the liver. Statins can also modestly lower triglycerides, another type of lipid, and have the ability to slightly raise HDL-C. Recent studies have shown that statins reduce the risk of illness or death from cardiovascular disease by approximately 30%. In clinical studies, statins have been shown to reduce the rate of progression of atherosclerosis in a majority of patients. However, statins have not been consistent in demonstrating regression of atherosclerotic disease.

## **Our Strategy**

The key elements of our business strategy are as follows:

*Develop a portfolio of novel drug candidates focused on enhancing reverse lipid transport (RLT) utilizing the beneficial properties of HDL.* Based on our understanding of the RLT pathway, we are developing a portfolio of product candidates that we believe could provide a broad spectrum of treatment options for patients with cardiovascular disease. These product candidates are focused on improving HDL function in the RLT pathway and removing excess cholesterol from artery walls and other tissues. Our portfolio currently consists of three distinct types of HDL therapies: HDL mimetics (ETC-216 and ETC-642), cholesterol sponges (ETC-588) and oral small molecules that stimulate the RLT pathway (ETC-1001). Each of these therapies is described in more detail in the section below entitled Our Products in Development.

*Leverage experienced scientific, drug discovery and drug development expertise.* We are managed by an experienced group of scientists with significant expertise in drug discovery. Roger S. Newton, Ph.D., President and Chief Executive Officer of Esperion, was the co-discoverer, chairman of the discovery team and a member of the development team for the drug atorvastatin (Lipitor®). In 2002, sales of Lipitor exceeded \$7.9 billion and approximately 44 million prescriptions were written for atorvastatin worldwide. Other members of our management team have participated in the discovery, clinical development and/or commercialization of many other high profile therapies, including Lopid®, Pravachol®, Glucophage® and Plavix®. We employ inventors of two of our product candidates currently in clinical development (ETC-588 and ETC-642). In addition, since our inception, we have discovered HDL elevating/lipid regulating agents.

*Optimize clinical and regulatory strategies.* We believe that by initially focusing on the development of biopharmaceutical product candidates for acute treatments, we can achieve an abbreviated development time, as compared to what would be expected with chronic treatments. This may result in a faster time to market, which will benefit patients with cardiovascular disease. We are performing clinical trials with our biopharmaceutical product candidates to assess efficacy for well-defined cardiovascular endpoints in the treatment of acute coronary events. Concurrently, we are discovering and developing small molecules that we intend to use as a chronic therapy to complement statins and other chronic treatments.

## **Table of Contents**

*Retain co-development and co-promotion rights to our product candidates.* Our goal is to retain a portion of the development and marketing rights to our product candidates. By completing the pre-clinical and early clinical development work independently and with contract research organizations, we hope to negotiate favorable terms with prospective partners. We intend to enter into strategic collaborations with established pharmaceutical companies on one or more individual product candidates to enhance the value of each program by broadening the commercial potential for each product candidate and by utilizing additional clinical and regulatory resources to maximize each product candidate's potential.

### **Our Products in Development**

Our initial product development efforts are focused on developing novel classes of drugs designed to treat both acute and chronic cardiovascular disease using HDL Therapy. Our product candidates are designed to enhance HDL function and the four steps of the RLT pathway. Our product development to date has used in vitro assays, testing procedures performed outside the body, animal models and human clinical testing. We currently have three product candidates actively in the clinical phase of development. We expect to continue clinical testing of these three product candidates during 2003, and are preparing to bring an additional product candidate, ETC-1001, into clinical development during 2003.

Our human clinical trials may not commence or proceed as anticipated and we may not be able to demonstrate the same levels of safety, efficacy or other results in clinical trials that have been suggested in our pre-clinical or early clinical trials, or in studies by third parties with material similar to ours.

#### *ETC-588 (LUV)*

We are developing ETC-588 (large unilamellar vesicles, or LUV), currently as a treatment for acute coronary syndromes. LUV are spherical particles composed of a naturally occurring phospholipid that upon infusion into humans would remain in the circulation to serve as a sponge for cholesterol. We believe the interaction between LUV and HDL already in the body results in the enhanced removal of cholesterol from atherosclerotic lesions. We believe that LUV have a high capacity to transport cholesterol to the liver for elimination from the body.

Two third party pre-clinical animal studies were published involving the administration of material similar to ETC-588. These studies showed the removal of cholesterol from arteries and the regression of atherosclerosis, thereby helping arteries regain their flexibility and function. None of the studies were conducted by us or on our behalf.

In 2000, Phase I single and multiple dose tolerance studies of ETC-588 in healthy volunteers were completed. Analysis of data from those studies indicates dose-dependent cholesterol mobilization.

The first Phase II study of ETC-588 was a double-blind, randomized, placebo-controlled, multiple-dose study designed to determine the optimal dose and dosing schedule and effect of ETC-588 in 36 patients with stable cardiovascular disease and HDL-C less than or equal to 45 milligrams per deciliter (indicating a low level of HDL-C). Patients were administered one of three dose strengths (50, 100 or 200 milligrams per kilogram) or placebo every four or seven days. Patients in the 100 and 200 mg/kg dose groups each received seven doses, while the 50 mg/kg dose groups received fourteen doses. The results of this study indicated that ETC-588 was safe and well-tolerated at all dose levels and dose regimens. Based on the data from this study, an optimal dosing schedule of every seven days has been defined for future study of ETC-588. Patients administered ETC-588 also showed evidence of dose-related cholesterol mobilization, as measured by the amount of cholesterol in the blood before and after treatment.

In addition, we conducted a sub-study in a small group of patients in this Phase II trial using magnetic resonance imaging (MRI) technology to assess its feasibility as an appropriate imaging modality. Based on the information gathered from this sub-study, this technology is being utilized in a second Phase II study of ETC-588 to assess a primary endpoint of changes in plaque volume. This second Phase II trial began enrolling in the second quarter of 2002 to, among other things, use MRI technology to assess the changes in plaque

**Table of Contents**

volume within the carotid arteries. Patients are given eight weekly doses of ETC-588, or placebo, in this study utilizing a dose of 200 mg/kg for treated patients. Each patient will have MRIs taken prior to treatment, after four weeks of treatment, after eight weeks of treatment and three months following treatment. These serial MRI readings should allow us to examine how ETC-588 is impacting the plaque, if at all, as well as how well the benefits of therapy might persist three months after treatment. Additional efficacy endpoints are also being studied. Enrollment in this trial is continuing.

In the fourth quarter of 2002, we initiated a third Phase II study, in which enrollment is continuing. The objective of this third Phase II study is to evaluate the safety and tolerability of ETC-588 in 150 patients with acute coronary syndromes, one of the patient populations we intend to target in our Phase III clinical trials. Patients in this trial are treated with eight weekly doses of ETC-588. The trial is a double-blind, randomized, placebo-controlled study with three groups of 50 patients each. The patients will receive either a fixed weekly dose of eight grams, a fixed weekly dose of fifteen grams or placebo.

*ETC-216 (AIM)*

We are developing ETC-216 (apolipoprotein A-I Milano/phospholipid complex, or AIM), for the treatment of patients with acute coronary syndromes. The clinical use of ETC-216 as a human recombinant protein complexed to phospholipid is to mimic naturally-occurring HDL and/or enhance its function. AIM is a variant form of apolipoprotein A-I, the major protein component of HDL. AIM is naturally present in a small group of Northern Italians with paradoxically low rates of cardiovascular disease despite low HDL-C levels, who tend to show a lower risk of cardiovascular disease, presumably due to enhanced reverse lipid transport.

We believe that infusion of ETC-216 in humans will enhance the RLT pathway. Published third party reports in 1998, 1999 and 2001 have shown that, in animal models, material similar to ETC-216 reduced atherosclerotic lesions and their lipid content and prevented inflammation and clotting. A 1999 report of *in vitro* tests showed that material similar to ETC-216 increased cholesterol removal. The 2001 report demonstrated rapid removal of lipid and decreased macrophage immunoreactive staining in atherosclerotic lesions within or at 48 hours after treatment. Also, published third party reports in 1994 and 1995 showed that material similar to ETC-216 inhibited restenosis following balloon angioplasty in two animal models. None of these studies were conducted for us or on our behalf.

We completed and reported data from a Phase I single-dose clinical trial of ETC-216 conducted in Europe in the first quarter of 2001. Consistent with our pre-clinical studies, an infusion of ETC-216 in participants in this study resulted in increased cholesterol mobilization. This study also demonstrated ETC-216 was safe at all doses, there were no serious adverse events observed, and that it was well tolerated. We initiated a multiple-dose, multi-center Phase II clinical study in patients with acute coronary syndromes in the fourth quarter of 2001. The purpose of this study is to provide evidence that ETC-216 is effective in regressing coronary atherosclerosis by measuring changes in plaque size utilizing intravascular ultrasound (IVUS). The trial is a randomized, double-blind study that is evaluating the efficacy and safety of ETC-216 at two different dose levels (15 mg/ kg and 45 mg/ kg) of intravenous infusions, compared to placebo, administered every seventh day with a maximum of five doses. The study will evaluate up to fifty patients with acute coronary syndromes, who are scheduled to undergo coronary angiography and/ or angioplasty. The primary endpoint is the effect of ETC-216 on plaque size of one targeted coronary artery, which will be measured by atheroma volume through the use of IVUS. In IVUS, a tiny ultrasound probe is inserted into a coronary artery to directly image atherosclerotic plaques. In this trial, an IVUS image is taken before the first dose is administered and within one week of the final dose. Enrollment was completed in March 2003 and we expect to present initial results in mid-2003.

We acquired exclusive worldwide rights for AIM from Pharmacia in July 1998. Under our license agreement with Pharmacia, at the completion of Phase II clinical trials, Pharmacia has the exclusive right of election to co-develop and the exclusive right to market products that include AIM as an active ingredient in countries outside of the United States and Canada. In addition, upon our pursuing a co-development and co-promotion arrangement in the United States and Canada, Pharmacia has the right of first negotiation.

**Table of Contents**

*ETC-642 (RLT Peptide)*

We are developing ETC-642 (RLT Peptide) currently for the treatment of patients with acute coronary syndromes. The peptide component of ETC-642 is a 22-amino acid peptide that mimics the biological properties of apolipoprotein A-I to promote cholesterol removal from artery walls and other tissues and enhance reverse lipid transport. ETC-642 is a complex of peptide and phospholipids that mimics the functions of HDL. In our pre-clinical studies, we have shown that ETC-642 increases HDL-C and enhances cholesterol mobilization. Because of these properties, we believe that administration of ETC-642 may enhance reverse lipid transport.

The patent applications that were filed in 1997 for the technology relating to series of RLT peptides describe experiments of the compounds in vitro and in vivo, including in human blood samples. These experiments showed that RLT peptides similar to ETC-642 interact with and activate important enzymes in the RLT pathway and stimulate cholesterol removal. The results of a pre-clinical animal model study described in the patents showed that the administration of an RLT peptide complexed to phospholipids similar to ETC-642 increased HDL-C levels in the blood. This study was not conducted for us or on our behalf. We exclusively license from the inventors the patents and patent applications covering the technology relating to these RLT peptides and our RLT Peptide.

Our goal is to establish that intravenous infusions of ETC-642 are safe and result in the removal of cholesterol from the walls of arteries, thus stabilizing vulnerable atherosclerotic plaques and preventing cardiovascular events, such as heart attacks, in clinical trials.

During 2001, we initiated a Phase I clinical study of ETC-642 in patients with existing cardiovascular disease. The Phase I clinical trial was a single-dose study in patients with stable atherosclerosis designed to determine the safety, tolerability, pharmacokinetic and cholesterol mobilization properties of ETC-642. We completed this Phase I study in the first half of 2002 and results indicate that ETC-642 was safe and well-tolerated at all dose levels tested. In addition, results were consistent with pre-clinical studies in showing evidence of rapid cholesterol mobilization, as well as evidence of increases in HDL-cholesterol levels. We initiated an additional single-dose, Phase I study in the second half of 2002 in the same patient population studied in the earlier trial to determine the maximum tolerated dose. Following the completion of this additional Phase I trial and review of the combined data from these two trials, we expect to conduct a multiple-dose study in patients beginning in the second half of 2003 to examine dosing regimens and certain efficacy parameters.

*ETC-1001 (HDL Elevating/ Lipid Regulating Agents)*

We are pursuing the discovery and development of oral small organic molecules that increase HDL-C levels and/or enhance the RLT pathway, as well as decrease LDL-C and triglycerides. Pre-clinical models suggest that some of these molecules may also possess anti-diabetic and anti-obesity properties. We have implemented several strategies to develop these product candidates. One strategy has led to the discovery of several classes of active molecules.

Our pre-clinical studies demonstrated that several classes of molecules elevate HDL-C in animal models. In these studies we have observed that these molecules can also regulate lipid production in liver cells of rats, hamsters and humans, and inhibit diet-induced atherosclerosis progression in an animal model. Our goal is to develop orally active molecules for the treatment of patients with lipid disorders.

We have identified a lead orally active small molecule product candidate that we have now designated ETC-1001 because we have chosen to submit it for clinical development (it was formerly designated ESP 31015). Upon completion of certain pre-clinical and toxicology studies, we intend to file an Investigational New Drug application, or IND, in 2003, and begin Phase I clinical testing on ETC-1001 in the first half of 2003. We are conducting additional testing and pre-clinical research on other small molecule candidates for potential clinical development in the future.

## **Table of Contents**

### *Other*

We have suspended development of ETC-276 (ProApolipoprotein A-I, or ProApoA-I), as an acute treatment for the improved blood flow to the arteries of the heart, brain and body. The decision to suspend development of this compound was made in the first half of 2002 and was based on the limited scope of the intellectual property position on this compound, the limited patent life remaining and complexities involved in developing a commercially viable manufacturing process for this compound.

### **Research and Development**

We have devoted substantially all of our resources since we began our operations in May 1998 to the research and development of pharmaceutical product candidates for cardiovascular disease. Our research and development expenses were \$22.0 million, \$21.5 million, \$22.6 million, and \$94.0 million in 2002, 2001, 2000 and the period from inception to December 31, 2002, respectively. Research and development expenses include both external and internal costs related to the research and development activities for our existing product candidates as well as discovery efforts on potential new product candidates. External costs include costs related to manufacturing, process development, clinical trials, toxicology or pharmacology studies performed by third parties, milestone payments under certain license agreements and other related expenses. Internal costs include all payroll and related costs attributable to research and development activities, as well as an allocation of overhead expenses that we incur.

We have implemented strategies in discovery, research and development that we believe will generate a pipeline of new drugs for the treatment of lipid disorders and related complications. These strategies include an intensive effort to identify orally active small molecules.

Small molecule discovery efforts, focused on lipid disorders, are aimed at identifying drugs that increase HDL-C levels and/or enhance their function to stimulate the RLT pathway. We have implemented approaches to identify drugs that stimulate pathways, which we believe will result in the synthesis of more HDL or the rapid replenishment of HDL components.

### **Clinical Testing**

We believe that the clinical development plan for our biopharmaceutical product candidates can be achieved by the following:

*Phase I.* Demonstrate the safety and tolerability of our product candidates in healthy volunteers or stable patients. In addition, we begin to look at dose levels and dosing regimens; that is, how much drug should be administered and how often. Finally, in Phase I, we look for evidence of increased cholesterol mobilization in humans. Mobilization can be measured easily using various clinical chemistry tests such as the level of cholesterol in the blood both before and after treatment. By showing increased cholesterol mobilization in the blood, we can speculate that our drug candidates are effectively pulling excess cholesterol from artery walls and other tissues.

*Phase II.* Continue to monitor safety and tolerability of our product candidates in different patient populations. We will attempt to identify the optimal dose and dosing regimen including the number of treatments and length of time between treatments. Finally, we will examine efficacy parameters including changes in vascular structure and function. This can be accomplished through the use of various imaging techniques such as MRI or IVUS to examine changes in plaque volume and/or composition. These measurements can provide evidence as to whether our product candidates are having an impact on reducing the plaque in the walls of the arteries. These imaging techniques are used to take measurements both pre- and post-treatment to determine if and how much of the plaque is being removed or stabilized.

*Phase III.* During Phase III, we believe that we will need to show evidence of clinical benefit and establish effectiveness of our product candidates through improvements in cardiovascular clinical outcomes such as morbidity, mortality, heart attacks, strokes, hospitalizations, revascularizations and other clinical events. By comparing clinical events in patients receiving our product candidates versus

## **Table of Contents**

patients who do not receive our product candidates, we can determine if there is clinical benefit from our therapies above the current standard of care. Because we are targeting acute treatments with our biopharmaceuticals, we need to show an impact on clinical events in a relatively short period of time following treatment.

For our small molecules, the clinical development will focus more on improving the lipid profile of patients by increasing HDL-C and improving HDL function as well as having secondary effects of reducing LDL-C and triglycerides. Since the small molecules are designed for chronic treatment and as a possible complement to statin drugs, which currently account for approximately 90% of the lipid regulation market, we expect that these trials would follow a much more traditional lipid regulation clinical development path, including well-established endpoints.

## **Marketing and Sales**

We currently have no sales or distribution capabilities. In order to successfully commercialize any of our product candidates, we must either internally develop full sales, marketing and distribution capabilities or make arrangements with third parties to perform these services. We may sell, market and distribute some products directly and rely on relationships with third parties to sell, market and distribute other products. To market any of our products directly, we must develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Since 2000, we have had a senior member of our management team working to develop commercialization strategies and conduct market research for our product candidates.

Inex Pharmaceuticals Corporation, the licensor and/or owner of some of the ETC-588 technology, and the group of inventors who are the licensors of the ETC-642 technology have granted us exclusive rights to market ETC-588 and ETC-642. We acquired exclusive worldwide rights for ETC-216, our other in-licensed product candidate, from Pharmacia in July 1998. Under this agreement, at the completion of Phase II clinical trials, Pharmacia has the exclusive right of election to co-develop and the exclusive right to market products that include AIM as an active ingredient in countries outside of the United States and Canada. In addition, upon pursuing a co-development and co-promotion arrangement in the United States and Canada, Pharmacia has the right of first negotiation.

We are currently pursuing corporate collaborations for our biopharmaceuticals and we believe the preferred partnering deal would consist of a co-development and co-promotion relationship in North America with one or more companies that have established distribution systems and direct sales forces. In international markets, we intend initially to seek strategic relationships pursuant to which the partner would develop, market, sell and distribute our product candidates. We have also recently initiated discussions with potential partners for our oral small molecule program. In that case, we are pursuing a research and development collaboration.

## **Manufacturing**

### *Manufacturing and Materials Supply*

We currently rely, and will continue to rely for at least the next few years, on contract manufacturers to produce sufficient quantities of our product candidates for use in our pre-clinical and clinical trials and ultimately for commercial purposes. We also rely, and intend to continue to rely, on third parties to provide the components of these product candidates, such as proteins, peptides, phospholipids, bulk chemical materials and active pharmaceutical ingredients.

There is currently a limited supply of some of the components needed to manufacture our product candidates. In particular, the production capacity available in the world for the proteins contained in ETC-216 is limited. In addition, the process for producing protein for ETC-216 will need to be enhanced to meet late-stage clinical trials supply and large-scale commercial production requirements for ETC-216. We believe, however, that if ETC-216 is shown to be efficacious in the current Phase II trial, we would focus on partnering opportunities that would leverage a prospective partner's manufacturing expertise in helping us to develop a more efficient manufacturing process for this product candidate. Other partnering objectives may include

## **Table of Contents**

pursuing partners with expertise in alternative delivery regimes for ETC-216. In this regard, pre-clinical data suggests that certain alternative delivery regimes for ETC-216 could have potential clinical benefit using significantly less ETC-216. Furthermore, the contract manufacturers that we have identified and worked with to date only have limited experience at manufacturing, formulating, analyzing, filling and finishing our product candidates in quantities sufficient for conducting clinical trials or for commercialization. There are companies throughout the world that have begun to make investments in additional capacity through the construction of new facilities or renovation of existing facilities; however, these facilities will take time to construct, require significant capital investment and must comply with regulatory specifications.

We do not have any direct or indirect experience in the commercial-scale manufacturing of ETC-588, ETC-216, ETC-642 or ETC-1001. Each of these product candidates has a unique manufacturing process and will require engineering and manufacturing expertise to scale up our current batch production methods to commercial scale manufacturing. Our product candidates will need to be manufactured in facilities and using processes that comply with current Good Manufacturing Practices, or cGMP, requirements and other similar regulations, including those from outside the United States. It takes a substantial period of time to produce proteins, peptides, and certain small molecules in compliance with such regulations. For example, the process for manufacturing proteins and formulating them into protein/lipid complexes is complicated. If we are unable to establish and maintain relationships with third parties for manufacturing sufficient quantities of our product candidates and their components that meet our planned time and cost parameters, the development and timing of our clinical trials and commercialization strategy may be adversely affected.

## **Intellectual Property and License Agreements**

Our ability to protect and use our intellectual property rights in the development and commercialization of our product candidates is crucial to our continued success. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets, or other proprietary information or know-how. We currently rely on a combination of issued patents and pending patent applications, some of which we license and some of which have been assigned to us, proprietary information, trade secrets and know-how to protect our interests in developing and commercializing our product candidates and technologies.

In connection with the agreements described below, we may be obligated to make various milestone payments, which could amount to \$28.3 million, and future royalty payments, pursuant to formulas in the agreements, in the future. At the present time, it is uncertain as to whether we will be required to make any of these additional payments.

### *ETC-588 (LUV)*

With respect to our LUV technology, we have a patent estate currently comprised of 10 issued U.S. patents, 1 European patent validated in 13 European countries, 6 pending U.S. patent applications and 2 international patent applications that are the basis of 10 pending foreign patent applications. Some of these patents and patent applications are licensed and/or sublicensed to us by Inex Pharmaceuticals Corp., or Inex, which either owns them or licenses them from the University of British Columbia. The other patents and patent applications are owned by us, some of which were acquired when we acquired Talaria Therapeutics, Inc., or Talaria, in September 2000. Collectively, the patents and pending applications claim the use of unilamellar liposomes for the treatment of atherosclerosis, a dosage form containing liposomes, methods and compositions for use in the treatment of disease, including atherosclerosis and other disorders such as angina, using those liposomes, methods of producing liposomes and methods of treating diseases with liposomes using specific dosing regimens. The U.S. patents expire no earlier than 2014 and the European patents expire in 2011.

We paid Inex \$250,000 at the time we entered into the license agreement with Inex for certain LUV technology in March 1999. Our license agreement with Inex, as amended, requires us to make payments to Inex as milestones are achieved and to pay Inex royalties on sales of any products that are covered by the licensed patents or developed using the licensed technology. The first milestone payment of \$100,000 was paid



**Table of Contents**

to Inex in the first quarter of 2001, based upon enrollment of our first patient in a Phase II clinical trial. Additional milestone payments will be paid to Inex if and when we achieve future development milestones as defined in the agreement, up to an aggregate amount of \$6.2 million. Under our license agreement with Inex, as amended, we are also required to pay Inex royalties on sales of products that are covered by the LUV technology that we acquired from Talaria. This license continues until the later of ten years from the first commercial sale of a product covered by this license or the last expiration date of any patent rights covered by this license, unless earlier terminated by a party in accordance with the terms of the license.

Our merger agreement with Talaria required us to issue 813,008 shares of common stock to former Talaria stockholders and requires us to pay: (i) up to \$6.3 million in cash and/or common stock based on the achievement of four development milestones; and (ii) royalties in cash and/or common stock based on net annual sales in North America of LUV products. The combined milestone payments and royalties are subject to a maximum aggregate ceiling of \$20.0 million. The first milestone was achieved in the first quarter of 2001 upon the enrollment of our first patient in a Phase II clinical trial. This milestone was paid in 2001 through the issuance of 58,626 shares of common stock. Of the initial 813,008 shares of common stock that were issued under the merger agreement, 10,127 shares were retired in 2001 in satisfaction of an indemnity obligation of the former Talaria stockholders under the merger agreement and related documents. Of the total shares of common stock paid to Talaria, 11,622 shares remain escrowed until no later than November 21, 2004 in order to satisfy maximum potential indemnity obligations by the former Talaria stockholders to us.

*ETC-216 (AIM)*

In June 1998, we acquired exclusive, worldwide rights to AIM from Pharmacia Corporation, subject to Pharmacia's exclusive right of election to co-develop and exclusive right to market AIM in countries other than the United States and Canada upon our completion of Phase II clinical trials. In addition, upon our pursuing a co-development and co-promotion arrangement in the United States and Canada with a third party, Pharmacia has the right of first negotiation to co-develop and co-promote in the United States and Canada. This license expires on the latter of 2018 or upon the last of the Pharmacia patents to expire, unless terminated earlier by either party in accordance with the terms of the license. Under our license agreement with Pharmacia, we acquired what is now seven issued U.S. patents, one allowed U.S. patent application, one pending U.S. patent application, two European patents and other related corresponding foreign patents and patent applications, covering various aspects of AIM, pending in other countries where we believe the market potential for ETC-216 is significant, including most of the European countries and some Asian countries, including Japan. These patents and patent applications claim methods and materials for producing AIM in bacteria and yeast, methods for purification and methods for treating atherosclerosis and other forms of cardiovascular disease with AIM. The issued U.S. patents expire no earlier than 2015, the corresponding foreign patents expire no earlier than 2012 and the two European patents expire in 2007 and 2010. We also own one pending U.S. patent application and have joint ownership with Cedars Sinai Medical Center of one additional pending U.S. patent application, both of which claim additional uses for AIM.

We paid Pharmacia \$750,000 at the time we entered into our license agreement in June 1998. Our license agreement with Pharmacia requires us to make payments to Pharmacia as milestones are achieved, and to pay Pharmacia royalties on sales of products that are covered by the Pharmacia patents or developed using the Pharmacia technology. The first milestone payment of \$1.0 million will be paid in cash or by issuance of a promissory note to Pharmacia if and when we have completed clinical trials showing preliminary safety and initial proof-of-concept (which may include the Phase II study that we expect to report on in 2003). We believe that this would mean clinical trials that show statistically significant results in safety and efficacy, allowing us to better define the details of any potential Phase III pivotal trials.

If Pharmacia exercises its exclusive right to co-develop and market AIM in countries other than the United States and Canada, we will make additional milestone payments, up to an aggregate of \$2.5 million, to Pharmacia. In this case, we will be entitled to royalties on sales of AIM outside the United States and Canada, and Pharmacia would be entitled to royalties on sales within the United States and Canada. If Pharmacia does not exercise its right to co-develop and market AIM in countries other than the United States and Canada, we will make additional milestone payments, up to an aggregate of \$13.5 million, to Pharmacia starting if and

## **Table of Contents**

when we enroll the first patient in the first Phase III clinical trial for an AIM product in the United States as well as royalties on sales of AIM worldwide. If the milestone payments are greater than 10% of our cash reserves at the time payment is required, we may make these payments to Pharmacia by issuing a promissory note in lieu of cash.

### *ETC-642 (RLT Peptide)*

Under an agreement entered into in September 1999, we exclusively licensed RLT Peptide technology from the group of its inventors. This now includes nine issued U.S. patents, two allowed U.S. patent applications, nine pending U.S. patent applications and corresponding foreign patents and pending patent applications. The RLT Peptide technology relates to peptides and proteins that have activity equal to or greater than, ApoA-I. The issued U.S. patents and corresponding foreign patents expire in 2017. The U.S. and foreign patents and patent applications are directed to peptides having ApoA-I activity, pharmaceutical compositions thereof, methods for their use, drug forms containing the peptides, pharmaceutical dosage forms of the peptides, methods for preparing the dosage forms and nucleotide sequences encoding the peptides.

We paid the inventors of our RLT Peptide technology an initial license fee of \$50,000 in January 2000. Our license agreement with the inventors requires us to make payments to them as milestones are achieved, and to pay them royalties on sales of any products that are covered by the inventors' patents or developed using the inventors' technology. The first milestone payment of \$50,000 was paid to the inventors in 2001. Additional milestone payments, up to an aggregate of \$2.1 million, will be paid to the inventors if and when we achieve future development milestones as defined in the agreement with the inventors. This license continues until ten years from the date of license execution or the last to expire of any of the inventors' patents, unless terminated earlier by a party in accordance with the terms of the license.

### *ETC-1001 (formerly designated ESP 31015) and other HDL Elevating/ Lipid Regulating Agents*

We are also researching and developing small organic molecules that increase HDL-C levels and/or enhance the RLT pathway, as well as decrease LDL-C and triglycerides. These molecules may also possess anti-diabetic and anti-obesity properties. We have three issued U.S. patents, 11 pending U.S. patent applications and corresponding pending foreign applications directed to classes of compounds and specific compounds that increase HDL-C levels and/or enhance the RLT pathway, compositions comprising these compounds, methods of the preparation of these compounds and methods for the use of these compounds. We are also pursuing, and will continue to pursue, patent protection for other classes of compounds that increase HDL-C levels and/or enhance the RLT pathway, which have been or will be identified in our laboratories. We had identified a lead candidate from this class of compounds in 2001 now designated ETC-1001 for which we intend to file an IND and begin Phase I clinical testing in 2003.

## **Government Regulation**

The U.S. Food and Drug Administration, or FDA, and comparable regulatory agencies in state and local jurisdictions and in countries outside of the United States impose substantial requirements on the pre-clinical and clinical development, manufacture and marketing of pharmaceutical product candidates. These agencies and other federal, state and local governmental entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record-keeping, approval and promotion of our product candidates. All of our product candidates will require regulatory approval before commercialization. In particular, therapeutic product candidates for human use are subject to rigorous pre-clinical and clinical testing and other requirements of the Federal Food, Drug, and Cosmetic Act, or FDC Act, and Public Health Service Act, or PHSA, implemented by the FDA, as set forth in the Code of Federal Regulations, as well as similar statutory and regulatory requirements of countries outside the United States. Obtaining these marketing approvals and subsequently complying with ongoing statutory and regulatory requirements is costly and time-consuming. Any failure or delay by us or our suppliers, CROs, collaborators, licensors or licensees in obtaining regulatory approvals or in complying with other requirements could adversely affect the commercialization of our product candidates and our ability to receive any product or royalty revenues.

**Table of Contents**

The steps required before a new drug product candidate may be distributed commercially in the U.S. generally include:

conducting appropriate pre-clinical laboratory evaluations of the product candidate's chemistry, formulation and stability, and pre-clinical studies to assess the potential safety and efficacy of the product candidate;

submitting the results of these evaluations and tests to the FDA, along with manufacturing information and analytical data, in an Investigational New Drug application, or IND;

initiating clinical trials under the IND after the IND becomes effective;

obtaining approval of Institutional Review Boards, or IRBs, to introduce the drug into humans in clinical studies;

conducting adequate and well-controlled human clinical trials that establish the safety and efficacy of the product candidate for the intended use, typically in the following three sequential, or slightly overlapping, stages:

*Phase I:* The product candidate is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, distribution, metabolism and excretion;

*Phase II:* The product candidate is studied in patients to identify possible adverse effects and safety risks, to establish the dose response relationship in the target population, to determine dosage tolerance and the optimal dosage, and to collect initial efficacy data; and

*Phase III:* The product candidate is studied in an expanded patient population at multiple clinical study sites, to confirm efficacy and safety at the optimized dose, by measuring a primary endpoint established at the outset of the study; agreement is reached with the FDA, in advance, on the clinical development program, including patient numbers and clinical endpoints required for marketing approval. Proposed label claims are also discussed with the FDA in advance of NDA submission;

submitting the results of preliminary research, pre-clinical studies, and clinical trials as well as chemistry, manufacturing and control information on the product candidate to the FDA in a New Drug Application, or NDA or Biologics Licensing Application, BLA; and

obtaining FDA approval of the NDA or BLA and final product labeling prior to any commercial sale or shipment of the product candidate.

Each NDA or BLA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act (PDUFA) and its amendments. According to the FDA, through September 30, 2003 the user fee for an application requiring clinical data, such as a full NDA or BLA, is \$533,400. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for prescription drugs and biologics (currently \$32,400), and an annual establishment fee (currently \$202,900) on facilities used to manufacture prescription drugs and biologics. We are not at the stage of development with our product candidates where we would have a Drug Registration Number and, therefore, we are not yet subject to these fees.

This process can take a number of years and requires substantial financial resources. There are no assurances that NDAs or BLAs for the product candidates will be filed, accepted or approved. The results of pre-clinical studies and initial clinical trials are not necessarily predictive of the results of these specific formulations or the results of large-scale clinical trials, and clinical trials may be subject to additional costs, delays or modifications due to a number of factors, including the difficulty in obtaining enough patients, clinical investigators, product candidate supply, or financial support. The FDA may also require testing and surveillance programs to monitor the effect of approved product candidates that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product candidate based on the results of these post-marketing programs. Upon approval, a product candidate may be marketed only in those dosage forms and for those indications approved in the NDA or BLA.

## **Table of Contents**

In addition to obtaining FDA approval for each product candidate, the manufacturing establishments for each product must register with the FDA, list products with the FDA, comply with the applicable FDA cGMP regulations and permit and pass manufacturing plant inspections by the FDA. Moreover, the submission of applications for approval may be delayed because of the need for additional time to complete the required manufacturing stability studies. Companies from outside the United States that manufacture products for distribution in the United States also must list their products with the FDA and comply with cGMPs. They are also subject to periodic inspection by the FDA or by local authorities under agreement with the FDA.

Under the FDC Act and related statutes, developers of new drugs are afforded certain limited protections against competition from generic drug companies. Under the 1984 Drug Price Competition and Patent Term Restoration Act, drug companies can have certain product patents extended to counter balance, in part, the duration of the FDA's review of their marketing applications. This Act also provides for marketing exclusivity (*i.e.*, protection from generic competition regardless of any available patent protection) for products for which clinical investigations are necessary to support FDA approval of a marketing application. Also, the recently enacted Best Pharmaceuticals for Children Act permits under certain circumstances an additional six months of marketing exclusivity ( pediatric exclusivity ) if the applicant files reports of investigations studying use of the drugs in the pediatric population. The pediatric exclusivity provision is scheduled to sunset on October 1, 2007 and there are no assurances that it will be reauthorized.

Any product candidates that we manufacture or distribute pursuant to FDA approvals are subject to extensive continuing regulation by the FDA, including record-keeping requirements and reporting adverse experiences with the product candidate. In addition to continued compliance with standard regulatory requirements, the FDA may also require further studies, including post-marketing studies and surveillance to monitor the safety and efficacy of the marketed product candidate. Results of post-marketing studies may limit or expand the further marketing of the products. Product candidate approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product candidate are discovered following approval. In addition, if any modifications to a product are proposed, including changes in indication, manufacturing process, manufacturing facility or labeling, a supplement to its NDA may be required to be submitted to the FDA and approved.

The FDC Act also mandates that product candidates be manufactured consistent with cGMP. In complying with the FDA's regulations on cGMP, manufacturers must continue to spend time, money and effort in production, recordkeeping, quality control, and auditing to ensure that the marketed product candidate meets applicable specifications and other requirements. The FDA periodically inspects manufacturing facilities to ensure compliance with cGMP. Failure to comply subjects the manufacturer to possible FDA action, such as warning letters, suspension of manufacturing, seizure of the product, voluntary recall of a product or injunctive action, as well as possible civil penalties, such as fines. We currently rely on, and intend to continue to rely on, third parties to manufacture our compounds and product candidates. These third parties are required to comply with cGMP.

Many of our current third-party manufacturers are located outside of the U.S., resulting in the possibility of difficulties in importing our product candidates and/or their components into the U.S., as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentations, or defective packaging.

Any products manufactured in the U.S. for distribution abroad will be subject to FDA regulations regarding export, as well as to the requirements of the country to which they are shipped. These latter requirements are likely to cover the conduct of clinical trials, the submission of marketing applications, and all aspects of manufacturing and marketing. Such requirements vary from country to country. As part of our strategic relationships, our collaborators may be responsible for the foreign regulatory approval process for our product candidates, although we may be legally liable for noncompliance.

We are also subject to various federal, state and local laws, rules, regulations and policies relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances used in connection with our research work.

## **Table of Contents**

Although we believe that our safety procedures for handling and disposing of such materials comply with current federal, state and local laws, rules, regulations and policies, the risk of accidental injury or contamination from these materials cannot be entirely eliminated.

The extent of government regulation that might result from future legislation or administrative action cannot be accurately predicted. In this regard, although the FDA Modernization Act of 1997 modified and created requirements and standards under the FDC Act with the intent of facilitating product candidate development and marketing, the FDA is still in the process of developing regulations implementing the FDA Modernization Act of 1997. Consequently, the actual effect of these developments on our business is uncertain and unpredictable.

The healthcare industry is changing rapidly as the public, government, medical professionals and the pharmaceutical industry examine ways to broaden medical coverage while controlling health care costs. Potential approaches that may affect us include managed care initiatives, pharmaceutical buying groups, formulary requirements, various proposals to offer an expanded Medicare prescription benefit, and efforts to regulate the prices of pharmaceuticals, which would include drugs for cardiovascular disease. We are unable to predict when any proposed healthcare reforms will be implemented, if ever, or the effect of any implemented reforms on our business.

## **Competition**

The pharmaceutical and biopharmaceutical industries are intensely competitive and are characterized by rapid and significant technological progress. Our competitors include large fully-integrated pharmaceutical companies, biopharmaceutical companies, biotechnology companies, universities and public and private research institutions that currently engage in, have engaged in or may engage in efforts related to the discovery and development of new pharmaceuticals and biopharmaceuticals, some of which are competitive with our own programs and efforts. Almost all of these entities have substantially greater research and development capabilities and/or financial, scientific, manufacturing, marketing and sales resources than we do, as well as more experience in research and development, clinical trials, regulatory matters, manufacturing, marketing and sales.

We are aware of companies that are developing technologies for the acute treatment of cardiovascular disease, such as atherosclerosis, that may compete with our product candidates for acute treatments. However, these technologies are dealing with a local treatment of cardiovascular disease rather than a systemic therapy such as with our biopharmaceuticals. Other companies with substantially greater research and development resources may attempt to develop products that are competitive with our product candidates for the acute treatment of cardiovascular disease or seek approval for drugs in later stages of development that have similar effects on cardiovascular disease as our acute treatments.

We are also aware of companies that are developing products for the chronic treatment of cardiovascular disease that may compete with our oral small molecule program for HDL elevation and lipid regulation. Other companies with substantially greater research and development resources are developing products that are competitive with our product candidates and will seek approval for drugs in later stages of development that have similar effects as our product candidates. Some examples of these lipid regulating therapies include cholesterol absorption inhibitors (one was recently approved by the FDA), ACAT inhibitors (Phase III development), CETP inhibitors and vaccines (Phase II development), and nuclear receptor agonists, or PPARs (Phase II/ III development).

If regulatory approvals for our product candidates are received, any such products may compete with several classes of existing drugs for the treatment of cardiovascular disease, some of which are available in generic form. For example, drugs currently available for the treatment of cardiovascular disease include fibrates, statins and niacin, all of which are available in pill or tablet, as compared to the intravenous administration method we intend to use for our biopharmaceuticals. There are also surgical treatments such as coronary artery bypass surgery and PCI that may be competitive with our products. For those patients, however, who do not respond adequately to existing therapies and remain symptomatic despite treatment with

## **Table of Contents**

existing drugs and who are not candidates for these surgical procedures, there is no currently effective treatment.

Our product candidates are still under development, and it is not possible to predict our competitive position in the future. However, we think that the principal competitive factors in the markets for ETC-588, ETC-216, ETC-642, and ETC-1001 are among the following:

safety and efficacy profile;

product price and degree of reimbursement;

ease of administration;

rapidity of effect;

duration and frequency of treatment;

product supply;

enforceability of patent and other proprietary rights; and

marketing and sales capability.

Our competitors also compete with us to:

attract qualified personnel;

attract parties for acquisitions, joint ventures or other collaborations;

license the proprietary technology that is competitive with the technology we are practicing; and

attract funding.

## **Employees**

As of December 31, 2002, we had 65 full-time employees. Of these employees, 41 were engaged in research, pre-clinical and clinical development, regulatory affairs and/or manufacturing activities and 24 were engaged in general and administrative activities.

## **Company Information Available on the Internet**

Our website address is *www.esperion.com*. Through the investor relations page on our website, *www.esperion.com/investorrelations*, we make available free of charge our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports as soon as reasonably practicable after we file such reports with the U.S. Securities and Exchange Commission, or the SEC.

## **Factors Affecting Our Future Prospects**

**We are a developmental stage biopharmaceutical company with a history of losses, and, even if our product candidates are approved and commercialized, we may never be profitable.**

We have devoted substantially all of our resources since we began our operations in July 1998 to the research and development of product candidates for cardiovascular disease. We have incurred substantial losses since we began our operations. As of December 31, 2002, we had a cumulative net loss of approximately \$94.0 million. These losses have resulted principally from costs incurred in our research and development programs, from our general and administrative expenses and from acquisition-related costs from our September 2000 acquisition of Talaria Therapeutics, Inc. To date, we have not generated revenue from product sales or royalties, and we do not expect to achieve any revenue from product sales or royalties until we receive regulatory approval and begin commercialization of our product candidates. We are not certain of

when, if ever, that will occur. We expect to incur significant additional operating losses for at least the next several years and until we generate sufficient revenue to offset expenses. Research and development costs

## **Table of Contents**

relating to our product candidates will continue to increase. Manufacturing, sales and marketing costs will increase as we prepare for the commercialization of our product candidates.

All of our current product candidates are in early stages of development, and we face the risks of failure inherent in developing drugs based on new technologies. In addition, three of our product candidates were in-licensed from third parties. We have limited in-house experience with these product candidates as well as with product candidates discovered and owned by us. Our product candidates are not expected to be commercially available for several years, if at all.

All of our current product candidates are designed to treat cardiovascular disease by exploiting the beneficial properties of HDL. We may defer or cease development of one or more of our product candidates if a product candidate does not show favorable clinical results, if we are unable to cost effectively manufacture a product candidate, if we decide to concentrate our resources on more promising product candidates, or for any other reason. Decisions regarding the selection of product candidates for development and the timing of the development of our product candidates may accelerate the pre-clinical or clinical testing of one or more product candidates while delaying or ceasing progress of one or more product candidates.

**All of our product candidates must be tested and submitted to the FDA and other regulatory agencies for approval before we can sell them, and even if the FDA approves our product candidates, that approval may be limited.**

Our product candidates must satisfy rigorous standards of safety and efficacy before they can be approved for commercial use by the FDA and international regulatory authorities. We will need to conduct significant additional research, including additional pre-clinical testing involving animals and clinical trials involving humans, before we can file applications for product approval.

Many of the product candidates in the pharmaceutical and biopharmaceutical industries do not successfully complete pre-clinical testing and clinical trials. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. For example, a number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials and in interim analyses. In addition, delays or rejections may be encountered based upon additional government regulations, including any changes in FDA policy, during the process of product development, clinical trials and regulatory approvals.

In order to receive FDA approval or approval from international regulatory authorities to market a product, we must demonstrate through human clinical trials that the product candidate is safe and effective for the treatment of a specific condition. Even if we believe the clinical trials demonstrate safety and efficacy of a product, the FDA and international regulatory authorities may not accept our assessment of the results and may require us to conduct additional advanced clinical trials. Approval of a product by comparable regulatory authorities is necessary in foreign countries prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. The approval procedure varies among countries and can involve additional testing. The time required may differ from that required for FDA approval. Although there are some procedures for unified filings for some European countries with the sponsorship of the country that first granted marketing approval, in general, each country has its own procedures and requirements, many of which are time consuming and expensive.

We do not know whether planned clinical trials will begin on time or will be completed on schedule or at all. If we experience significant delays in testing or approvals, or if we need to perform more or larger clinical trials than planned, our product development costs will increase. Any of our future clinical studies might be delayed or halted because the drug is not safe and effective, or physicians think that the drug is not safe or effective; patients experience severe and/or unexpected side effects during treatment; patients die during a clinical study because their disease is too advanced or they experience medical problems that are not related to the drug being studied; patients do not enroll in the studies at the rate we expect; or drug supplies are not sufficient to treat the patients in the studies.



## **Table of Contents**

Our clinical studies may also be limited by, delayed or halted because of the nature of the clinical study; the size of the potential patient population; the distance between patients and the clinical trial sites; the number of trials utilizing the same patient population; delays in enrolling patients; or the eligibility and exclusion criteria for patients in the trial.

Any product approvals we receive from the FDA in the future could also include significant restrictions on the use or marketing of any of our future products. Product approvals, if granted, can be withdrawn for failure to comply with regulatory requirements or upon the occurrence of adverse events following commercial introduction of the products.

**If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop our product candidates or retain rights to our product candidates.**

Significant additional capital will be required in the next several years to fund our operations. We do not know whether additional financing will be available on acceptable terms when needed. We have used substantial cash resources to date and expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure and research and development activities. If adequate funds are unavailable, we may be required to:

delay, reduce the scope of, or eliminate one or more of our research or development programs;

license rights to our technologies or product candidates on terms that are less favorable to us than might otherwise be available; or

obtain funds through arrangements that may require us to relinquish rights to product candidates that we would otherwise seek to develop or commercialize ourselves.

**Our freedom to operate our business or profit fully from any sales of our future products may be limited if we enter into collaborative agreements. The inability to establish one or more collaborative arrangements could adversely affect our ability to develop and commercialize products.**

We are seeking to collaborate with pharmaceutical companies to gain access to their research, drug development, regulatory, manufacturing, marketing, sales and financial resources. However, we may not be able to negotiate arrangements with any collaborative partners on favorable terms, if at all, or enter into collaborations that will be commercially successful. Any collaborative relationships that we enter into may include restrictions on our freedom to operate our business or may limit any sales of our future products. If a collaborative arrangement is established, the collaborative partner may discontinue funding any particular program or may, either alone or with others, pursue alternative technologies or indications or develop alternative product candidates for the diseases we are targeting. Competing products, developed by a collaborative partner or to which a collaborative partner has rights, may result in the collaborative partner withdrawing support as to all or a portion of our technology.

Without collaborative arrangements, we must fund our own research, development, manufacturing, marketing and sales activities that would accelerate the depletion of our cash and require us to raise substantial additional cash to enable us to develop our own development, regulatory, manufacturing, marketing and sales capabilities. Therefore, if we are unable to establish and maintain satisfactory collaborative arrangements and if other sources of cash are not available, we could experience a material adverse effect on our ability to develop products and, if developed and approved, to manufacture, market and sell them successfully.

**We expect our quarterly and annual results to fluctuate significantly.**

During the next several years, we expect our quarterly and annual operating results to fluctuate significantly, depending primarily on the following factors:

timing of pre-clinical studies and clinical trials;

**Table of Contents**

interruptions or delays in the supply of our product candidates or components;

timing of payments to licensors and other third parties;

whether we enter into collaboration agreements and the timing and accounting treatment of payments, if any, to us under those agreements;

timing of patent prosecution and maintenance fees and costs;

timing of investments in new technologies; and

other costs, which may be unexpected.

**If the third-party clinical research organizations that we rely on to conduct our clinical trials do not perform in an acceptable and timely manner, or if we are not able to manage or administer multiple clinical trials simultaneously, our clinical trials could be delayed or unsuccessful.**

We do not currently have the ability to independently conduct clinical trials and obtain regulatory approvals for all of our product candidates, and we currently rely and intend to continue to rely on third party clinical investigators and contract research organizations to perform these functions. If we cannot locate acceptable contractors to run our clinical trials or enter into favorable agreements with them, or if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we will be unable to obtain required approvals and will be unable to commercialize our product candidates on a timely basis, if at all.

To date, we have not managed multiple late stage clinical trials simultaneously. During 2003, we will expect to have four trials in progress and expect to initiate two additional clinical trials. It may be difficult or we may be unable to retain individuals qualified to administer these and future late stage clinical trials due to the complexity of the protocols and the size of the studies. We may be unable to complete multiple late stage clinical trials concurrently as effectively or as quickly as we currently anticipate, which could have a material adverse effect on our business, financial condition and results of operations.

**If our current and future manufacturing and supply strategies are unsuccessful, then we may be unable to complete any future clinical trials and/or commercialize our product candidates in a timely manner, if at all.**

Completion of our clinical trials and commercialization of our product candidates will require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. We do not have the resources, facilities or experience to manufacture our product candidates on our own and do not intend to develop or acquire facilities for the manufacture of product candidates for clinical trials or commercial purposes in the foreseeable future. We currently rely, and will continue to rely for at least the next few years, on contract manufacturers to produce sufficient quantities of our product candidates. We are currently exploring ways to improve the manufacturing process for our ETC-216 product candidate, as the yield from the current process will need to be enhanced in order to meet late-stage clinical trial supply and commercial-scale requirements. If we are unable to improve the current manufacturing process, we may be unable to complete future clinical trials for, or to cost-effectively commercialize, this product candidate. Most of our contract manufacturers have limited experience at manufacturing, formulating, analyzing, filling and finishing our particular product candidates. Our manufacturing strategy presents the following risks:

we may not be able to locate acceptable manufacturers or enter into favorable long-term agreements with them;

third parties may not be able to successfully manufacture our product candidates in a cost effective and/or timely manner or in quantities needed for clinical trials or commercial sales;

delays in, or failures to achieve, scale-up to commercial quantities, or changes to current raw material suppliers or product manufacturers (whether the change is attributable to us or the vendor) could delay clinical studies, regulatory submissions and commercialization of our product candidates;

we may not have intellectual property rights, or may have to share intellectual property rights, to the manufacturing processes for our product candidates;

## **Table of Contents**

manufacturing and validation of manufacturing processes and materials are complicated and time-consuming and may not provide yields adequate to meet clinical trial supply or commercial scale-up requirements;

because many of our current third-party manufacturers are located outside of the United States, there may be difficulties in importing our product candidates and/or their components into the United States as a result of, among other things, FDA import inspections, increased customs security measures, incomplete or inaccurate import documentation, or defective packaging; and

manufacturers of our product candidates are subject to the FDA's current Good Manufacturing Practices regulations, the FDA's current Good Laboratory Practices regulations and similar foreign standards and we do not have control over compliance with these regulations by our third-party manufacturers.

If any manufacturer of our product candidates fails to comply with applicable FDA or other regulatory requirements including manufacturing, quality control, labeling, safety surveillance, promoting and reporting, such failure may result in our criminal prosecution, levy of civil penalties against us, recall or seizure of any of our future products, total or partial suspension of production or an injunction, as well as other regulatory actions against our manufacturers, our potential products or us. Discovery of previously unknown problems with a product, supplier, manufacturer or facility may result in restrictions on the sale of a future product, including a withdrawal of the product from the market.

### **The technology underlying our product candidates is uncertain and unproven.**

All of our current product development efforts are based on unproven technologies and therapeutic approaches that have not been widely tested or used or approved for marketing in any country. To date, no products that use our technology have been commercialized. Our product candidates have not been proven to be safe and effective in humans, and the technology on which they are based has been used only in pre-clinical tests and early clinical trials. Application of our technology to cardiovascular disease is in early research stages. Clinical trials of our product candidates may be viewed as a test of our entire approach to developing therapies for cardiovascular disease. If our product candidates do not work as intended, or if the data from our clinical trials indicate that our product candidates are not safe and effective, the applicability of our technology for treating cardiovascular disease will be highly uncertain. As a result, there is a significant risk that our therapeutic approaches will not prove to be successful, and there can be no guarantee that our drug discovery technologies will result in any commercially successful products.

### **If one of our biopharmaceutical product candidates does not show safety and efficacy in early clinical trials, it could impact the development path for our other biopharmaceutical product candidates.**

The development of each of our biopharmaceutical product candidates (ETC-588, ETC-216 and ETC-642) is based on our knowledge and understanding of HDL and how HDL particles contribute to reverse lipid transport. Until clinical efficacy can be shown, the success of our biopharmaceutical product candidates is unknown. While there are important differences in each of the product candidates in terms of their composition and properties, each product candidate is focused on affecting different stages of the RLT pathway. In addition, the three biopharmaceutical product candidates are infused, rather than orally administered, and are currently being targeted for the treatment of patients with acute coronary syndromes.

As a result of these similarities, our product candidates may be perceived to have overlapping utility in the treatment of cardiovascular disease. Since we are developing these product candidates in parallel, we expect to learn from the results of each trial and apply some of our findings to the development of the other product candidates. If one of the product candidates has negative clinical trial results or is shown to be ineffective, it could impact the development path and/or future development of the other biopharmaceutical product candidates. If we find that one of the biopharmaceutical product candidates is shown to be unsafe, we may be unable to raise sufficient capital to fund the development of the other biopharmaceutical product candidates due to any resultant negative perceptions about HDL as an infused, acute treatment for cardiovascular disease.

## **Table of Contents**

### **If we fail to secure and enforce patents and other intellectual property rights underlying our product candidates and technologies, we may be unable to develop our product candidates or compete effectively.**

The pharmaceutical and biopharmaceutical industries place considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, on our ability, and the ability of our licensors, to obtain and enforce our exclusive rights to our product candidates and technologies under the patent laws of the United States and other countries. Our success also will depend on our ability to prevent others, including our employees, from using our trade secrets, know how and other confidential information. In addition, we must operate in a way that does not infringe, or violate, the patent, trade secret and other intellectual property rights of other parties.

The standards that the United States Patent and Trademark Office uses to grant patents can change. Consequently, we may be unable to determine the type and extent of patent claims that will be issued to us or to our licensors in the future. Any patents that do issue may not contain claims that will permit us to stop competitors from using the same or similar technology.

Patent prosecution and maintenance is also very costly and successful prosecution and defense may depend on the patent strategies that are pursued.

The standards that courts use to interpret patents can change, particularly as new technologies develop. Consequently, we cannot know how much protection, if any, our patents will provide. If we choose to seek a court order that prohibits a third party from using the inventions claimed in our patents, the third party may ask the court to rule that our patents are invalid and unenforceable. This type of lawsuit is expensive and time consuming and could be unsuccessful. There is also the risk that, even if the validity of our patents is upheld, the court will refuse to stop the third party on the ground that its activities do not infringe the patent.

### **If our licensing arrangements with third parties are breached or terminated, we may lose rights to commercialize our product candidates.**

Most of our product candidates have been in-licensed from third parties. We depend, and will continue to depend, on these and other licensing arrangements. If any of our licenses with third parties are terminated or breached, we may lose our rights to develop and commercialize our product candidates or lose patent and/or trade secret protection for our product candidates.

Disputes may arise with respect to our licensing agreements and strategic relationships regarding ownership rights to technology developed by or with other parties. Such disputes could lead to delays in or termination of the research, development, manufacture and commercialization of our product candidates, or to litigation.

### **We may face significant expense and liability as a result of litigation or other proceedings relating to patents and other intellectual property rights of others.**

Should third parties file patent applications, or be issued patents, claiming technology also claimed by us or our licensors in pending applications or issued patents, we may be required to participate in interference proceedings in the United States Patent and Trademark Office to determine priority of invention. An adverse outcome in an interference proceeding could require us to forfeit our patents or applications involved in the interference, cease using the technology or license rights from prevailing third parties. We could also be subject to allegations of trade secret violations and other claims relating to the intellectual property rights of third parties.

### **If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of any of our future products.**

Our business exposes us to product liability risks that are inherent in the clinical testing, manufacturing, marketing and sale of pharmaceutical and biopharmaceutical products. We may not be able to avoid product liability claims. Product liability insurance for the pharmaceutical and biopharmaceutical industries is generally expensive, if available at all. We have clinical trial liability insurance for our product candidates in clinical trials; however, there can be no assurance that such insurance coverage is or will continue to be

## **Table of Contents**

adequate or available. We may not be able to secure greater or broader product liability insurance coverage on acceptable terms or at reasonable costs when needed. If we are unable to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to commercialize our product candidates. A successful product liability claim brought against us for damages in an amount that exceeds our insurance coverage, if any, may cause us to incur substantial liabilities and our business may fail.

### **If our competitors develop and commercialize products faster than we do or commercialize products that are superior to our product candidates, our commercial opportunities will be reduced or eliminated.**

The extent to which any of our product candidates achieve market acceptance will depend on competitive factors, many of which are beyond our control. Competition in the pharmaceutical and biopharmaceutical industries is intense and has been accentuated by the rapid pace of technology development. Our competitors include large fully-integrated pharmaceutical companies, biopharmaceutical companies, biotechnology companies, universities and public and private research institutions. Almost all of these entities have substantially greater research and development capabilities and financial, scientific, manufacturing, marketing and sales resources than we do, as well as more experience in research and development, clinical trials, regulatory matters, manufacturing, marketing and sales. These organizations also compete with us to:

attract parties for acquisitions, joint ventures or other collaborations;

license the proprietary technology that is competitive with our technology;

attract funding; and

attract and hire scientific talent.

Our competitors may succeed in developing and commercializing products earlier, and obtaining regulatory approvals from the FDA more rapidly, than we do. Our competitors may also develop products or technologies that are superior to those we are developing, and render our product candidates or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever be profitable.

### **Our product candidates may not be commercially successful because physicians, patients, and government agencies and other third-party payors may not accept them.**

Even if regulatory authorities approve our product candidates, they may not be commercially successful. Third parties may develop superior products or less costly alternative products, or have proprietary rights that preclude us from marketing any of our future products. We also expect that most of our product candidates will be considered expensive, if approved. Patient acceptance of and demand for any product candidates for which we obtain regulatory approval will also depend upon acceptance by physicians of any of our product candidates as safe and effective therapies and the extent, if any, of reimbursement of drug and treatment costs by government agencies and other third-party payors.

In addition, any of our product candidates could cause adverse events, such as immunologic or allergic reactions. These reactions may not be observed in clinical trials, but may nonetheless occur after commercialization. If any of these reactions occur, they may render any commercialized product ineffective in some patients and thereby hinder the sales of such product.

### **Our failure to obtain an adequate level of reimbursement or acceptable prices for any of our future products could diminish any revenues we may be able to generate.**

Our ability to commercialize any future products successfully, alone or with collaborators, will depend in part on the extent to which reimbursement for the products will be available from:

government and health administration authorities;

private health insurers; and

other third-party payors.

**Table of Contents**

Government and other third-party payors increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs. Third party private health insurance coverage may not be available to patients for any of our future products.

The continuing efforts of government and other third-party payors to contain or reduce the costs of healthcare through various means may limit our commercial opportunity and reduce any associated revenue and profits. We expect proposals to implement similar government control to continue. In addition, increasing emphasis on managed care will continue to put pressure on the pricing of pharmaceutical and biopharmaceutical products. Cost control initiatives could decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our profitability. In addition, in some countries other than the United States, pricing and profitability of prescription pharmaceuticals and biopharmaceuticals are subject to government control.

**Even if we obtain regulatory approval of any of our product candidates, we will not be able to successfully commercialize such product candidates if we are unable to create sales, marketing and distribution capabilities.**

In order to successfully commercialize any of our product candidates, we must either internally develop full sales, marketing and distribution capabilities or make arrangements with third parties to perform these services. We have no experience in developing, training or managing a sales force and will incur substantial additional expenses in doing so. The cost of establishing and maintaining a sales force may exceed its cost effectiveness. In addition, we will compete with many companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete successfully against these companies.

**If we fail to recruit, retain and motivate skilled personnel, our product development programs and our research and development efforts may be delayed.**

Our success depends on our ability to recruit, retain and motivate highly qualified management and scientific personnel including skilled chemists and clinical development personnel, for which competition is intense. Our loss of the services of any of our key personnel, in particular, Roger S. Newton, Ph.D., our President and Chief Executive Officer, could significantly impede the achievement of our research and development objectives and could delay our product development programs and strategies.

**If we use biological and hazardous materials in a manner that causes injury, we may be liable for damages.**

Our research and development activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for damages, and such liability could exceed our resources. We are subject to federal, state and local and international laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could become significant.

**Notice Regarding Arthur Andersen LLP**

Arthur Andersen LLP audited our consolidated financial statements for the two years in the period ended December 31, 2001, and the period from our inception in May 1998 to December 31, 2001 and issued a report thereon dated January 18, 2002. Arthur Andersen LLP has not reissued their report and has not consented either to the inclusion of their report on our financial statements in this report or the incorporation by reference of their report into any of our registration statements filed with the SEC, and we have relied on Rule 437a under the Securities Act of 1933, as amended, in filing this report without such a consent. On June 15, 2002, Arthur Andersen LLP was convicted of obstruction of justice by a federal jury in Houston, Texas in connection with Arthur Andersen LLP's work for Enron Corp. On September 15, 2002, a federal judge upheld this conviction. Arthur Andersen LLP ceased its audit practice before the Commission on August 31, 2002. Effective April 18, 2002, we terminated the engagement of Arthur Andersen LLP as our independent accountants and engaged PricewaterhouseCoopers LLP to serve as our independent accountants

**Table of Contents**

for the fiscal year ending December 31, 2002. Because Arthur Andersen LLP has not consented to the inclusion of their report in this report and because of the circumstances affecting Arthur Andersen LLP, as a practical matter, Arthur Andersen LLP may not be able to satisfy any claims arising from the provision of auditing services to us, including claims you may have that are available to security holders under federal and state securities laws.

**Executive Officers of Registrant**

The following table presents information about our executive officers.

Name	Age	Position
Roger S. Newton, Ph.D.	52	President, Chief Executive Officer
Timothy M. Mayleben	42	Chief Operating Officer and Chief Financial Officer
Brian R. Krause, Ph.D.	53	Senior Vice President, Preclinical Research and Discovery
Jean-Louis H. Dasseux, Ph.D.	44	Vice President, Chemistry and Technologies
Frank E. Thomas	33	Vice President, Finance and Investor Relations
William F. Brinkerhoff	37	Vice President, Business Development

*Dr. Newton* has served as our President and Chief Executive Officer and as a director since July 1998. From August 1981 until May 1998, Dr. Newton was employed at Parke-Davis Pharmaceutical Research, Warner-Lambert Company, a publicly-held company, including as a Distinguished Research Fellow in Vascular and Cardiac Diseases, and where he was also the co-discoverer, chairman of the discovery team and a member of the development team for the drug atorvastatin (Lipitor®). Dr. Newton received an A.B. in Biology from Lafayette College, an M.S. in Nutritional Biochemistry from the University of Connecticut and a Ph.D. in Nutrition from the University of California, Davis. Dr. Newton specialized in atherosclerosis research during a post-doctoral fellowship at the University of California, San Diego. He currently holds a faculty appointment in the Department of Pharmacology at the University of Michigan Medical School. Since 2001, Dr. Newton has been a member of the Board of Directors of Rubicon Genomics, Inc., a privately-held company. He is a member of the steering committee of the Michigan Life Sciences Corridor and was formerly the Executive Director of the Great Lakes Venture Quest.

*Mr. Mayleben* has served as our Chief Financial Officer since January 1999 and our Chief Operating Officer since April 2002. Mr. Mayleben served as Senior Vice President, Operations and Finance from January 2002 until April 2002, after serving as Vice President, Finance from January 1999 until January 2002. Mr. Mayleben has more than 16 years experience working with high-growth technology companies. Prior to joining Esperion, Mr. Mayleben served as a Director of Business Development for Engineering Animation, Inc., a publicly-held company, from September 1998 to December 1998. From July 1997 to September 1998, Mr. Mayleben served as Chief Operating Officer and Chief Financial Officer of Transom Technologies, Inc., a privately-held company that was acquired by Engineering Animation, Inc. From September 1990 to July 1997, Mr. Mayleben served in various managerial positions, including as Director of Operations of Applied Intelligent Systems, Inc., a privately-held company. Prior to that, Mr. Mayleben was a manager with the Enterprise Group of Arthur Andersen & Co. Mr. Mayleben received a B.B.A. from the University of Michigan and an M.B.A. from the Northwestern University Kellogg Graduate School of Management. Mr. Mayleben was formerly a member of the Board of Directors of Computer Challenge Inc., a non-profit corporation.

*Dr. Krause* has served as our Senior Vice President, Preclinical Research and Discovery since February 2003, after serving as Senior Vice President, Preclinical Research and Development since January 2002 and as Vice President, Development Pharmacology since March 2001. Prior to joining Esperion, Dr. Krause was a Research Fellow within the Cardiovascular Therapeutics Division of Pfizer Global Research, a publicly-held company, where he also served as Chair of the Dyslipidemia Team and Group Leader of the Lipoprotein Metabolism Section. Prior to the merger of Pfizer Inc. and Warner-Lambert Company in 2000, Dr. Krause was a scientist at the Parke-Davis Research Division of Warner-Lambert Company, a publicly-held company,

**Table of Contents**

since 1982. Dr. Krause received a B.S. in Biological Sciences from the University of Illinois and a Ph.D. in Physiology from LSU Medical Center in New Orleans. Dr. Krause was an NIH-sponsored post-doctorate fellow with Paul Roheim, M.D., and is a member of the American Heart Association's Council on Arteriosclerosis, Thrombosis and Vascular Biology.

*Dr. Dasseux* has served as our Vice President, Chemistry and Technologies since August 2000, after serving as our Senior Director of Chemistry since January 1999. Dr. Dasseux has more than 15 years of experience in the pharmaceutical industry focusing on chemistry, lipoprotein metabolism and atherosclerosis. Dr. Dasseux has more than 22 years experience in physical chemistry and lipid-protein/peptide interactions. From June 1987 until April 1998, Dr. Dasseux was employed by Fournier Laboratories, France. Dr. Dasseux created and managed the Fournier Pharma Research Center in Heidelberg, Germany and held the position of Director of Research from September 1988 to April 1998. Dr. Dasseux received his M.S. in Biochemistry from the University of Bordeaux II, France and his Ph.D. in Physical Chemistry from the University of Bordeaux I, France. He was a postdoctoral research scientist in the Department of Chemistry at the University of Laval, Quebec, Canada; in the Department of Physics, The University of Tennessee, Knoxville, Tennessee, and in the European Molecular Biology Laboratory, Heidelberg, Germany.

*Mr. Thomas* was appointed Vice President, Finance and Investor Relations in April 2002 after serving as our Senior Director, Finance and Investor Relations since January 2002. Prior to that, Mr. Thomas served as our Director of Finance and Controller from March 2000 to January 2002. Prior to joining Esperion, Mr. Thomas served as Director of Finance and Controller for Mechanical Dynamics, Inc., a publicly-held software company, from September 1997 to March 2000. From July 1992 to September 1997, Mr. Thomas worked for Arthur Andersen LLP, including as an audit manager in the Detroit office. Mr. Thomas received a B.B.A. from the University of Michigan in 1992.

*Mr. Brinkerhoff* was appointed Vice President, Business Development in May 2002. Mr. Brinkerhoff has more than 13 years of experience in the pharmaceutical and biotechnology industries. From January 1999 to May 2002, Mr. Brinkerhoff was employed by Sankyo Pharma Inc., the U.S. subsidiary of the Tokyo-based pharmaceutical company Sankyo Co., Ltd., as Director of Business Development. From November 1996 to December 1998, he served as Director of Market Planning & Sales Operations at Sankyo Pharma Inc., after serving as Manager of Market Research for Sankyo USA Corporation from June 1995 to November 1996, during which time he was a member of the senior negotiating team that formed the Sankyo/ Parke-Davis joint venture. Prior to that, Mr. Brinkerhoff worked as an account manager for the pharmaceutical industry group at Oracle Corporation, a publicly-held company, from 1994 to 1995, and worked in various sales, marketing and manufacturing management positions for the Lederle Laboratories division of American Cyanamid, a publicly-held company, from 1989 to 1994. Mr. Brinkerhoff received B.S. and M.S. degrees in Industrial and Operations Engineering and an M.B.A. from the University of Michigan. Mr. Brinkerhoff has been a member of the Licensing Executives Society since 1999.

**Item 2. Properties**

Our leased corporate and research facilities in Ann Arbor, Michigan currently occupy approximately 30,000 square feet. Approximately 5,000 square feet of that space is covered by a lease that expires in December 2003. The lease for the remaining space also expires in December 2003, but includes an option to extend for one additional three-year term. We lease a lab facility in Kalamazoo, Michigan, which is approximately 3,300 square feet and is used primarily for medicinal chemistry activities for our oral small molecule program. The lease expires in April 2003, but includes an option to extend for three additional six-month terms. Outside of the United States, we lease office space in Bromma, Sweden, which currently occupies approximately 4,600 square feet. This lease expires in June 2004. We believe that our existing facilities are adequate for our current needs. Prior to the expiration of our existing leases, we may look for additional or alternate space for our operations and we believe that suitable additional or alternative space will be available at such times on commercially reasonable terms.



**Table of Contents**

**Item 3. Legal Proceedings**

Not applicable.

**Item 4. Submission of Matters to a Vote of Security Holders**

No matters were submitted to a vote of stockholders during the last quarter of the year ended December 31, 2002.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity and Related Stockholder Matters****Markets**

The Company's common stock trades on the Nasdaq National Market under the symbol ESPR. The range of high and low sale prices for the Company's common stock on Nasdaq's automated quotation system for each of the quarters since the Company's initial public offering on August 10, 2000 are as follows:

	<b>Market Prices</b>	
	<b>High</b>	<b>Low</b>
Year ended December 31, 2002:		
Fourth quarter	\$ 7.20	\$ 5.14
Third quarter	6.34	4.15
Second quarter	6.63	4.03
First quarter	7.43	4.50
Year ended December 31, 2001:		
Fourth quarter	\$ 8.35	\$ 6.00
Third quarter	9.78	5.26
Second quarter	11.50	3.90
First quarter	12.00	4.00
Year ended December 31, 2000:		
Fourth quarter	\$ 21.13	\$ 10.38
Third quarter (beginning August 10, 2000)	19.38	9.38

**Holdings**

As of December 31, 2002, there were approximately 307 stockholders of record of our common stock. This may not be an accurate indication of the total number of beneficial owners of our common stock as of December 31, 2002, since many shares are held by nominees in street name for beneficial owners.

**Dividend Information**

The Company has never declared or paid cash dividends on its capital stock and anticipates that, for the foreseeable future, it will continue to retain any earnings for use in the operation of its business.

**Recent Sales of Unregistered Securities**

Not applicable.

**Table of Contents****Item 6. Selected Consolidated Financial Data**

The following historical and pro forma selected consolidated financial data of Esperion should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations on page 31, the consolidated financial statements and notes beginning on page 39. The selected consolidated financial data for the years ended December 31, 2002, 2001, 2000, 1999 and the period from inception (May 18, 1998) through December 31, 1998 are derived from our audited consolidated financial statements.

**Consolidated Statement of Operations Data (in thousands, except share and per share data):**

	Year Ended December 31,				Inception to	Inception to
	2002	2001	2000	1999	December 31, 1998	December 31, 2002
Operating expenses:						
Research and development	\$ 21,991	\$ 21,454	\$ 22,596	\$ 8,484	\$ 1,923	\$ 76,448
General and administrative	5,955	5,023	3,156	2,518	464	17,116
Goodwill amortization		839	250			1,089
Purchased in-process research and development(1)			4,000			4,000
Operating loss	(27,946)	(27,316)	(30,002)	(11,002)	(2,387)	(98,653)
Other income (expense), net	(780)	2,385	2,426	332	244	4,607
Net loss	(28,726)	(24,931)	(27,576)	(10,670)	(2,143)	(94,046)
Beneficial conversion feature(2)			(22,870)			(22,870)
Net loss attributable to common stockholders	\$ (28,726)	\$ (24,931)	\$ (50,446)	\$ (10,670)	\$ (2,143)	\$ (116,916)
Basic and diluted net loss per share	\$ (0.98)	\$ (0.91)	\$ (4.50)	\$ (5.91)	\$ (1.46)	
Shares used in computing basic and diluted net loss per share(3)	29,260,930	27,309,502	11,222,319	1,806,255	1,466,615	
Pro forma basic and diluted net loss per share			\$ (2.45)	\$ (1.14)		
Shares used in computing pro forma basic and diluted net loss per share(3)			20,603,313	9,392,499		

**Consolidated Balance Sheet Data (in thousands):**

Edgar Filing: ESPERION THERAPEUTICS INC/MI - Form 10-K

	<u>2002</u>	<u>2001</u>	<u>2000</u>	<u>1999</u>	<u>1998</u>
Cash, cash equivalents and short-term investments	\$ 44,853	\$ 70,286	\$ 70,228	\$ 5,904	\$ 12,541
Working capital	40,330	64,926	64,181	3,143	12,390
Total assets	51,407	78,340	77,877	7,999	13,414
Long-term debt, less current portion	7,731	5,482	3,027	2,284	
Convertible preferred stock				105	105
Deficit accumulated during the development stage	(94,046)	(65,320)	(40,389)	(12,813)	(2,143)
Total stockholders' equity	38,743	66,498	67,691	2,815	13,187

- (1) We recorded a \$4.0 million charge to operations in 2000, for the write-off of purchased in-process research and development related to the acquisition of Talaria Therapeutics, Inc.

**Table of Contents**

- (2) We recorded approximately \$22.9 million relating to the beneficial conversion feature of the series C and series D preferred stock in the first quarter of fiscal 2000 through equal and offsetting adjustments to additional paid-in-capital with no net impact on stockholders' equity. The beneficial conversion feature was considered in the determination of our loss per common share amounts.
- (3) Basic and diluted net loss per share amounts have been calculated using the weighted average number of shares of common stock outstanding during the respective periods. Pro forma basic and diluted net loss per share amounts include the shares used in computing basic and diluted net loss per share and the assumed conversion of all outstanding shares of preferred stock from the original date of issuance.

**Table of Contents****Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**  
**Overview***Background*

We have devoted substantially all of our resources since we began our operations in May 1998 to the research and development of pharmaceutical product candidates for the treatment of cardiovascular disease. We are a development stage biopharmaceutical company and have not generated any revenues from any source, including from product sales. We have incurred a cumulative net loss of approximately \$94.0 million from inception (May 18, 1998) through December 31, 2002. These losses have resulted principally from costs incurred in research and development activities and general and administrative expenses. We expect to incur significant additional operating losses for at least the next several years and until we generate sufficient revenue to offset expenses. Research and development costs relating to product candidates will continue to increase. Manufacturing, sales and marketing costs will be incurred and will increase in preparation for the commercialization of our product candidates. Until we generate positive cash flow, we will rely on financing our operations with our existing cash balance, additional equity or debt offerings and/or payments from potential strategic relationships with partners that we may enter into in the future.

**Results of Operations***Operating Expenses*

<i>In thousands</i>	<b>Year Ended December 31,</b>				
	<b>2002</b>	<b>% Change</b>	<b>2001</b>	<b>% Change</b>	<b>2000</b>
Research and development	\$ 21,991	2.5%	\$ 21,454	-5.0%	\$ 22,596
% of total	78.7%		78.6%		75.3%
General and administrative	\$ 5,955	18.6%	\$ 5,023	59.2%	\$ 3,156
% of total	21.3%		18.4%		10.5%
Goodwill amortization	\$ 0	(100.0)%	\$ 839	235.6%	\$ 250
% of total	0.0%		3.0%		0.8%
Purchased in-process R&D	\$ 0		\$ 0	(100.0)%	\$ 4,000
% of total	0.0%		0.0%		13.4%

*Year Ended December 31, 2002.*

*Research and Development Expenses.* Research and development expenses include both internal and external costs related to the research and development activities for our existing product candidates, as well as discovery efforts on potential new product candidates. External costs include costs related to manufacturing, process development, clinical trials, toxicology or pharmacology studies performed by third parties, milestone payments under certain license and other agreements and other related expenses. Internal costs include all payroll and related costs attributable to research and development activities, as well as an allocation of overhead expenses. Research and development expenses increased to approximately \$22.0 million for the year ended December 31, 2002 compared to approximately \$21.5 million for the year ended December 31, 2001. This 2.5% increase is primarily due to the following:

*Higher clinical trial costs for our product candidates.* During 2002, patients were being enrolled in the following four clinical trials, the costs of which were higher than for clinical trials in 2001, partly because the clinical trials in 2002 were more costly per subject enrolled: Phase II trials of our ETC-216 ( AIM ) and ETC-588 ( LUV ) product candidates and two Phase I trials of our ETC-642 ( RLT Peptide ) product candidate. The ETC-216-002 trial began in November 2001 and represents the first Phase II clinical trial for this product candidate. The study will evaluate up to 50 patients with acute coronary syndromes and evaluate the changes in plaque volume in each patient's coronary arteries between pre- and post-treatment with ETC-216. The ETC-588-004 trial began in June 2002 and the ETC-588-005 trial began in December 2002, representing the second and third Phase II clinical trials for this product candidate. The ETC-588-004 trial is expected to evaluate 32 patients with carotid

**Table of Contents**

atherosclerosis and evaluate changes in plaque volume in each patient's carotid arteries using magnetic resonance imaging after administration of ETC-588. The ETC-588-005 trial will evaluate 150 patients who have been hospitalized for acute coronary syndrome to determine the safety and tolerability of ETC-588. Also during 2002, the ETC-642-001 trial was completed and the ETC-642-002 trial began (September 2002). These two studies examine an escalating, single-dose of ETC-642 to examine the safety and tolerability of the product candidate in patients with stable atherosclerosis. During 2001, the Company incurred costs related to four clinical trials: the completion of the ETC-216-001 Phase I trial, the initiation of the ETC-216-002 Phase II trial, ongoing enrollment in the ETC-588-003 Phase II trial and initiation of the ETC-642-001 Phase I trial.

*Higher pre-clinical costs in development of oral small molecule lead candidate.* During 2002, we prepared for an Investigational New Drug application (IND) for our lead oral small molecule product candidate, ETC-1001 (formerly designated ESP 31015). This resulted in higher costs related to process development and pharmacology and toxicology studies for this product candidate during 2002 as compared to 2001.

*Product candidate supply costs.* In preparation for current and future pre-clinical and clinical studies, we incur costs related to process development, scale-up and production for each product candidate. During 2002, the costs related to these activities were higher than in 2001 due to the increased material supply needed to support the future and current clinical trials, as well as an increase in patient numbers and dosage regimens being tested.

The magnitude of our operating expenses, particularly research and development expense, is largely dependent upon the progress, number, timing, nature and size of clinical trials. As our product candidates progress through development, clinical trial costs will continue to increase due to the need for more advanced clinical trials that require more patients.

*General and Administrative Expenses.* General and administrative expenses included the cost of salaries, employee benefits, and other costs associated with our finance, accounting, human resources, legal, administrative and executive management functions, as well as an allocation of overhead expenses. General and administrative expenses increased to approximately \$6.0 million for the year ended December 31, 2002 compared to approximately \$5.0 million for the year ended December 31, 2001. This 18.6% increase primarily relates to \$605,000 of one time charges during the year ended December 31, 2002 that were classified as general and administrative expenses in the accompanying statements of operations. The charges represented approximately 2% of our annual operating expenses and included the following:

The write-down of assets no longer being used in the Company's development programs totaling approximately \$410,000;

Employee severance and benefits of approximately \$168,000 resulting from actions announced in March 2002 to curtail or significantly reduce spending on certain pre-clinical research and other activities that lie outside of the Company's primary areas of focus in cardiovascular disease; and

The remaining obligations of \$27,000 under an operating lease for a laboratory facility in Sweden that is no longer being used.

In addition, the increase resulted from a greater number of general and administrative personnel, as well as increased overhead and related costs.

*Goodwill Amortization.* We adopted SFAS No. 142, effective January 1, 2002, under which goodwill and certain indefinite lived intangible assets are no longer amortized, but are reviewed at least annually for impairment. In connection with the adoption of SFAS No. 142, we have completed the transitional goodwill impairment test, which requires us to compare its fair value to the carrying value of its net assets. Based on this analysis, we have concluded that no impairment existed at the time of adoption, and, accordingly, we have not recognized any transitional impairment loss.

Goodwill amortization reflects the amortization amount of the excess of the purchase price over net assets in our September 2000 acquisition of Talaria Therapeutics, Inc. ( Talaria ) and the milestone payments

**Table of Contents**

made to date under the related merger agreement. Goodwill amortization expense was \$0 and \$839,000 for the years ended December 31, 2002 and 2001, respectively. Net goodwill included in our Consolidated Balance Sheets was \$3.1 million at December 31, 2002 and December 31, 2001.

*Other Income (Expense).* Other income (expense) consists of interest income, interest expense, foreign currency transaction gain (loss), and other non-operating income and expenses. Interest income decreased to approximately \$1.1 million for the year ended December 31, 2002, compared to approximately \$2.8 million for the year ended December 31, 2001. The decrease is primarily attributable to lower cash levels combined with lower yields on our invested assets in 2002 compared to 2001, as well as the use of more conservative investment instruments in 2002 as compared to 2001. Interest expense for the years ended December 31, 2002 and December 31, 2001 was approximately \$1.1 million and \$766,000, respectively, and represents interest incurred on equipment financing facilities and a special project loan. The increase in interest expense resulted from higher outstanding borrowings in 2002 as compared to the same period in 2001.

During the year ended December 31, 2002, we recorded approximately \$703,000 of unrealized foreign currency transaction losses compared to approximately \$400,000 of unrealized foreign currency transaction gains for the year ended December 31, 2001. These transaction gains (losses) result from liabilities denominated in foreign currencies, primarily the Swedish Kronor and the Euro. As the exchange rate between the U.S. Dollar and these currencies fluctuates, we record a gain (loss) on these transactions. During the year ended December 31, 2002, the U.S. Dollar has generally weakened against these foreign currencies causing these unrealized losses, whereas the opposite was true during the year ended December 31, 2001.

*Net Loss.* Our net loss was approximately \$28.7 million for the year ended December 31, 2002, compared to approximately \$24.9 million for the year ended December 31, 2001. The increase in net loss resulted primarily from the decrease in interest income of approximately \$1.8 million, the increase in unrealized foreign currency transaction losses of approximately \$1.1 million, and the increases in general and administrative expenses of approximately \$932,000, offset in part by the decrease in goodwill amortization of approximately \$839,000.

*Year Ended December 31, 2001.*

*Research and Development Expenses.* Research and development expenses included both external and internal costs related to the research and development activities for our existing product candidates as well as discovery efforts on potential new product candidates. External costs include costs related to manufacturing, process development, clinical trials, toxicology or pharmacology studies performed by third parties, milestone payments under certain license agreements and other related expenses. Internal costs include all payroll and related costs attributable to research and development activities, as well as an allocation of overhead expenses. Research and development expenses decreased to approximately \$21.5 million for the year ended December 31, 2001 compared to approximately \$22.6 million for the year ended December 31, 2000. This 5.0% decrease is primarily due to lower manufacturing costs related to material used in our clinical trials, as well as lower costs related to pre-clinical development of our biopharmaceutical product candidates during 2001. These decreases were partially offset by increased clinical trial costs. Clinical trial costs increased in 2001 as compared to 2000 as a result of conducting more trials and because the types of clinical trials in 2001 were more costly per subject enrolled. The magnitude of our operating expenses, particularly research and development expenses, is largely dependent upon the timing and size of the clinical trials and manufacturing material used in those clinical trials.

*General and Administrative Expenses.* General and administrative expenses included the cost of salaries, employee benefits, and other costs associated with our finance, accounting, human resources, legal, administrative and executive management functions, as well as an allocation of overhead expenses. General and administrative expenses increased to approximately \$5.0 million for the year ended December 31, 2001 compared to approximately \$3.2 million for the year ended December 31, 2000. This 59.2% increase resulted from higher payroll, overhead and related costs in support of our growing research and development activities as compared to 2000. The increased payroll resulted from an increase in general and administrative personnel from 14 at the end of 2000 to 20 at the end of 2001. Also included in the increased general and administrative



## **Table of Contents**

expenses in 2001 are costs associated with a market research study performed by a third party to provide us with some preliminary assessments about product positioning, product acceptance and market potential of certain product candidates. In addition, we incurred higher costs in 2001 related to our first full annual reporting cycle as a public company including legal, accounting, printing and related services.

*Goodwill Amortization.* Goodwill amortization reflects the amortization of the excess of the purchase price over net assets in our September 2000 acquisition of Talaria and the milestone payments made to date. Total goodwill was \$3.1 million and \$3.5 million at December 31, 2001 and 2000, respectively. Goodwill amortization expense was \$839,000 and \$250,000 for the years ended December 31, 2001 and 2000, respectively. The increase in goodwill amortization expense was a result of a full year of amortization in 2001 as well as increased goodwill being amortized upon the achievement of certain LUV clinical development milestones in early 2001. We had been amortizing this goodwill over five years, which represents the period estimated to be benefited from the acquisition, after considering such factors as product development timelines, revenue potential, competition and patent life.

*Other Income (Expense).* Other income increased to approximately \$2.8 million for the year ended December 31, 2001, compared to approximately \$2.6 million for the year ended December 31, 2000. The increase was attributable to higher levels of cash and cash equivalents available for investment in 2001, partially offset by lower yields on our invested assets in 2001, as compared to 2000. Interest expense for the same periods was approximately \$766,000 and \$408,000, respectively, and represented interest incurred on equipment financing facilities and a special project loan. We recorded approximately \$400,000 and \$201,000 for the year ended December 31, 2001 and 2000, respectively, of foreign currency transaction gains on transactions denominated in various currencies of European countries, primarily the Swedish kronor.

*Net Loss.* The net loss was approximately \$24.9 million for the year ended December 31, 2001, compared to approximately \$27.6 million for the year ended December 31, 2000. The decrease in 2001, as compared to 2000, was primarily attributable to the non-cash \$4.0 million purchased in-process research and development write-off in 2000 related to our acquisition of Talaria.

## **Liquidity and Capital Resources**

As of December 31, 2002 and 2001, we had cash, cash equivalents and short-term investments of approximately \$45.0 million and \$70.3 million, respectively. Our investment policy emphasizes liquidity and preservation of principal over other portfolio considerations. We select investments that maximize interest income to the extent possible by investing cash in securities with different maturities to match projected cash needs and limit risk by diversifying our investments. We believe that our current cash position, will be sufficient to fund our operations as currently planned, capital expenditures and debt service until at least the second half of 2004.

During the years ended December 31, 2002, 2001 and 2000, net cash used in operating activities was approximately \$26.6 million, \$22.8 million and \$18.0 million, respectively. This cash was used to fund our net losses for the periods, adjusted for non-cash expenses and changes in operating assets and liabilities.

Net cash used in investing activities for the years ended December 31, 2002, 2001 and 2000 was \$5.5 million, \$2.1 million and \$2.0 million, respectively, primarily the result of net purchases of short-term investments in 2002 of approximately \$4.4 million, and the acquisition of laboratory equipment, furniture, fixtures and office equipment. In addition, the Company used approximately \$233,000 in cash in connection with the acquisition of Talaria in 2000.

Net cash proceeds from financing activities were \$1.4 million, \$25.0 million and \$84.1 million for the years ended December 31, 2002, 2001 and 2000, respectively. The net cash proceeds from financing activities for the year ended December 31, 2002 resulted from \$2.1 million of additional borrowings on a special project loan and certain equipment term loans and \$384,000 raised through the issuance of common stock to employees as part of our equity compensation plans. The proceeds were partially offset by \$1.1 million of cash used to repay borrowings under certain equipment term loans. The net cash proceeds from financing activities for the year ended December 31, 2001 resulted primarily from \$22.3 million raised in our July 2001 private

**Table of Contents**

placement of 3,183,335 shares of common stock and \$3.5 million in additional borrowings on a special project loan and certain equipment term loans. The proceeds were partially offset by \$956,000 of cash used to repay borrowings under certain equipment term loans. The net cash proceeds from financing activities for the year ended December 31, 2000 resulted primarily from \$56.2 million raised in the initial public offering of common stock, \$26.9 million raised in preferred stock financings prior to the initial public offering, \$1.5 million in additional borrowings on a special project loan and certain equipment term loans, and \$123,000 raised from the issuance of common stock to employees as part of our equity compensation plans. The proceeds in 2000 were partially offset by \$518,000 of cash used to repay borrowings under certain equipment term loans.

We continue to evaluate opportunities to issue additional equity, obtain credit from lenders, enter into strategic relationships, or to otherwise strengthen our financial position. The issuance of additional equity, whether publicly or privately, could result in dilution to our current stockholders. From time to time, we may consider the acquisition of or investment in complementary businesses, products or technologies that might affect our liquidity requirements or position or cause us to issue additional securities. There can be no assurance that financing will be available to us in amounts or on terms acceptable to us, if at all.

In 2003, we plan to enter into a corporate collaboration with respect to one or more of our product candidates. We are seeking to collaborate with one or more established pharmaceutical companies that can provide substantial and complementary drug development, regulatory, manufacturing, promotional and financial skills and resources. The goals of any such collaboration will be to retain a portion of the development and marketing rights with respect to the product candidates while broadening the commercial potential for each product candidate.

We believe that, for our biopharmaceuticals, the preferred collaboration will include co-development and co-promotion rights in North America. Internationally, we will seek a collaboration with a partner who would develop, market, sell and distribute our product candidates outside of North America. We have also recently initiated discussions with potential partners for our oral small molecule program. In that case, we are pursuing a research and development collaboration.

As of December 31, 2002, we had the following credit facilities and outstanding borrowings:

A \$2.0 million credit facility with a U.S. bank that may be used to finance purchases of equipment that is pledged as collateral: Borrowings under this facility bear interest at the bank's prime rate (4.25% at December 31, 2002). Borrowings outstanding under this facility as of December 31, 2002 amounted to approximately \$1.1 million and must be repaid by May 2006. No additional borrowings are allowed. In connection with the agreement, the Company has to maintain a minimum tangible net worth of \$9.0 million and invest a minimum of \$10.0 million with the U.S. bank. The Company's investment with the U.S. bank was below the required threshold at December 31, 2002. However, the Company obtained a waiver from the U.S. bank and has corrected the non-compliance.

An additional credit facility with a U.S. lending institution to finance purchases of equipment that is pledged as collateral: This facility allowed for borrowings of up to \$2.5 million. Approximately \$1.2 million was outstanding under this facility at a weighted average interest rate of 12% as of December 31, 2002. Outstanding amounts under this facility must be repaid by November 2004 and no additional borrowings are allowed.

A credit facility with a Swedish entity totaling a principal amount of 50 million Swedish Kronor (\$5.8 million as of December 31, 2002): The proceeds from this facility may only be used to fund the development of our ETC-216 ( AIM ) product candidate. If results achieved by the AIM project are not capable of being used commercially, our obligation to repay the loan plus a portion of accrued interest may be forgiven. Borrowings under the loan facility bear interest at 17.0% of which 9.5% is payable quarterly. The remaining 7.5% of interest together with principal is payable in five equal annual installments starting in December 2004. The outstanding borrowings, including accrued interest of 7.5 million Swedish kronor (\$859,000), amounted to 52.5 million Swedish Kronor (\$6.1 million) as of December 31, 2002. We are in discussions with the Swedish entity regarding the principal amount of 5 million Swedish Kronor remaining under the facility, disbursement of which is related to completion

**Table of Contents**

of the final milestone under the facility. The milestone may be achieved in the future; however, the funds may be unavailable to us due to the ramp down of our operations in Sweden during 2002. A condition under the credit facility is that the project be principally carried out in Sweden.

An agreement with a Michigan non-profit corporation whereby we can borrow up to \$447,000 for equipment purchases, pledged as collateral, at an interest rate of 4%: As of December 31, 2002, outstanding borrowings under this arrangement totaled \$447,000 and must be repaid by November 2008. As required by the agreement, the Company will begin making principal payments in August 2004.

We anticipate that our capital expenditures for the next twelve months will be approximately \$700,000. We expect that these expenditures will primarily relate to lab and computer equipment.

Our fixed material external commitments based on contractual obligations are as follows (in thousands):

	<u>Total</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008 and Beyond</u>
Current and long term debt(1)	\$ 8,792	\$ 1,061	\$ 2,161	\$ 1,513	\$ 1,275	\$ 1,520	\$ 1,262
Operating lease commitments(2)	758	723	35				
Capital expenditure(2)(3)	400	400					
	<u>\$ 9,950</u>	<u>\$ 2,184</u>	<u>\$ 2,196</u>	<u>\$ 1,513</u>	<u>\$ 1,275</u>	<u>\$ 1,520</u>	<u>\$ 1,262</u>

(1) We have various credit facilities and outstanding borrowings as described above.

(2) We lease our corporate and research and development facilities under operating leases expiring at various times through June 2004. Under certain arrangements, including our headquarters facility arrangement, we may extend these leases for one or more additional periods.

(3) We entered into an agreement with a scientific instrument manufacturer to purchase a specialized piece of equipment for \$1,000,000, \$600,000 of which has been paid. We are obligated to pay the remaining \$400,000 upon approval by us of the instrument meeting the original specifications.

We also have material external commitments that total approximately \$35.2 million that may change as certain factors change. We enter into various agreements with third parties related to the research and development activities of our existing product candidates as well as discovery efforts on potential new product candidates. These agreements include costs related to manufacturing, clinical trials and toxicology or pharmacology studies performed by third parties. We estimate that the remaining amount to be incurred under these agreements total approximately \$5.0 million as of December 31, 2002. The amount and timing of these commitments may change, as they are largely dependent on the enrollment and timing of the clinical trials. We also have entered into license and other agreements with certain third parties, which require us to make payments upon any achievement of the milestones set forth in the agreements. The remaining payments that we could be obligated to make under those agreements could over time amount to up to \$30.2 million. Some of these payments may be fulfilled through the issuance of common stock, at our option. If we sell products using technology licensed or owned under the agreements, we would be obligated to make royalty payments to the third parties pursuant to formulas in the agreements. There can be no assurance that we will meet any or all of the milestones in, or sell any products requiring royalty payments under, our license agreements.

We expect that our operating expenses and capital expenditures will increase in future periods. We intend to hire additional research and development, clinical and administrative staff. Our capital expenditure requirements will depend on numerous factors, including the progress of our research and development programs, the time required to file and process regulatory approval applications, the development of commercial manufacturing capability, the ability to obtain additional licensing arrangements, and the demand for our product candidates, if and when approved by the FDA or other regulatory authorities.

**Income Taxes**

As of December 31, 2002 and 2001, we had operating loss carryforwards of approximately \$63.9 million and \$41.1 million, respectively. These net operating loss carryforwards expire beginning in 2013. Additionally,



## **Table of Contents**

utilization of net operating loss carryforwards may be limited under Section 382 of the Internal Revenue Code. These and other deferred income tax assets are fully reserved by a valuation allowance due to historical losses.

### **Employees**

As of December 31, 2002, we had 65 full-time employees. Of these employees, 41 were engaged in research, pre-clinical and clinical development, regulatory affairs and/or manufacturing activities and 24 were engaged in general and administrative activities.

### **Critical Accounting Policies**

Management's discussion and analysis of the Company's financial condition and results of operations are based upon the Company's Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of any contingent assets and liabilities as of the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Management regularly reviews its estimates and assumptions, which are based on historical experience and on various other factors and judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates and assumptions.

Management believes that the following critical accounting policy is affected by significant judgments and estimates used in the preparation of its consolidated financial statements:

We record estimated expenses under the contracts with third parties on a percentage of completion basis. These contracts cover ongoing clinical trials, manufacturing and supply agreements, and third party toxicology or pharmacology studies. These contracts generally have terms ranging from a couple of months to approximately two years. The expenses are recorded as the work under the contract is completed and we may record an accrued liability or prepaid expense on our Consolidated Balance Sheet, depending on the payment terms under each contract. As of December 31, 2002, we had total potential obligations of approximately \$10.2 million under contracts accounted for on the percentage of completion basis. Management estimates that approximately \$5.2 million of the contract obligations had been incurred through December 31, 2002 and approximately \$1.0 million is included in accrued liabilities in the accompanying balance sheet, for expenses under contracts on the percentage of completion basis.

### **New Accounting Pronouncements**

In December 2002, the Financial Accounting Standards Board issued SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure (SFAS 148). SFAS 148 amends SFAS No. 123 Accounting for Stock-Based Compensation (SFAS 123) to provide alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting for stock-based employee compensation. It also amends the disclosure provisions of SFAS 123 to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation. SFAS 148 also amends APB Opinion No. 28, Interim Financial Reporting, to require disclosure about the effects of SFAS 148 in interim financial information. This statement is effective for fiscal years ending after December 15, 2002. We intend to continue to use the intrinsic value method to account for stock based employee compensation.

In July 2002, the Financial Accounting Standards Board issued SFAS No. 146, Accounting for Restructuring Costs, (SFAS 146) which applies to costs associated with an exit activity, including restructuring, or with a disposal of long-lived assets. SFAS 146 requires that a liability be recorded for costs associated with exit or disposal activity when the liability is incurred and can be measured at fair value, rather than at the date of commitment to an exit activity. SFAS 146 also requires disclosures about exit and disposal activities, the related costs, and changes in those costs in the notes to the financial statements that include the period in which an exit activity is initiated and in any subsequent period until the activity is completed. SFAS 146 is effective prospectively for exit or disposal activities initiated after December 31, 2002, although

**Table of Contents**

earlier adoption is encouraged. We do not expect the adoption of SFAS 146 to have a material effect on our financial statements.

In November 2002, the FASB released FASB Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*: an interpretation of FASB Statements No. 5, 57 and 107 and rescission of FASB Interpretation No. 34. FIN 45 establishes new disclosure and liability-recognition requirements for direct and indirect debt guarantees with specified characteristics. The initial measurement and recognition requirements of FIN 45 are effective prospectively for guarantees issued or modified after December 31, 2002. However, the disclosure requirements are effective for interim and annual financial-statement periods ending after December 15, 2002. We have adopted the disclosure provisions and we do not expect the full adoption of FIN 45 to have a material impact on our results of operations or financial position.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

Our exposure to market risk for changes in interest rates relates primarily to the increase or decrease in the amount of interest income that we can earn on our investment portfolio and on the increase or decrease in the amount of interest expense that we must pay with respect to our various outstanding debt instruments. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. We ensure the safety and preservation of our invested funds by limiting default risks, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities and limiting our exposure to any one security. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments at December 31, 2002. Declines in interest rates reduce our interest income as described on page 33 in Management's Discussion and Analysis, under the subcaption *Year Ended December 31, 2002, Other Income (Expense)*, while increases in interest rates increase our interest expense.

The functional currency for our foreign operation is the Swedish Kronor. As such, changes in exchange rates between the Swedish Kronor and the U.S. Dollar could adversely affect our future net income (loss). Given the level of activity we currently have with our foreign operations, we consider this exposure to be minimal. A 10% change in exchange rates would not have a significant impact on our future net income (loss). Additionally, at December 31, 2002, we had approximately \$6.0 million in inter-company advances denominated in Swedish Kronor for which changes in the exchange rate will result in foreign currency transaction gains or losses that are charged to Other income (expense) in the accompanying Statements of Operations.

**Table of Contents**

**Item 8. Financial Statements and Supplementary Data**

**INDEX TO FINANCIAL STATEMENTS**

**ESPERION THERAPEUTICS, INC.**

**(A Company in the Development Stage)**

	<b>Page</b>
Reports of Independent Accountants	40
Consolidated Balance Sheets	42
Consolidated Statements of Operations	43
Consolidated Statements of Stockholders' Equity	44
Consolidated Statements of Cash Flows	46
Notes to Consolidated Financial Statements	47

**Table of Contents**

**REPORT OF INDEPENDENT ACCOUNTANTS**

To the Board of Directors and Shareholders of Esperion Therapeutics, Inc.:

In our opinion, the accompanying consolidated balance sheet as of December 31, 2002 and the related consolidated statements of operations, of stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Esperion Therapeutics, Inc. and its subsidiaries (a development stage enterprise) at December 31, 2002, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audit. We did not audit the cumulative totals of the company for the period from May 18, 1998 (date of inception) to December 31, 2001, which totals reflect a deficit of \$65,320,000 accumulated during the development stage. Those cumulative totals were audited by other independent accountants who have ceased operations and whose report dated January 18, 2002, expressed an unqualified opinion on the cumulative amounts. We conducted our audit of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion. The financial statements of Esperion Therapeutics, Inc. as of December 31, 2001, and for each of the two years in the period ended December 31, 2001, prior to the revisions described in Note 2 to the financial statements, were audited by other independent accountants who have ceased operations. Those independent accountants expressed an unqualified opinion on those financial statements in their report dated January 18, 2002.

Effective in 2002, and as discussed in Note 2, the Company adopted Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets*.

As discussed above, the consolidated financial statements of Esperion Therapeutics, Inc. and subsidiaries as of December 31, 2001, and for each of the two years in the period ended December 31, 2001, were audited by other independent accountants who have ceased operations. As described in Note 2, these financial statements have been revised to include the transitional disclosures required by Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets*, which was adopted by the Company as of January 1, 2002. We audited the transitional disclosures described in Note 2. In our opinion, the transitional disclosures for 2001 and 2000 in Note 2 are appropriate. However, we were not engaged to audit, review, or apply any procedures to the 2001 or 2000 financial statements of the Company other than with respect to such disclosures and, accordingly, we do not express an opinion or any other form of assurance on the 2001 or 2000 financial statements taken as a whole.

PRICEWATERHOUSECOOPERS LLP

Detroit, Michigan  
January 21, 2003



**Table of Contents**

**THE FOLLOWING IS A COPY OF A REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP ( ANDERSEN ). THIS REPORT HAS NOT BEEN REISSUED BY ANDERSEN AND ANDERSEN DID NOT CONSENT TO THE INCORPORATION BY REFERENCE OF THIS REPORT (AS INCLUDED IN THIS FORM 10-K) INTO ANY OF THE COMPANY S REGISTRATION STATEMENTS.**

**AS DISCUSSED IN THE GOODWILL AND OTHER INTANGIBLES NOTE, THE COMPANY HAS REVISED ITS FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2001 AND 2000 TO INCLUDE THE TRANSITIONAL DISCLOSURES REQUIRED BY STATEMENT OF FINANCIAL ACCOUNTING STANDARDS NO. 142, GOODWILL AND OTHER INTANGIBLE ASSETS. THE ANDERSEN REPORT DOES NOT EXTEND TO THESE CHANGES. THE REVISIONS TO THE 2001 AND 2000 FINANCIAL STATEMENTS RELATED TO THESE TRANSITIONAL DISCLOSURES WERE REPORTED ON BY PRICEWATERHOUSECOOPERS LLP, AS STATED IN THEIR REPORT APPEARING HEREIN.**

**REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To the Board of Directors and Shareholders of Esperion Therapeutics, Inc.:

We have audited the accompanying consolidated balance sheets of Esperion Therapeutics, Inc. (a Delaware corporation in the development stage) and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001, and the period from inception to December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Esperion Therapeutics, Inc. and subsidiaries as of December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, and the period from inception to December 31, 2001, in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Ann Arbor, Michigan,  
January 18, 2002.

**Table of Contents****ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES****(A Company in the Development Stage)****CONSOLIDATED BALANCE SHEETS**

	<b>December 31, 2002</b>	<b>December 31, 2001</b>
<i>In thousands, except share data</i>		
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 40,499	\$ 70,286
Short-term investments	4,354	
Prepaid expenses and other	410	1,000
	<hr/>	<hr/>
Total current assets	45,263	71,286
Furniture and equipment, less accumulated depreciation of \$3,690 and \$2,415 at December 31, 2002 and 2001, respectively	3,001	3,313
Goodwill, less accumulated amortization of \$1,089 at December 31, 2001	3,108	3,108
Deposits and other assets	35	633
	<hr/>	<hr/>
	\$ 51,407	\$ 78,340
	<hr/>	<hr/>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Current portion of long-term debt	\$ 1,061	\$ 863
Accounts payable	1,687	2,925
Accrued liabilities	2,185	2,572
	<hr/>	<hr/>
Total current liabilities	4,933	6,360
	<hr/>	<hr/>
Long-term debt, less current portion above	7,731	5,482
	<hr/>	<hr/>
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Preferred stock, \$0.01 par value; 5,000,000 shares authorized including 500,000 shares authorized as Series A, Junior Participating Preferred stock, \$0.01 par value; none issued or outstanding		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 29,368,808 and 29,191,526 shares issued and outstanding at December 31, 2002 and 2001, respectively	29	29
Additional paid-in capital	133,411	133,143
Notes receivable	(3)	(15)
Accumulated deficit during the development stage	(94,046)	(65,320)
Deferred stock compensation	(589)	(1,476)
Accumulated other comprehensive income (loss)	(59)	137
	<hr/>	<hr/>
Total stockholders' equity	38,743	66,498
	<hr/>	<hr/>
	\$ 51,407	\$ 78,340
	<hr/>	<hr/>

The accompanying notes are an integral part of these consolidated financial statements.



**Table of Contents****ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**

(A Company in the Development Stage)

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31, 2002	Year Ended December 31, 2001	Year Ended December 31, 2000	Inception to December 31, 2002
<i>In thousands, except share and per share data</i>				
Operating expenses:				
Research and development	\$ 21,991	\$ 21,454	\$ 22,596	\$ 76,448
General and administrative	5,955	5,023	3,156	17,116
Goodwill amortization		839	250	1,089
Purchased in-process research and development			4,000	4,000
Total operating expenses	<u>27,946</u>	<u>27,316</u>	<u>30,002</u>	<u>98,653</u>
Loss from operations	<u>(27,946)</u>	<u>(27,316)</u>	<u>(30,002)</u>	<u>(98,653)</u>
Other income (expense):				
Interest income	1,070	2,824	2,633	7,197
Interest expense	(1,119)	(766)	(408)	(2,385)
Other, net	(731)	327	201	(205)
Total other income (expense)	<u>(780)</u>	<u>2,385</u>	<u>2,426</u>	<u>4,607</u>
Net loss before taxes	<u>(28,726)</u>	<u>(24,931)</u>	<u>(27,576)</u>	<u>(94,046)</u>
Provision for income taxes				
Net loss	<u>(28,726)</u>	<u>(24,931)</u>	<u>(27,576)</u>	<u>(94,046)</u>
Beneficial conversion feature upon issuance of preferred stock			(22,870)	(22,870)
Net loss attributable to common stockholders	<u>\$ (28,726)</u>	<u>\$ (24,931)</u>	<u>\$ (50,446)</u>	<u>\$ (116,916)</u>
Basic and diluted net loss per share	<u>\$ (0.98)</u>	<u>\$ (0.91)</u>	<u>\$ (4.50)</u>	
Weighted average shares used in computing basic and diluted net loss per share	<u>29,260,930</u>	<u>27,309,502</u>	<u>11,222,319</u>	
Pro forma basic and diluted net loss per share			<u>\$ (2.45)</u>	
Weighted average shares used in computing pro forma basic and diluted net loss per share			<u>20,603,313</u>	

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**

(A Company in the Development Stage)

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

<i>In thousands, except share data</i>	<b>Date of Transaction</b>	<b>Convertible Preferred Stock</b>	<b>Common Stock</b>	<b>Additional Paid-In Capital</b>
<b>Balance Inception (May 18, 1998)</b>		\$	\$	\$
Issuance of 1,329,399 shares of common stock for cash	July 6		2	
Issuance of 10,500,000 shares of Series A and B preferred stock for cash	July 6- August 11	105		15,224
Issuance of 375,700 shares of common stock for notes	September 1- December 11			78
Net loss				
Foreign currency translation adjustment				
		_____	_____	_____
Comprehensive loss				
<b>Balance December 31, 1998</b>		\$ 105	\$ 2	\$ 15,302
Issuance of 231,200 shares of common stock for notes	June 4-July 1			48
Decrease in notes receivables				
Deferred stock compensation related to stock options				1,117
Amortization of deferred stock compensation				
Net loss				
Foreign currency translation adjustment				
		_____	_____	_____
Comprehensive loss				
<b>Balance December 31, 1999</b>		105	2	16,467
Issuance of 310,217 shares of common stock, net, upon exercise of stock options and under stock purchase plan	March 1- December 31			123
Issuance of 10,252,879 shares of Series C preferred stock for cash and services	January 7	102		22,457
Issuance of 1,136,363 shares of Series D preferred stock for cash	February 22	11		4,989

Edgar Filing: ESPERION THERAPEUTICS INC/MI - Form 10-K

Conversion of preferred stock	August 9	(218)	16	202
Issuance of 6,000,000 shares of common stock for initial public offering net of \$1.6 million in offering expenses	August 10		6	48,614
Issuance of 900,000 shares of common stock for underwriters over-allotment	September 5		1	7,532
Issuance of 813,008 shares of common stock for acquisition of Talaria Therapeutics, Inc.	September 21		1	7,316
Deferred stock compensation related to stock options				2,950
Amortization of deferred stock compensation				
Decrease in notes receivable				
Net loss				
Foreign currency translation adjustment				
Comprehensive loss				

[Additional columns below]

[Continued from above table, first column(s) repeated]

<i>In thousands, except share data</i>	<u>Notes Receivable</u>	<u>Accumulated Deficit During the Development Stage</u>	<u>Deferred Stock Compensation</u>	<u>Accumulated Other Comprehensive Income/(Loss)</u>	<u>Total Stockholders Equity</u>	<u>Comprehensive Loss</u>
<b>Balance Inception (May 18, 1998)</b>	\$	\$	\$	\$	\$	
Issuance of 1,329,399 shares of common stock for cash					2	
Issuance of 10,500,000 shares of Series A and B preferred stock for cash					15,329	
Issuance of 375,700 shares of common stock for notes	(78)					
Net loss		(2,143)			(2,143)	\$ (2,143)
Foreign currency translation adjustment				(1)	(1)	(1)
Comprehensive loss						\$ (2,144)
<b>Balance December 31, 1998</b>	\$ (78)	\$ (2,143)	\$	\$ (1)	\$ 13,187	
Issuance of 231,200 shares of common stock	(48)					

Edgar Filing: ESPERION THERAPEUTICS INC/MI - Form 10-K

for notes						
Decrease in notes receivables	20				20	
Deferred stock compensation related to stock options			(1,117)			
Amortization of deferred stock compensation			279		279	
Net loss		(10,670)			(10,670)	\$ (10,670)
Foreign currency translation adjustment				(1)	(1)	(1)
Comprehensive loss						\$ (10,671)
<b>Balance December 31, 1999</b>	(106)	(12,813)	(838)	(2)	2,815	
Issuance of 310,217 shares of common stock, net, upon exercise of stock options and under stock purchase plan					123	
Issuance of 10,252,879 shares of Series C preferred stock for cash and services					22,559	
Issuance of 1,136,363 shares of Series D preferred stock for cash					5,000	
Conversion of preferred stock						
Issuance of 6,000,000 shares of common stock for initial public offering net of \$1.6 million in offering expenses					48,620	
Issuance of 900,000 shares of common stock for underwriters over-allotment					7,533	
Issuance of 813,008 shares of common stock for acquisition of Talaria Therapeutics, Inc.					7,317	
Deferred stock compensation related to stock options			(2,950)			
Amortization of deferred stock compensation			1,014		1,014	
Decrease in notes receivable	39				39	
Net loss		(27,576)			(27,576)	\$ (27,576)
Foreign currency translation adjustment				247	247	247
Comprehensive loss						\$ (27,329)

**Table of Contents****ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**

(A Company in the Development Stage)

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (Continued)**

	<u>Date of Transaction</u>	<u>Convertible Preferred Stock</u>	<u>Common Stock</u>	<u>Additional Paid-In Capital</u>
<i>In thousands, except share data</i>				
<b>Balance December 31, 2000</b>			26	110,650
Issuance of 185,216 shares of common stock, net, upon exercise of options and under stock purchase plan	January 5- December 31			198
Issuance of 58,626 shares of common stock for milestone payment to Talaria Therapeutics, Inc.	January 8			447
Issuance of 3,183,335 shares of common stock for private placement, net of \$1.5 million in offering expenses	July 27		3	22,339
Forgiveness of notes receivable				
Retirement of 10,127 shares of common stock related to indemnification agreement with Talaria Therapeutics, Inc.	November 15			(91)
Deferred stock compensation adjustment	December 1			(400)
Amortization of deferred stock compensation				
Decrease in notes receivable				
Net loss				
Foreign currency translation adjustment				
Comprehensive loss				
<b>Balance December 31, 2001</b>			29	133,143
Issuance of 177,282 shares of common stock, net, upon exercise of options and under stock purchase plan	January 28- December 31			383
Expense related to 8,000 stock options granted to non-employees	August 21			21
Deferred stock compensation adjustment				(136)
Amortization of deferred stock compensation				
Decrease in notes receivable				
Net loss				
Foreign currency translation adjustment				
Unrealized gain on investments				
Comprehensive loss				
<b>Balance December 31, 2002</b>		\$	\$ 29	\$ 133,411

[Additional columns below]



Edgar Filing: ESPERION THERAPEUTICS INC/MI - Form 10-K

[Continued from above table, first column(s) repeated]

	Notes Receivable	Accumulated Deficit During the Development Stage	Deferred Stock Compensation	Accumulated Other Comprehensive Income/(Loss)	Total Stockholders Equity	Comprehensive Loss
<i>In thousands, except share data</i>						
<b>Balance December 31, 2000</b>	(67)	(40,389)	(2,774)	245	67,691	
Issuance of 185,216 shares of common stock, net, upon exercise of options and under stock purchase plan					198	
Issuance of 58,626 shares of common stock for milestone payment to Talaria Therapeutics, Inc.					447	
Issuance of 3,183,335 shares of common stock for private placement, net of \$1.5 million in offering expenses					22,342	
Forgiveness of notes receivable	38				38	
Retirement of 10,127 shares of common stock related to indemnification agreement with Talaria Therapeutics, Inc.					(91)	
Deferred stock compensation adjustment			400			
Amortization of deferred stock compensation			898		898	
Decrease in notes receivable	14				14	
Net loss		(24,931)			(24,931)	\$ (24,931)
Foreign currency translation adjustment				(108)	(108)	(108)
Comprehensive loss						\$ (25,039)
<b>Balance December 31, 2001</b>	(15)	(65,320)	(1,476)	137	66,498	
Issuance of 177,282 shares of common stock, net, upon exercise of options and under stock purchase plan					383	
Expense related to 8,000 stock options granted to non-employees					21	
Deferred stock compensation adjustment			136			
Amortization of deferred stock compensation			751		751	
Decrease in notes receivable	12				12	
Net loss		(28,726)			(28,726)	\$ (28,726)
Foreign currency translation adjustment				(200)	(200)	(200)
Unrealized gain on investments				4	4	4
Comprehensive loss						\$ (28,922)
<b>Balance December 31, 2002</b>	\$ (3)	\$ (94,046)	\$ (589)	\$ (59)	\$ 38,743	

The accompanying notes are an integral part of these consolidated financial statements.



**Table of Contents****ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES****(A Company in the Development Stage)****CONSOLIDATED STATEMENTS OF CASH FLOWS**

<i>In thousands</i>	<b>Year Ended December 31, 2002</b>	<b>Year Ended December 31, 2001</b>	<b>Year Ended December 31, 2000</b>	<b>Inception to December 31, 2002</b>
<b>Cash Flows from Operating Activities:</b>				
Net loss	\$ (28,726)	\$ (24,931)	\$ (27,576)	\$ (94,046)
Adjustments to reconcile net loss to net cash used in operating activities				
Purchased in-process research and development			4,000	4,000
Depreciation and amortization	1,291	2,014	1,036	4,813
Stock-based compensation expense	771	898	1,427	3,650
Decrease in notes receivable	12	52	39	123
Loss on sale of furniture and equipment	169	22		191
Non-cash interest included in long-term debt	384	243	145	787
Increase (decrease) in cash resulting from changes in				
Prepaid expenses and other	596	(440)	(1,256)	(1,238)
Other assets	599	6	(85)	520
Accounts payable	(1,242)	(816)	2,619	1,956
Accrued liabilities	(418)	185	1,697	2,182
Net cash used in operating activities	<u>(26,564)</u>	<u>(22,767)</u>	<u>(17,954)</u>	<u>(77,062)</u>
<b>Cash Flows from Investing Activities:</b>				
Purchases of furniture and equipment	(1,155)	(2,023)	(1,341)	(6,946)
Deposit on equipment		(107)	(450)	(557)
Acquisition of Talaria Therapeutics, Inc.			(233)	(233)
Proceeds from sale of furniture and equipment	30	2		32
Purchases of short-term investments	(37,215)			(37,215)
Maturities of short-term investments	32,861			32,861
Net cash used in investing activities	<u>(5,479)</u>	<u>(2,128)</u>	<u>(2,024)</u>	<u>(12,058)</u>
<b>Cash Flows from Financing Activities:</b>				
Proceeds from issuance of convertible preferred stock			26,871	42,200
Proceeds from issuance of common stock	384	22,449	56,276	79,111
Proceeds from long-term debt	2,132	3,523	1,489	10,171
Repayments of long-term debt	(1,075)	(956)	(518)	(2,797)
Net cash provided by financing activities	<u>1,441</u>	<u>25,016</u>	<u>84,118</u>	<u>128,685</u>
Effect of Exchange Rate Changes on Cash	815	(63)	184	934
Increase (Decrease) in Cash and Cash Equivalents	(29,787)	58	64,324	40,499
Cash and Cash Equivalents Beginning of Period	70,286	70,228	5,904	
Cash and Cash Equivalents End of Period	<u>\$ 40,499</u>	<u>\$ 70,286</u>	<u>\$ 70,228</u>	<u>\$ 40,499</u>

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**

**(A Company in the Development Stage)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(1) Description of the Business**

Esperion Therapeutics, Inc. (formerly Metapharma, Inc.) was incorporated on May 18, 1998. Esperion Therapeutics, Inc. and its subsidiaries, Esperion AB and Esperion LUV Development, Inc. (collectively referred to as the Company), are devoting substantially all of their efforts towards conducting drug discovery and development, initiating and overseeing clinical trials, pursuing regulatory approval for products under development, recruiting personnel, raising capital, and building infrastructure. The Company's main focus is the research and development of pharmaceutical product candidates for cardiovascular disease.

In the course of such activities, the Company has sustained significant operating losses and expects such losses, which will likely increase as the Company expands its research and development activities, to continue for at least the next several years. The Company has not generated any revenues or product sales and has not achieved profitable operations or positive cash flows from operations. The Company's accumulated deficit during the development stage totaled approximately \$94.0 million through December 31, 2002. The Company plans to finance its operations with a combination of stock issuances, license payments, and payments from strategic research and development arrangements and, if its product candidates are commercialized, with revenues from product sales. There are no assurances that the Company will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of its planned products.

**(2) Significant Accounting Policies**

*Principles of Consolidation and Translation*

The accompanying consolidated financial statements include the accounts of Esperion Therapeutics, Inc., Esperion AB (Sweden) and Esperion LUV Development, Inc. All significant intercompany accounts and transactions have been eliminated in consolidation.

The financial statements of Sweden are translated using exchange rates in effect at the end of the period for assets and liabilities and at average rates during the period for results of operations. The resulting foreign currency translation adjustment is reflected as a separate component of stockholders' equity. Other foreign currency transaction gains/losses totaled approximately a loss of \$703,000, a gain of \$400,000, a gain of \$201,000 and a loss of \$102,000 for the years ended December 31, 2002, 2001, 2000, and for the period from inception to December 31, 2002, respectively, and are included in other income in the statements of operations.

*Research and Development*

Research and development expenses include both external and internal costs related to the research and development activities of our existing product candidates as well as discovery efforts on potential new product candidates. External costs include costs related to manufacturing, clinical trials, toxicology and pharmacology studies performed by third parties, milestone payments under certain license and other agreements, and other related expenses. Internal costs include all payroll and related costs attributable to research and development activities, as well as an allocation of overhead expenses incurred by the Company.

The Company records estimated research and development expenses under contracts with third parties on a percentage of completion basis. These contracts cover ongoing clinical trials, manufacturing and supply agreements and third-party toxicology or pharmacology studies. The expenses are recorded as the work under the contract is completed and the Company may record an accrued liability or prepaid expense on the accompanying balance sheets, depending on the payment terms under each contract.

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

*Licensed Technology and Patents*

Costs incurred in obtaining the license rights to certain technology and patents in the development stage are expensed as incurred due to the uncertainty regarding potential alternative future uses and the uncertainty regarding future operating cash flows expected to be derived from the licensed technology and patents.

*Cash and Cash Equivalents*

The Company considers all financial instruments purchased with initial maturities of three months or less to be cash equivalents.

*Short-term Investments*

The Company considers all financial instruments purchased with initial maturities of greater than three months and less than one year to be short-term investments. Investments under this classification are recorded at fair market value and unrealized gains and losses are recorded as a separate component of stockholders' equity. Short-term investments at December 31, 2002 consist of government agency notes and municipal bonds with a weighted average maturity of approximately ten months. Investments are maintained with high quality institutions, and management regularly monitors the composition and maturities of investments. Generally, these securities are traded in a highly liquid market, may be redeemed upon demand and bear minimal risk. By policy, the Company limits the amount of credit exposure to any one financial institution or commercial issuer. The Company has not experienced any material losses on its investments.

*Furniture and Equipment*

Furniture and equipment is stated at cost and depreciated over the estimated useful lives of the related assets using the straight-line method. Office furniture and equipment is depreciated over a seven-year period, laboratory equipment is depreciated over a five-year period and computer equipment is depreciated over a three-year period. The Company recorded depreciation expense of \$1.3 million, \$1.2 million and \$786,000 for the years ended December 31, 2002, 2001 and 2000, respectively. Furniture and equipment consist of the following (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2002</b>	<b>2001</b>
Laboratory equipment	\$ 3,894	\$ 2,957
Computer equipment	2,217	2,110
Office furniture and equipment	580	661
	6,691	5,728
Less accumulated depreciation	(3,690)	(2,415)
	\$ 3,001	\$ 3,313

*Goodwill*

The Company adopted Statement of Financial Accounting Standard No. 142, Goodwill and Other Intangible Assets (SFAS 142), effective January 1, 2002. Under SFAS 142, goodwill and certain indefinite lived intangible assets are no longer amortized but are reviewed at least annually for impairment. In connection with the adoption of SFAS 142, the Company has completed the transitional goodwill impairment test, which requires the Company to compare its fair value to the carrying value of its net assets. Based on this



**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

analysis, the Company has concluded that no impairment existed at the time of adoption, and, accordingly, the Company has not recognized any transitional impairment loss.

Goodwill reflects the excess of the purchase price over net assets in the Company's September 2000 acquisition of Talaria Therapeutics, Inc. (Talaria) and the milestone payments made to date under the related merger agreement. The gross carrying amount of goodwill is approximately \$3.1 million as of December 31, 2002 and \$4.2 million, with accumulated amortization of approximately \$1.1 million, as of December 31, 2001. The assets acquired from Talaria relate to one of the Company's ongoing development projects, ETC-588. This product candidate is currently in Phase II clinical development for the treatment of cardiovascular disease.

As required by SFAS 142, the results of operations for periods prior to its adoption have not been restated. Had SFAS 142 been adopted prior to January 1, 2002, the pro forma loss for the periods ended December 31, 2001 and December 31, 2000 and for the period from inception to December 31, 2001 would have been as follows (in thousands, except per share data):

	<u>Year Ended December 31,</u>		<u>Inception to</u> <u>December 31,</u>
	<u>2001</u>	<u>2000</u>	<u>2001</u>
Net loss:			
Net loss	\$ (24,931)	\$ (27,576)	\$ (65,320)
Beneficial conversion feature upon issuance of preferred stock		(22,870)	(22,870)
	<u>(24,931)</u>	<u>(50,446)</u>	<u>(88,190)</u>
Net loss attributable to common stockholders	(24,931)	(50,446)	(88,190)
Goodwill amortization	839	250	1,089
	<u>(24,092)</u>	<u>(50,196)</u>	<u>(87,101)</u>
Adjusted net loss attributable to common stockholders	\$ (24,092)	\$ (50,196)	\$ (87,101)
Basic and diluted net loss per share:			
Reported basic and diluted net loss per share	\$ (0.91)	\$ (4.50)	
Goodwill amortization	0.03	0.03	
	<u>(0.88)</u>	<u>(4.47)</u>	
Adjusted basic and diluted net loss per share	\$ (0.88)	\$ (4.47)	
Pro forma basic and diluted net loss per share:			
Pro forma basic and diluted net loss per share		\$ (2.45)	
Goodwill amortization		0.02	
		<u>(2.43)</u>	
Adjusted pro forma and diluted net loss per share		\$ (2.43)	
Shares used in computing basic and diluted net loss per share	<u>27,309,502</u>	<u>11,222,319</u>	
Shares used in computing pro forma and diluted net loss per share		<u>20,603,313</u>	

*Impairment of Long-Lived Assets*



## Edgar Filing: ESPERION THERAPEUTICS INC/MI - Form 10-K

SFAS No. 144, Accounting for the Impairment or Disposal of Long Lived Assets ( SFAS 144 ), supersedes SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of , and the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions , for the disposal of a segment of a business (as

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

previously defined in that Opinion). SFAS 144 retains the previous cash flow test for impairment and broadens the presentation of discontinued operations. SFAS 144 was effective for the Company's fiscal year beginning January 1, 2002 and did not have a material impact upon effectiveness. The Company's long-lived assets consist primarily of computer and lab equipment that are depreciated over short useful lives to prevent impairment issues.

*Accrued Liabilities*

Accrued liabilities consist of the following (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2002</b>	<b>2001</b>
Accrued external costs	\$ 1,257	\$ 1,511
Accrued compensation	560	649
Accrued professional fees	198	226
Accrued other	170	186
	\$ 2,185	\$ 2,572

Accrued external costs relate primarily to work that is outsourced to third parties related to research and/or development of the Company's product candidates. These contracts are accounted for under the percentage of completion basis, resulting in accrued liabilities for work completed, but not yet billed to the Company as of the balance sheet date.

*Stock-Based Compensation*

The Company accounts for stock-based compensation to employees using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25 (APB 25), Accounting for Stock Issued to Employees, and related interpretations. Accordingly, compensation cost for stock options is measured as the excess, if any, of the fair value of the Company's common stock as of the date of the grant over the amount the employee must pay to acquire the stock.

SFAS 148 amends SFAS 123 to provide alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting for stock-based employee compensation. It also amends the disclosure provisions of SFAS 123 to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation. SFAS 148 also amends APB Opinion No. 28, Interim Financial Reporting, to require disclosure about the effects of SFAS 148 in interim financial information. This statement is effective for fiscal years ending after December 15, 2002.

Using the intrinsic value method under APB 25, no compensation expense has been recognized in the accompanying consolidated statements of operations for options granted to employees at fair value. Had compensation expense been determined based on the fair value at the date of grant consistent with SFAS 123,

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

the reported net loss would have increased to the following pro forma amounts, which may not be representative of that to be expected in future years (in thousands, except per share data):

	December 31,		
	2002	2001	2000
Net loss:			
As Reported	\$ (28,726)	\$ (24,931)	\$ (50,446)
Pro Forma	\$ (31,502)	\$ (27,010)	\$ (51,267)
Basic and diluted loss per share:			
As Reported	\$ (0.98)	\$ (0.91)	\$ (4.50)
Pro Forma	\$ (1.08)	\$ (0.99)	\$ (4.57)

The fair value of options was estimated at the date of grant using the Black Scholes Single Option valuation method under SFAS 123 with the following assumptions as of December 31, 2002, 2001 and 2000, respectively: weighted average risk free interest rate of 2.82%, 4.27% and 4.98%; dividend yield of 0%; volatility of 51.71%, 110.67% and 130.22%; and expected life of options of five years. The weighted-average fair values of options granted during 2002, 2001 and 2000 were \$2.75, \$5.60 and \$5.08 per share, respectively. Option valuation models require the input of highly subjective assumptions. Because changes in subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing model does not necessarily provide a reliable single measure of the fair value of the Company's stock options.

*Supplemental Disclosures of Cash Flow Information*

The Company paid cash for interest of approximately \$701,000, \$526,000, \$282,000, and \$1,575,000 in 2002, 2001, 2000 and the period from inception to December 31, 2002, respectively.

*Basic, Diluted and Pro Forma Net Loss per Share*

Basic and diluted net loss per share amounts have been calculated using the weighted average number of shares of common stock outstanding during the respective periods. Pro forma basic and diluted net loss per share amounts include the shares used in computing basic and diluted net loss per share and the assumed conversion of all outstanding shares of preferred stock from the original date of issuance.

The following table presents the calculation of pro forma basic and diluted net loss per share (in thousands, except share and per share data):

	December 31, 2000
Net loss attributable to common stockholders	\$ (50,446)
Weighted average shares used in computing basic and diluted net loss per share	11,222,319
Pro forma adjustment to reflect assumed conversion of Series A and Series B convertible preferred stock	4,614,965
Pro forma adjustment to reflect assumed conversion of Series C and Series D convertible preferred stock	4,766,029
	20,603,313
Weighted average shares used in computing pro forma basic and diluted net loss per share	20,603,313

## Edgar Filing: ESPERION THERAPEUTICS INC/MI - Form 10-K

Pro forma basic and diluted net loss per share	\$	(2.45)
--	----	--------

---

In 2002, 2001 and 2000, 318,808, 502,516 and 898,736 options, respectively, for the purchase of common stock were not included in the calculation of diluted loss per share as doing so would have been anti-dilutive. The Company has entered into certain agreements that can be settled by issuing shares of the Company's common stock. The effect of these settlements has not been included in the calculation of diluted loss per share as doing so would have been anti-dilutive.

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

*Comprehensive Loss*

Comprehensive loss is the total of net loss and all other non-owner changes in equity. The difference between net loss, as reported in the accompanying consolidated statements of operations, and comprehensive loss is the foreign currency translation adjustment and an unrealized gain on short-term investments for the period ended December 31, 2002, and the foreign currency translation adjustment for the period ended December 31, 2001 and 2000.

*New Accounting Pronouncements*

SFAS 146 Accounting for Restructuring Costs, ( SFAS 146 ), applies to costs associated with an exit activity, including a restructuring, or with a disposal of long-lived assets. SFAS 146 requires that a liability be recorded for costs associated with exit or disposal activity when the liability is incurred and can be measured at fair value, rather than at the date of commitment to an exit activity. SFAS 146 also requires disclosures about exit and disposal activities, the related costs, and changes in those costs in the notes to the financial statements that include the period in which an exit activity is initiated and in any subsequent period until the activity is completed. SFAS 146 is effective prospectively for exit or disposal activities initiated after December 31, 2002, and is not expected to have a material impact to the Company's financial statements upon effectiveness.

In November 2002, the FASB released FASB Interpretation No. 45 (FIN 45), Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others: an interpretation of FASB Statements No. 5, 57 and 107 and rescission of FASB Interpretation No. 34. FIN 45 establishes new disclosure and liability-recognition requirements for direct and indirect debt guarantees with specified characteristics. The initial measurement and recognition requirements of FIN 45 are effective prospectively for guarantees issued or modified after December 31, 2002. However, the disclosure requirements are effective for interim and annual financial-statement periods ending after December 15, 2002. The Company has adopted the disclosure provisions and the full adoption of FIN 45 is not expected to have a material impact on the Company's results of operations or financial position.

*Use of Estimates*

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

**(3) Stockholders' Equity**

On March 24, 2000, the stockholders of the Company approved an amendment and restatement to the Company's certificate of incorporation that, as of August 9, 2000, effected (i) an increase in the number of authorized shares of common stock to 50,000,000, and (ii) a reduction in the number of authorized shares of preferred stock from 15,000,000 to 5,000,000. All references in the consolidated financial statements and accompanying notes have also been adjusted to reflect the amendment and restatement of the certificate of incorporation.

*Reverse Stock Split*

The Company effected a 0.7225-for-1 reverse stock split of all outstanding shares of common stock and stock options as of March 24, 2000. All references to the number of shares and per share amounts have been retroactively restated to reflect this reverse stock split.

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

*Common Stock*

Holders of common stock are entitled to one vote per share on all matters submitted to a vote of holders of shares of common stock, and do not have any cumulative voting rights. In the event of a liquidation, dissolution or winding-up of the Company, the holders of shares of common stock are entitled to share equally and ratably in the assets of the Company, if any, remaining after payment of debts and liabilities of the Company, subject to the prior liquidation rights of any outstanding shares of preferred stock.

In July 2001, the Company completed a private placement of its stock, which resulted in the issuance of 3,183,335 shares of common stock at \$7.50 per share. The net proceeds from the private placement were approximately \$22.3 million. In August 2001, the Company filed a Registration Statement under the Securities Act of 1933, as amended, to register the resale of these shares by the purchasers of such shares. The Registration Statement was declared effective by the Securities and Exchange Commission on September 4, 2001.

In August 2000, the Company completed the initial public offering of its common stock, which resulted in the issuance of 6,000,000 shares of common stock at \$9.00 per share. In connection with the offering, all of the outstanding shares of preferred stock were converted to common stock. In September 2000, an additional 900,000 shares of common stock were sold by the Company at \$9.00 per share to cover the underwriters over-allotment. As a result of those sales, the Company received net proceeds of approximately \$56.3 million.

*Preferred Stock*

The Board of Directors is authorized to issue up to 5,000,000 shares of preferred stock in one or more series. Under each issuance of a series of preferred stock, the Board of Directors is permitted to fix the designations, preferences, powers and relative rights and restrictions thereof, including without limitation, the dividend rate, conversion rights, voting rights, redemption price and liquidation preference.

*Series A Junior Participating Preferred Stock*

On April 18, 2002, the Company's Board of Directors approved a stockholder rights plan as set forth in the Rights Agreement dated April 18, 2002 between the Company and StockTrans, Inc., as rights agent (the "Rights Agreement"). In connection with the approval of the Rights Agreement, the Board of Directors declared a distribution of one Right for each outstanding share of the Company's common stock, par value \$.001 per share, to stockholders of record at the close of business on April 18, 2002. Each Right, if and when exercisable, will entitle the holder to purchase from the Company one one-hundredth (1/100) of a share of the Series A Junior Participating Preferred Shares, par value \$.01 per share, or a combination of securities and assets of equivalent value, at a per unit, adjustable Purchase Price of \$50.00. The rights will not be exercisable until the earlier of (i) ten business days following the first public announcement that a person or group of persons together with all affiliates and associates has acquired beneficial ownership of 15% or more of the then-outstanding Common Stock, or (ii) ten business days following the commencement of a tender offer or exchange offer, that if consummated, would result in a person or group of persons together with all affiliates and associates beneficially owning 15% or more of the then-outstanding Common Stock. The Rights will expire at the close of business on April 18, 2012, unless earlier redeemed or terminated by the Company.

On November 26, 2002, the Board of Directors approved an amendment ( "Amendment No. 1") to the Rights Agreement. Amendment No. 1 revises the definition of "Acquiring Person" to exclude the Sacane Group (as defined in Amendment No. 1) unless and until the earlier of such time as the Sacane Group, together with all affiliates and associates, directly or indirectly, becomes the beneficial owner of 25% or more of the shares of Common Stock then outstanding or ceases to hold any of the Common Stock of which it is the beneficial owner without any intention of changing or influencing control of the Company.

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

*Series C and Series D Preferred Stock*

In January and February 2000, the Company issued shares of Series C and Series D preferred stock. Total cash proceeds to the Company were approximately \$21.9 million and \$5.0 million relating to the issuance of 10,252,879 shares of Series C and 1,136,363 shares of Series D, respectively. As a part of the Series C offering, the Company issued 127,414 shares to the chief executive officer and another member of the Board of Directors for services rendered to the Company during 1999. The Company recorded the related expense of \$275,215 as an increase to compensation expense during 1999.

In accordance with EITF 98-5, the Company recorded approximately \$22.9 million relating to the beneficial conversion feature of the Series C and Series D preferred stock in the first quarter of fiscal 2000 through equal and offsetting adjustments to additional paid-in capital with no net impact on stockholders' equity, as the preferred stock was convertible immediately on the date of issuance. The beneficial conversion feature was considered in the determination of the Company's loss per common share amounts. The Company also recorded an additional \$412,819 relating to the Series C shares issued to the chief executive officer and the Board member in the first quarter of fiscal 2000. This non-cash charge was reflected through entries to compensation expense and additional paid-in-capital.

*Conversion of Preferred Stock*

In connection with the initial public offering, each of the Company's outstanding shares of Series A, Series B, Series C and Series D preferred stock (Series A, Series B, Series C and Series D, respectively, together Preferred Stock) was automatically converted into approximately 0.7225 shares of common stock.

**(4) Acquisition**

On September 21, 2000, the Company acquired all of the outstanding shares of stock of Talaria Therapeutics, Inc. (Talaria) in exchange for the issuance of 813,008 shares of the Company's restricted common stock to Talaria stockholders, valued at a price of \$9.00 per share. Additionally, the merger agreement provides for the following additional consideration to Talaria stockholders: (i) payment by the Company of up to \$6.3 million in cash and/or common stock based on the achievement of four development milestones; and (ii) payment by the Company of royalties in cash and/or common stock based on net annual sales of large unilamellar vesicles, or LUV, in North America. The milestones are due upon the enrollment of the first patient in certain clinical trials and upon each of the filing and approval of a new drug application in the United States. On January 8, 2001, the Company achieved the first of the milestones. This milestone payment was settled through the issuance of 58,626 shares of restricted common stock with an aggregate value of \$447,000. This milestone payment was accounted for as an increase in the purchase price and added to goodwill during the first quarter of 2001. No milestones were achieved under this agreement during 2002. The royalty payments will be included in cost of sales in the period when the respective sales are recognized. The combined milestone payments and royalties are subject to a maximum aggregate ceiling of \$20.0 million.

The acquisition was accounted for under the purchase method of accounting. In connection with this acquisition, the Company recorded a \$4.0 million non-cash charge to operations in 2000 associated with the write-off of in-process research and development acquired in the transaction that had not reached technological feasibility. The allocation of the purchase price was based on an appraisal of the fair values on the closing date. The Company recorded approximately \$3.75 million as goodwill, representing the excess of the purchase price over the fair value of the net assets acquired. This amount included \$265,000 of acquisition-related costs. The operating results of Talaria have been included in the consolidated results of operations from the date of the merger.

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

The purchase price allocation based on the net assets of Talaria at the closing date is as follows (in thousands):

Net assets (liabilities)	\$ (168)
In-process research and development	4,000
Goodwill	3,750
	<hr/>
Total purchase price	\$ 7,582
	<hr/>

The unaudited pro forma operations for the year ended December 31, 2000, set forth below, report results as if the Company and Talaria had been combined as of the beginning of the year. The pro forma results include estimates and assumptions which management believes are reasonable. However, pro forma results do not include the write-off of in-process research and development, any anticipated cost savings or other effects of the planned integration of the Company and Talaria, and are not necessarily indicative of the results which would have occurred if the business combination had been in effect for the period presented below, or which may result in the future (in thousands, except share and per share data).

	<b>Pro forma Year ended December 31, 2000</b>
Operating expenses	\$ 27,941
	<hr/>
Net loss	(29,682)
	<hr/>
Basic and diluted net loss per share	\$ (2.51)
	<hr/>
Shares used in computing basic and diluted net loss per share	11,809,492
	<hr/>

**(5) Equity Compensation Plans***2000 Equity Compensation Plan*

In 2000, the Company established the 2000 Equity Compensation Plan (as amended and restated, the 2000 Plan). The 2000 Plan provides for grants of incentive stock options, nonqualified stock options, stock awards and performance units to the Company's employees, advisors, consultants and non-employee directors.

The 2000 Plan authorizes the issuance of up to 3,069,000 shares of common stock. No stock awards or performance units have been granted to date under the 2000 Plan. Grants may be made to any of the Company's employees, members of our board of directors, and consultants and advisors who perform services for us. The exercise price of stock options will be determined by the compensation committee of the board of directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted.

Options generally become exercisable over a period of four years from the date of grant, and expire ten years after the grant date.





**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

A summary of stock option activity under the 2000 Plan for the years ended December 31, 2002, 2001 and 2000 is as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
Outstanding at December 31, 1999		
Options granted	160,000	\$ 11.53
Options cancelled		
Options exercised		
Outstanding at December 31, 2000	160,000	\$ 11.53
Options granted	609,125	\$ 7.01
Options cancelled	(25,000)	\$ 7.16
Options exercised		
Outstanding at December 31, 2001	744,125	\$ 7.98
Options granted	1,887,000	\$ 5.77
Options cancelled	(541,181)	\$ 7.16
Options exercised	(531)	\$ 5.00
Outstanding at December 31, 2002	<u>2,089,413</u>	\$ 6.19

As of December 31, 2002, there were 979,056 shares of common stock available for issuance under the 2000 Plan.

During 2002, the Company issued 8,000 options to purchase common stock to consultants under the 2000 plan. The options were issued at fair value on the date of the grant. The Company recorded an expense of approximately \$21,000 in the accompanying consolidated statements of operations that represents the fair value at the date of grant using the Black Scholes Single Options valuation method, with assumptions as described under Note 2 to Consolidated Financial Statements.

*1998 Stock Option Plan*

In 1998, the Company established the 1998 Stock Option Plan (the 1998 Plan) to increase its ability to attract and retain key individuals. Options granted under the 1998 Plan may be either incentive stock options, which are granted at the fair market value of the common stock on the date of grant or higher (as determined under the plan), or nonqualified stock options, which may be granted at less than the fair market value of the common stock on the date of grant. Options are granted at the discretion of the Board of Directors. The maximum number of shares that may be granted under the 1998 Plan is 1,784,575. Options granted generally become exercisable over a period of four years from the date of grant. Outstanding options generally expire nine years after the date of grant.

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

A summary of stock option activity under the 1998 Plan for the years ended December 31, 2002, 2001 and 2000 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 1999	867,630	\$ 0.24
Options granted	904,291	\$ 4.86
Options cancelled	(5,104)	\$ 5.40
Options exercised	(333,966)	\$ 0.22
Outstanding at December 31, 2000	1,432,851	\$ 3.14
Options granted	116,846	\$ 9.05
Options cancelled	(146,915)	\$ 2.54
Options exercised	(222,532)	\$ 0.35
Outstanding at December 31, 2001	1,180,250	\$ 4.33
Options granted	36,500	\$ 6.26
Options cancelled	(139,515)	\$ 7.53
Options exercised	(161,244)	\$ 1.90
Outstanding at December 31, 2002	915,991	\$ 4.34

As of December 31, 2002, there were 150,843 shares of common stock available for issuance under the 1998 Plan.

The options outstanding and exercisable at December 31, 2002 under both the 1998 and 2000 Plans are as follows:

Price Per Share	Options Outstanding	Weighted Average Exercise Price	Weighted Average Contractual Remaining Life	Options Exercisable	Weighted Average Exercise Price
\$0.14-\$4.19	508,820	\$ 2.05	6.1	357,265	\$ 1.77
\$4.33-\$4.80	332,033	\$ 4.61	7.1	177,646	\$ 4.58
\$5.00	545,500	\$ 5.00	9.4	68,190	\$ 5.00
\$5.19-\$6.18	194,833	\$ 5.51	9.0	45,574	\$ 5.58
\$6.26	872,000	\$ 6.26	9.0	163,512	\$ 6.26
\$6.27-\$9.94	470,361	\$ 8.17	7.9	185,453	\$ 8.52
\$11.50-\$18.88	81,857	\$ 15.20	6.7	45,189	\$ 15.38
	3,005,404	\$ 5.63	8.1	1,042,829	\$ 5.12

*Deferred Stock Compensation*

## Edgar Filing: ESPERION THERAPEUTICS INC/MI - Form 10-K

The Company recorded approximately \$4.0 million of deferred stock compensation in 2000 and 1999 relating to stock options granted to employees at less than the board of director's estimate of fair value. These amounts are included as a reduction in stockholders' equity and are being amortized on a straight-line basis to expense over the related vesting periods. For the years ended December 31, 2002, 2001 and 2000, the Company recorded deferred stock compensation amortization of approximately \$751,000, \$898,000 and \$1 million, respectively, which is included in operating expenses.

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

*Employee Stock Purchase Plan*

The Company's Employee Stock Purchase Plan (the "Purchase Plan") was approved by the Company's Board of Directors in 2000. A total of 500,000 shares of common stock have been reserved for issuance under the Purchase Plan. The Purchase Plan provides that the Company will sell shares to employees who elect to participate in the Purchase Plan at a price equal to 85% of the lesser of the fair market value of the common stock on the first trading day of an offering period or the last trading day of such offering period.

Under the Purchase Plan, the Company issued 15,507, 22,291 and 6,042 shares of common stock in 2002, 2001 and 2000, respectively, to various employees. These shares were issued with a weighted average price per share of \$4.82, \$5.96 and \$9.14 as of December 31, 2002, 2001 and 2000, respectively. At December 31, 2002, there were 456,160 shares of common stock remaining to be issued under the Purchase Plan.

**(6) Income Taxes**

As of December 31, 2002 and 2001, the Company had net operating loss carryforwards of approximately \$63.9 million and \$41.5 million, respectively. These net operating loss carryforwards begin to expire in 2013 through 2022. Additionally, utilization of net operating loss carryforwards may be limited under Section 382 of the Internal Revenue Code. These and other deferred income tax assets are fully reserved by a valuation allowance due to historical operating losses.

The Company's effective tax rate is 0%, resulting from losses incurred in the development stage. This effective rate differs from the statutory rate of 34% due to the Company providing a valuation allowance against deferred tax assets, which primarily consists of net operating loss carryforwards. The Company's income tax provision (benefit) consisted of the following:

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Current	\$	\$	\$
Deferred	(9,744)	(7,283)	(8,477)
Change in valuation allowance	9,744	7,283	8,477
	<u>\$</u>	<u>\$</u>	<u>\$</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets for financial reporting and the amount used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	<u>December 31,</u>		
	<u>2002</u>	<u>2001</u>	<u>2000</u>
Start-up costs	\$ 6,997	\$ 5,081	\$ 3,230
Net operating loss carryforward	21,732	13,964	8,555
Asset basis differences	133	73	50
Less Valuation allowance	(28,862)	(19,118)	(11,835)
	<u>\$</u>	<u>\$</u>	<u>\$</u>

**(7) Commitments and Contingencies**

*Lease Commitments*

The Company leases its office space under operating leases that expire at various dates through June 2004. Total rent expense under all leases was approximately \$797,000, \$540,000 and \$505,000 in 2002, 2001

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

and 2000, respectively. Future minimum payments under noncancellable operating leases at December 31, 2002 are as follows (in thousands):

2003	\$ 723
2004	35
	\$ 758
	\$ 758

*Capital Expenditures*

The Company entered into an agreement with a scientific instrument manufacturer to purchase a specialized piece of equipment. The Company is obligated to pay a total of \$1,000,000 for the equipment. As of December 31, 2002, the Company has paid \$600,000 for the equipment. This portion is classified in Furniture and Equipment in the accompanying Balance Sheets. The additional \$400,000 is due upon receipt and approval of an upgrade that is expected to occur during 2003. No liability or expense was recorded in 2002 related to this remaining \$400,000 purchase commitment.

*Committed Research and Development*

The Company enters into various agreements with third parties related to the research and development activities of its existing product candidates as well as discovery efforts on potential new product candidates. These agreements include costs related to manufacturing, clinical trials and toxicology or pharmacology studies performed by third parties. The estimated remaining amount to be incurred under these agreements totals approximately \$5.0 million as of December 31, 2002. The amount and timing of these commitments may change, as they are largely dependent on the enrollment and timing of the clinical trials.

*License Agreements*

In June 1998, the Company entered into a license agreement with a pharmaceutical company for one of the Company's product candidates (the 1998 Agreement). The Company paid initial license fees of \$750,000 under the 1998 Agreement and may be obligated to make additional payments up to \$14.5 million in the aggregate upon reaching certain milestones.

In March 1999, the Company entered into a license agreement with a pharmaceutical company for one of the Company's product candidates (the 1999 Agreement). During 2001, the Company paid \$100,000 upon obtaining the first milestone under the 1999 Agreement and may be obligated to make additional payments of up to \$6.2 million in the aggregate upon reaching certain other milestones.

In September 1999, the Company entered into a license agreement with a group of inventors for one of the Company's product candidates. The initial license fee of \$50,000 was paid in 2000. The Company paid \$50,000 upon reaching the first milestone in 2001 and may be obligated to make additional payments of up to \$2.1 million in the aggregate upon reaching certain other milestones.

In February 2000, the Company entered into a license agreement with a European entity for one of the Company's product candidates. The Company made an initial license payment of \$25,000.

In September 2000, the Company acquired all of the outstanding shares of stock of Talaria pursuant to a merger agreement and related documents. The Company made the first milestone payment under the merger agreement in 2001 and may be obligated to make additional payments of up to \$5.5 million in the aggregate upon reaching certain other milestones as discussed in Note 4.

In September 2001, the Company entered into a license agreement with an educational institution for a discovery project. The Company paid an initial combined license and maintenance fee of \$25,000 and is obligated to pay additional annual license maintenance fees of up to an

aggregate of \$905,000. The Company may also be obligated make payments of up to \$995,000 in the aggregate upon reaching certain milestones.



**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

All of the payments were charged to research and development expenses in the accompanying consolidated statements of operations.

In connection with the above agreements, the Company may be obligated to make milestone and license maintenance payments, as defined in the respective license and other agreements relating to the Company's proprietary rights, up to an aggregate remaining amount of \$30.2 million. Some of these payments may be fulfilled through the issuance of the Company's common stock, at the Company's option. Upon reaching certain milestones, the payments are charged to research and development expenses in the accompanying consolidated statements of operations. There were no such milestones achieved or payments made during 2002. At the present time, the Company can give no assurances that any such milestones will be achieved. In addition to the milestone and license maintenance payments, the Company may be obligated to make royalty payments on future sales pursuant to formulas in the agreements.

*Employee Benefit Plan*

The Company maintains a 401(k) plan covering substantially all of its employees in the United States. The Board of Directors has authorized an amendment to the 401(k) plan to allow, at the discretion of the Board of Directors, the Company to make matching and/or discretionary contributions on behalf of all participants who have elected to make deferrals to the 401(k) plan. During 2002, the Company recorded approximately \$125,000 related to matching contributions. These contributions will be paid in 2003 in the form of shares of Common Stock.

**(8) Long-Term Debt**

As of December 31, 2002, the Company has the following credit facilities and outstanding borrowings:

A \$2.0 million credit facility with a U.S. bank that may be used to finance purchases of equipment that is pledged as collateral: Borrowings under this facility bear interest at the bank's prime rate (4.25% at December 31, 2002). Borrowings outstanding under this facility as of December 31, 2002 amounted to approximately \$1.1 million and must be repaid by May 2006. No additional borrowings are allowed. In connection with the agreement, the Company has to maintain a minimum tangible net worth of \$9.0 million and invest a minimum of \$10.0 million with the U.S. bank. The Company's investment with the U.S. bank was below the required threshold at December 31, 2002. However, the Company obtained a waiver from the U.S. bank and has corrected the non-compliance.

An additional credit facility with a U.S. lending institution to finance purchases of equipment that is pledged as collateral: This facility allowed for borrowings of up to \$2.5 million. Approximately \$1.2 million was outstanding under this facility at a weighted average interest rate of 12% as of December 31, 2002. Outstanding amounts under this facility must be repaid by November 2004 and no additional borrowings are allowed.

A credit facility with a Swedish entity totaling a principal amount of 50 million Swedish Kronor (\$5.8 million as of December 31, 2002): The proceeds from this facility may only be used to fund the development of our ETC-216 (AIM) product candidate. If results achieved by the AIM project are not capable of being used commercially, the Company's obligation to repay the loan plus a portion of accrued interest may be forgiven. Borrowings under the loan facility bear interest at 17.0% of which 9.5% is payable quarterly. The remaining 7.5% of interest together with principal is payable in five equal annual installments starting in December 2004. The outstanding borrowings, including accrued interest of 7.5 million Swedish kronor (\$859,000), amounted to 52.5 million Swedish Kronor (\$6.1 million) as of December 31, 2002. The Company is in discussions with the Swedish entity regarding the principal amount of 5 million Swedish Kronor remaining under the facility, disbursement

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

of which is related to completion of a final milestone under the facility. The milestone may be achieved in the future; however, the funds may be unavailable to the Company due to the ramp down of operations in Sweden during 2002. A condition under the credit facility is that the project be principally carried out in Sweden.

An agreement with a Michigan non-profit corporation whereby the Company can borrow up to \$447,000 for equipment purchases, pledged as collateral, at an interest rate of 4%. As of December 31, 2002, outstanding borrowings under this arrangement totaled \$447,000 and must be repaid by November 2008. As required by the agreement, the Company will begin making principal payments in August 2004. As of December 31, 2002, maturities of long-term debt are as follows (in thousands):

2003.	\$	1,061
2004		2,161
2005		1,513
2006		1,275
2007		1,520
Thereafter		1,262
		8,792
Less current portion		(1,061)
		\$ 7,731

**(9) Related Party Transactions**

Certain stockholders have provided consulting and other professional services to the Company. Total expense for these services was \$177,000 in 2002, \$367,000 in 2001 and \$305,000 in 2000. At December 31, 2002 and 2001, amounts due to related parties totaled \$20,000 and \$80,000, respectively, and are classified as accounts payable or accrued liabilities in the accompanying consolidated balance sheets.

The Company had a consulting agreement with one former member, and continues to have a consulting agreement with one current member, of the Board of Directors. Total fees and expenses for these services were approximately \$126,000, \$128,000 and \$119,000 for 2002, 2001 and 2000, respectively. At December 31, 2002 and 2001, amounts due under the agreements totaled \$0 and \$33,000, respectively, and are classified as accounts payable or accrued liabilities in the accompanying consolidated balance sheets.

The Company incurred expenses for fees to the Board of Directors for their services. Total fees and expenses for these services were approximately \$46,000, \$14,000 and \$0 for 2002, 2001 and 2000, respectively. At December 31, 2002 and 2001, amounts due to board members for board services totaled approximately \$16,000 and \$12,000, respectively, and are classified as accounts payable or accrued liabilities in the accompanying consolidated balance sheets.

**Table of Contents**

**ESPERION THERAPEUTICS, INC. AND SUBSIDIARIES**  
**(A Company in the Development Stage)**

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

**(10) Quarterly Results of Operations (Unaudited)**

The following table summarizes selected unaudited quarterly financial information for 2002 and 2001. The Company believes that all adjustments, consisting of normal recurring adjustments considered necessary for a fair presentation, have been included in the selected quarterly information (in thousands, except per share data).

	<u>Three Months Ended</u>				<u>Year Ended</u>
	<u>March 31,</u> <u>2002</u>	<u>June 30,</u> <u>2002</u>	<u>September 30,</u> <u>2002</u>	<u>December 31,</u> <u>2002</u>	<u>December 31,</u> <u>2002</u>
Operating expense	\$ 7,350	\$ 7,306	\$ 7,093	\$ 6,197	\$ 27,946
Operating loss	(7,350)	(7,306)	(7,093)	(6,197)	(27,946)
Net loss	(7,303)	(7,824)	(6,980)	(6,619)	(28,726)
Basic and diluted net loss per common share	\$ (0.25)	\$ (0.27)	\$ (0.24)	\$ (0.23)	\$ (0.98)

	<u>Three Months Ended</u>				<u>Year Ended</u>
	<u>March 31,</u> <u>2001</u>	<u>June 30,</u> <u>2001</u>	<u>September 30,</u> <u>2001</u>	<u>December 31,</u> <u>2001</u>	<u>December 31,</u> <u>2001</u>
Operating expense	\$ 7,168	\$ 6,990	\$ 6,507	\$ 6,651	\$ 27,316
Operating loss	(7,168)	(6,990)	(6,507)	(6,651)	(27,316)
Net loss	(5,981)	(6,325)	(6,281)	(6,344)	(24,931)
Basic and diluted net loss per common share	\$ (0.23)	\$ (0.24)	\$ (0.22)	\$ (0.22)	\$ (0.91)

Because of the method used in calculating per share data, the quarterly per share data will not necessarily add to the per share data as computed for the year.

**Table of Contents**

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**PART III**

**Items 10, 11, 12 and 13. Directors and Executive Officers of the Registrant; Executive Compensation; Security Ownership of Certain Beneficial Owners and Management; Certain Relationships and Related Transactions**

The information called for by Part III (Items 10, 11, 12 and 13) is incorporated by reference from the Company's definitive Proxy Statement to be filed in connection with its 2003 Annual Meeting of Stockholders, except that the information regarding the Company's executive officers called for by Item 401(b) of Regulation S-K pursuant to Item 10 has been included in Part I of this report and the information called for by Items 402(k) and 402(l) of Regulation S-K pursuant to Item 11 is not incorporated by reference.

**Item 14. Controls and Procedures**

An evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of March 1, 2003 was carried out by the Company under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures have been designed and are being operated in a manner that provides reasonable assurance that the information required to be disclosed by the Company in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. A controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Subsequent to the date of the most recent evaluation of our internal controls, there were no significant changes in our internal controls or in other factors that could significantly affect the internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

**Table of Contents****PART IV****Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K**

## (a) Financial Statements

1. These financial statements are set forth in Item 8.
2. No financial statement schedules are required.

**Notice Regarding Arthur Andersen LLP**

Arthur Andersen LLP audited our consolidated financial statements for the two years in the period ended December 31, 2001, and the period from our inception in May 1998 to December 31, 2001 and issued a report thereon dated January 18, 2002. Arthur Andersen LLP has not reissued their report and has not consented either to the inclusion of their report on our financial statements in this report or the incorporation by reference of their report into any of our registration statements filed with the SEC, and we have relied on Rule 437a of the Securities Act of 1933, as amended, in filing this report without such a consent. On June 15, 2002, Arthur Andersen LLP was convicted of obstruction of justice by a federal jury in Houston, Texas in connection with Arthur Andersen LLP's work for Enron Corp. On September 15, 2002, a federal judge upheld this conviction. Arthur Andersen LLP ceased its audit practice before the Commission on August 31, 2002. Effective April 18, 2002, we terminated the engagement of Arthur Andersen LLP as our independent accountants and engaged PricewaterhouseCoopers LLP to serve as our independent accountants for the fiscal year ending December 31, 2002. Because Arthur Andersen LLP has not consented to the inclusion of their report in this report and because of the circumstances affecting Arthur Andersen LLP, as a practical matter, Arthur Andersen LLP may not be able to satisfy any claims arising from the provision of auditing services to us, including claims you may have that are available to security holders under federal and state securities laws.

## (b) Reports on Form 8-K

A report on Form 8-K was filed on November 26, 2002 under Item 5, Other Events.

## (c) Exhibits

Number	Exhibit
2.1	Agreement and Plan of Merger and Reorganization by and among Esperion Therapeutics, Inc., Esperion Mergerco, Inc. and Talaria Therapeutics, Inc. dated as of September 21, 2000. Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed October 6, 2000.
2.2	Indemnification, Escrow and Participation Agreement by and among Esperion Therapeutics, Inc., the stockholders of Talaria Therapeutics, Inc., Rock Hill Ventures, Inc. and Sills Cummis Radin Tischman Epstein & Gross dated as of September 21, 2000. Incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K filed October 6, 2000.
2.3	Non-Competition Agreement by and among Esperion Therapeutics, Inc. Esperion Mergerco, Inc. and certain Talaria Parties dated as of September 21, 2000. Incorporated by reference to Exhibit 2.3 to the Company's Current Report on Form 8-K filed October 6, 2000.
3.3	Fifth Amended and Restated Certificate of Incorporation of the Company. Incorporated by reference to Exhibit 3.3 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2000.
3.4	Amended and Restated Bylaws of the Company. Incorporated by reference to Exhibit 3.4 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2000.

**Table of Contents**

Number	Exhibit
3.5	Certificate of Designations, Preferences, Related Rights, Qualifications, Limitations and Restrictions Of Series A Junior Participating Preferred Shares of Esperion Therapeutics, Inc. Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed April 23, 2002.
4.1	Form of Common Stock Certificate of the Company. Incorporated by reference to Exhibit 4.1 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on August 4, 2000.
4.2	Rights Agreement between Esperion Therapeutics, Inc. and StockTrans, Inc., as Rights Agent, dated as of April 18, 2002. Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed April 23, 2002.
4.3	Amendment No. 1. to Rights Agreement between Esperion Therapeutics, Inc. and StockTrans, Inc., as Rights Agent, dated November 26, 2002. Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed November 26, 2002.
10.2	Collaboration and License Agreement between Esperion Therapeutics, Inc. and Pharmacia & Upjohn AB dated June 24, 1998. Incorporated by reference to Exhibit 10.2 to Amendment No. 3 to the Company's Registration Statement non Form S-1 (Reg. No. 333-31032) filed on August 9, 2000.
10.3	License Agreement among Esperion Therapeutics, Inc., Jean-Louis Dasseux as the Inventors' Representative and the Inventors named therein dated September 15, 1999. Incorporated by reference to Exhibit 10.3 to Amendment No. 3 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on August 9, 2000.
10.4	License Agreement between Inex Pharmaceuticals Corporation and Esperion Therapeutics, Inc. dated March 16, 1999. Incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on February 24, 2000.
10.5	Letter Agreement among Esperion Therapeutics, Inc., Inex Pharmaceuticals Corporation and the University of British Columbia dated March 12, 1999. Incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on February 24, 2000.
10.6	License Agreement between Esperion Therapeutics, Inc. and Region Wallonne dated February 17, 2000. Incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on February 24, 2000.
10.7	Lease between Esperion Therapeutics, Inc. and State-94 Limited Partnership dated November 30, 1998, as amended. Incorporated by reference to Exhibit 10.7 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.8	Lease between Esperion Therapeutics, Inc. and Maxey, LLC dated January 4, 1999. Incorporated by reference to Exhibit 10.8 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.9	Loan and Security Agreement between Silicon Valley Bank, doing business as Silicon Valley East, and Esperion Therapeutics, Inc., dated March 31, 1999. Incorporated by reference to Exhibit 10.9 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.11*	Esperion Therapeutics, Inc. Employee Stock Purchase Plan. Incorporated by reference to Exhibit 10.11 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.12	Loan Agreement between Stiftelson Industrifonden and Esperion Therapeutics, Inc. dated May 19, 1999. Incorporated by reference to Exhibit 10.12 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.

**Table of Contents**

Number	Exhibit
10.16	Amendment No. 3 to the Investors Rights Agreement among Esperion Therapeutics, Inc. and the parties set forth therein dated February 22, 2000. Incorporated by reference to Exhibit 10.16 to Amendment No. 1 to the Company s Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000. [delete?]
10.17	Restricted Stock Purchase Agreement between Esperion Therapeutics, Inc. and Roger S. Newton dated July 6, 1998. Incorporated by reference to Exhibit 10.17 to Amendment No. 1 to the Company s Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.18	Advisory Relationship letter between Scheer & Company, Inc. and Esperion Therapeutics, Inc. dated March 31, 1999. Incorporated by reference to Exhibit 10.18 to Amendment No. 1 to the Company s Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.23	Form of Restricted Stock Purchase Agreement. Incorporated by reference to Exhibit 10.23 to Amendment No. 2 to the Company s Registration Statement on Form S-1 (Reg. No. 333-31032) filed on August 4, 2000.
10.27	Third Amendment to Lease between Esperion Therapeutics, Inc. and State-94 Limited Partnership dated December 20, 2000. Incorporated by reference to Exhibit 10.29 to the Company s Annual Report on Form 10-K for the year ended December 31, 2000.
10.28	Lease Extension between Esperion Therapeutics, Inc. and Maxey, LLC dated December 20, 2000. Incorporated by reference to Exhibit 10.29 to the Company s Annual Report on Form 10-K for the year ended December 31, 2000.
10.29	Amendment to License Agreement between Esperion Therapeutics, Inc. and Inex Pharmaceuticals Corp. dated October 23, 2000. Incorporated by reference to Exhibit 10.29 to the Company s Annual Report on Form 10-K for the year ended December 31, 2000.
10.30	Fourth Amendment to Lease between Esperion Therapeutics, Inc. and Kosmos Associates, LLC, successor to State 94 Limited Partnership, dated February 15, 2001. Incorporated by reference to Exhibit 10.30 to the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2001.
10.31	Master Loan and Security Agreement between Transamerica Business Credit Corporation and Esperion Therapeutics, Inc. dated as of December 27, 2000. Incorporated by reference to Exhibit 10.31 to the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2001.
10.32	Form of Amendment to Restricted Stock Purchase Agreement. Incorporated by reference to Exhibit 10.32 to the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2001.
10.33	Commercial Sublease between SWMF Holdings Corporation and Esperion Therapeutics, Inc. dated as of June 22, 2001. Incorporated by reference to Exhibit 10.33 to the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001.
10.34	Lease Extension Second Renewal Term between Maxey LLC and Esperion Therapeutics, Inc. dated September 21, 2001. Incorporated by reference to Exhibit 10.34 to the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001.
10.35	License Agreement Michigan File 1855 Technology between the Regents of the University of Michigan and Esperion Therapeutics, Inc. dated effective September 18, 2001. Incorporated by reference to Exhibit 10.35 to the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001.
10.37	Memorandum of Understanding between SWMF Holdings Corporation and Esperion Therapeutics, Inc. dated July 11, 2001. Incorporated by reference to Exhibit 10.37 to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2001.

**Table of Contents**

Number	Exhibit
10.38	Loan and Security Agreement between Silicon Valley Bank and Esperion Therapeutics, Inc. dated October 31, 2001. Incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001.
10.39	Loan Modification Agreement between Silicon Valley Bank and Esperion Therapeutics, Inc. entered into as of December 7, 2001, effective as of October 31, 2001. Incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001.
10.40	Confirmation of Sublease Terms between Southwest Michigan Holdings Corporation and Esperion Therapeutics, Inc. dated effective October 15, 2001. Incorporated by reference to Exhibit 10.40 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001.
10.41	Amendment of Sublease Terms between SWMF Holdings Corporation and Esperion Therapeutics, Inc. dated effective February 1, 2002. Incorporated by reference to Exhibit 10.41 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002.
10.42*	Esperion Therapeutics, Inc. 1998 Stock Option Plan (Amended, effective April 18, 2002). Incorporated by reference to Exhibit 10.42 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2002.
10.43*	Esperion Therapeutics, Inc. 2000 Equity Compensation Plan (Amended and Restated, effective April 18, 2002). Incorporated by reference to Exhibit 10.43 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2002.
10.44*	Employment arrangement between William F. Brinkerhoff and Esperion Therapeutics, Inc. dated April 19, 2002. Incorporated by reference to Exhibit 10.44 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2002.
10.46	Master Lease Agreement between Southwest Michigan Innovation Center, Inc. and Esperion Therapeutics, Inc. effective as of July 12, 2001. Incorporated by reference to Exhibit 10.46 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002.
10.47	Second Amendment to Commercial Sublease Agreement between Southwest Michigan Innovation Center, Inc. (formerly known as SWMF Holdings Corporation) and Esperion Therapeutics, Inc. dated September 10, 2002.
10.48	Lease Extension Third Renewal Term between Maxey, LLC and Esperion Therapeutics, Inc. dated September 21, 2002.
10.49*	Employment arrangement between Roger S. Newton and Esperion Therapeutics, Inc. dated July 6, 1998.
10.50*	Employment arrangement between Timothy M. Mayleben and Esperion Therapeutics, Inc. dated November 25, 1998.
10.51*	Employment arrangement between Brian R. Krause and Esperion Therapeutics, Inc. dated February 20, 2001.
10.52*	Employment arrangement between Jean-Louis Dasseux and Esperion Therapeutics, Inc. dated December 9, 1998.
10.53*	Employment arrangement between Frank Thomas and Esperion Therapeutics, Inc. dated February 26, 2000.
21.1	Subsidiaries of Esperion Therapeutics, Inc.
23.1	Consent of PricewaterhouseCoopers LLP.



**Table of Contents**

<b>Number</b>	<b>Exhibit</b>
99.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Confidential treatment granted with respect to portions of this Exhibit.

\* Compensation plans or arrangements in which directors and/or executive officers are eligible to participate.





**Table of Contents**

**CERTIFICATIONS**

I, Roger S. Newton, certify that:

1. I have reviewed this annual report on Form 10-K of Esperion Therapeutics, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ ROGER S. NEWTON

---

Roger S. Newton  
Chief Executive Officer

Date: March 26, 2003

**Table of Contents**

I, Timothy M. Mayleben, certify that:

1. I have reviewed this annual report on Form 10-K of Esperion Therapeutics, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ TIMOTHY M. MAYLEBEN

---

Timothy M. Mayleben  
Chief Financial Officer

Date: March 26, 2003

**Table of Contents****INDEX TO EXHIBITS**

Number	Exhibit
2.1	Agreement and Plan of Merger and Reorganization by and among Esperion Therapeutics, Inc., Esperion Mergerco, Inc. and Talaria Therapeutics, Inc. dated as of September 21, 2000. Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed October 6, 2000.
2.2	Indemnification, Escrow and Participation Agreement by and among Esperion Therapeutics, Inc., the stockholders of Talaria Therapeutics, Inc., Rock Hill Ventures, Inc. and Sills Cummis Radin Tischman Epstein & Gross dated as of September 21, 2000. Incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K filed October 6, 2000.
2.3	Non-Competition Agreement by and among Esperion Therapeutics, Inc. Esperion Mergerco, Inc. and certain Talaria Parties dated as of September 21, 2000. Incorporated by reference to Exhibit 2.3 to the Company's Current Report on Form 8-K filed October 6, 2000.
3.3	Fifth Amended and Restated Certificate of Incorporation of the Company. Incorporated by reference to Exhibit 3.3 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2000.
3.4	Amended and Restated Bylaws of the Company. Incorporated by reference to Exhibit 3.4 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2000.
3.5	Certificate of Designations, Preferences, Related Rights, Qualifications, Limitations and Restrictions Of Series A Junior Participating Preferred Shares of Esperion Therapeutics, Inc. Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed April 23, 2002.
4.1	Form of Common Stock Certificate of the Company. Incorporated by reference to Exhibit 4.1 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on August 4, 2000.
4.2	Rights Agreement between Esperion Therapeutics, Inc. and StockTrans, Inc., as Rights Agent, dated as of April 18, 2002. Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed April 23, 2002.
4.3	Amendment No. 1. to Rights Agreement between Esperion Therapeutics, Inc. and StockTrans, Inc., as Rights Agent, dated November 26, 2002. Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed November 26, 2002.
10.2	Collaboration and License Agreement between Esperion Therapeutics, Inc. and Pharmacia & Upjohn AB dated June 24, 1998. Incorporated by reference to Exhibit 10.2 to Amendment No. 3 to the Company's Registration Statement non Form S-1 (Reg. No. 333-31032) filed on August 9, 2000.
10.3	License Agreement among Esperion Therapeutics, Inc., Jean-Louis Dasseux as the Inventors' Representative and the Inventors named therein dated September 15, 1999. Incorporated by reference to Exhibit 10.3 to Amendment No. 3 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on August 9, 2000.
10.4	License Agreement between Inex Pharmaceuticals Corporation and Esperion Therapeutics, Inc. dated March 16, 1999. Incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on February 24, 2000.
10.5	Letter Agreement among Esperion Therapeutics, Inc., Inex Pharmaceuticals Corporation and the University of British Columbia dated March 12, 1999. Incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on February 24, 2000.

**Table of Contents**

Number	Exhibit
10.6	License Agreement between Esperion Therapeutics, Inc. and Region Wallonne dated February 17, 2000. Incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on February 24, 2000.
10.7	Lease between Esperion Therapeutics, Inc. and State-94 Limited Partnership dated November 30, 1998, as amended. Incorporated by reference to Exhibit 10.7 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.8	Lease between Esperion Therapeutics, Inc. and Maxey, LLC dated January 4, 1999. Incorporated by reference to Exhibit 10.8 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.9	Loan and Security Agreement between Silicon Valley Bank, doing business as Silicon Valley East, and Esperion Therapeutics, Inc., dated March 31, 1999. Incorporated by reference to Exhibit 10.9 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.11*	Esperion Therapeutics, Inc. Employee Stock Purchase Plan. Incorporated by reference to Exhibit 10.11 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.12	Loan Agreement between Stiftelson Industrifonden and Esperion Therapeutics, Inc. dated May 19, 1999. Incorporated by reference to Exhibit 10.12 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.17	Restricted Stock Purchase Agreement between Esperion Therapeutics, Inc. and Roger S. Newton dated July 6, 1998. Incorporated by reference to Exhibit 10.17 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.18	Advisory Relationship letter between Scheer & Company, Inc. and Esperion Therapeutics, Inc. dated March 31, 1999. Incorporated by reference to Exhibit 10.18 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on July 10, 2000.
10.23	Form of Restricted Stock Purchase Agreement. Incorporated by reference to Exhibit 10.23 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (Reg. No. 333-31032) filed on August 4, 2000.
10.27	Third Amendment to Lease between Esperion Therapeutics, Inc. and State-94 Limited Partnership dated December 20, 2000. Incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.
10.28	Lease Extension between Esperion Therapeutics, Inc. and Maxey, LLC dated December 20, 2000. Incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.
10.29	Amendment to License Agreement between Esperion Therapeutics, Inc. and Inex Pharmaceuticals Corp. dated October 23, 2000. Incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.
10.30	Fourth Amendment to Lease between Esperion Therapeutics, Inc. and Kosmos Associates, LLC, successor to State 94 Limited Partnership, dated February 15, 2001. Incorporated by reference to Exhibit 10.30 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2001.
10.31	Master Loan and Security Agreement between Transamerica Business Credit Corporation and Esperion Therapeutics, Inc. dated as of December 27, 2000. Incorporated by reference to Exhibit 10.31 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2001.

## Edgar Filing: ESPERION THERAPEUTICS INC/MI - Form 10-K

### Table of Contents

Number	Exhibit
10.32	Form of Amendment to Restricted Stock Purchase Agreement. Incorporated by reference to Exhibit 10.32 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2001.
10.33	Commercial Sublease between SWMF Holdings Corporation and Esperion Therapeutics, Inc. dated as of June 22, 2001. Incorporated by reference to Exhibit 10.33 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001.
10.34	Lease Extension - Second Renewal Term between Maxey LLC and Esperion Therapeutics, Inc. dated September 21, 2001. Incorporated by reference to Exhibit 10.34 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001.
10.35	License Agreement Michigan File 1855 Technology between the Regents of the University of Michigan and Esperion Therapeutics, Inc. dated effective September 18, 2001. Incorporated by reference to Exhibit 10.35 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001.
10.37	Memorandum of Understanding between SWMF Holdings Corporation and Esperion Therapeutics, Inc. dated July 11, 2001. Incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001.
10.38	Loan and Security Agreement between Silicon Valley Bank and Esperion Therapeutics, Inc. dated October 31, 2001. Incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001.
10.39	Loan Modification Agreement between Silicon Valley Bank and Esperion Therapeutics, Inc. entered into as of December 7, 2001, effective as of October 31, 2001. Incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001.
10.40	Confirmation of Sublease Terms between Southwest Michigan Holdings Corporation and Esperion Therapeutics, Inc. dated effective October 15, 2001. Incorporated by reference to Exhibit 10.40 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001.
10.41	Amendment of Sublease Terms between SWMF Holdings Corporation and Esperion Therapeutics, Inc. dated effective February 1, 2002. Incorporated by reference to Exhibit 10.41 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002.
10.42*	Esperion Therapeutics, Inc. 1998 Stock Option Plan (Amended, effective April 18, 2002). Incorporated by reference to Exhibit 10.42 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2002.
10.43*	Esperion Therapeutics, Inc. 2000 Equity Compensation Plan (Amended and Restated, effective April 18, 2002). Incorporated by reference to Exhibit 10.43 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2002.
10.44*	Employment arrangement between William F. Brinkerhoff and Esperion Therapeutics, Inc. dated April 19, 2002. Incorporated by reference to Exhibit 10.44 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2002.
10.46	Master Lease Agreement between Southwest Michigan Innovation Center, Inc. and Esperion Therapeutics, Inc. effective as of July 12, 2001. Incorporated by reference to Exhibit 10.46 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002.
10.47	Second Amendment to Commercial Sublease Agreement between Southwest Michigan Innovation Center, Inc. (formerly known as SWMF Holdings Corporation) and Esperion Therapeutics, Inc. dated September 10, 2002.
10.48	Lease Extension - Third Renewal Term between Maxey, LLC and Esperion Therapeutics, Inc. dated September 21, 2002.



**Table of Contents**

Number	Exhibit
10.49*	Employment arrangement between Roger S. Newton and Esperion Therapeutics, Inc. dated July 6, 1998.
10.50*	Employment arrangement between Timothy M. Mayleben and Esperion Therapeutics, Inc. dated November 25, 1998.
10.51*	Employment arrangement between Brian R. Krause and Esperion Therapeutics, Inc. dated February 20, 2001.
10.52*	Employment arrangement between Jean-Louis Dasseux and Esperion Therapeutics, Inc. dated December 9, 1998.
10.53*	Employment arrangement between Frank Thomas and Esperion Therapeutics, Inc. dated February 26, 2000.
21.1	Subsidiaries of Esperion Therapeutics, Inc.
23.1	Consent of PricewaterhouseCoopers LLP.
99.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Confidential treatment granted with respect to portions of this Exhibit.

\* Compensation plans or arrangements in which directors and/or executive officers are eligible to participate.