CONCEPTUS INC
Form 10-K
March 31, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2004

or

o 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: **0-27596**

CONCEPTUS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**94-3170244**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1021 Howard Avenue
San Carlos, CA 94070
(Address of principal executive offices)

Registrant's telephone number, including area code: **(650) 628-4700**

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.003 par value per share

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 ý NO o

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. o

Indicate by checkmark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). YES ý NO o

The aggregate market value of the voting and non-voting stock held by nonaffiliates of the Registrant based on the closing sale price of the Registrant's Common Stock on the Nasdaq National Market on June 30, 2004 was approximately $134,657,000 as of such date. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

There were 25,692,411 shares of Registrant's Common Stock issued and outstanding as of February 28, 2005.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant's 2005 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

CONCEPTUS, INC.
FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

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The following information should be read in conjunction with the Consolidated Financial Statements and the notes thereto. This annual report on Form 10-K, and in particular the Management's Discussion and Analysis of Financial Condition and Results of Operations, contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. In this report, the words "believes," "anticipates," "intends," "expects," "plans," "should," "will," "seeks" and words of similar import identify forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: our limited operating and sales history; the uncertainty of market acceptance of our product; dependence on obtaining and maintaining reimbursement; effectiveness and safety of our product over the long-term; our ability to obtain and maintain the necessary governmental clearances or approvals to market our product; our ability to develop and maintain proprietary aspects of our technology; our ability to manage our expansion; our limited history of manufacturing our product; our dependence on single source supplies, third party manufacturers and co-marketers; intense competition in the medical device industry; the inherent risk of exposure to product liability claims and product recalls and other factors referenced in this Form 10-K. These factors are discussed in more detail below. Given these uncertainties, persons evaluating our business are cautioned not to place undue reliance on such forward-looking statements. We assume no obligation to update these forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements.

Market, Ranking and Other Data

This Form 10-K contains various estimates related to the women's healthcare, contraception and medical device markets. Some of these estimates have been included in studies published by government agencies and market research firms and some are our estimates and are based on management's knowledge and experience in the markets in which we operate. Additionally, other estimates have been produced by industry analysts based on trends to date, their knowledge of technologies and markets, and customer research, but these are forecasts only and are thus subject to inherent uncertainty. Our estimates have been based on information provided by customers, suppliers, trade and business organizations and other contacts in the markets in which we operate. We believe these estimates to be accurate as of the date of this Form 10-K. However, this information may prove to be inaccurate because of the method by which we obtain some of the data for our estimates or because this information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties inherent in a survey of market size. As a result, you should be aware that market, ranking and other similar data included in this Form 10-K, and estimates and beliefs based on that data, may not be reliable.

PART I

ITEM 1. BUSINESS

Overview

We develop, manufacture and market Essure®, an innovative and proprietary non-incisional permanent birth control device for women which was approved for marketing in the United States in November 2002 by the United States Food and Drug Administration, or FDA. Essure is a soft and flexible micro-insert delivered into a woman's fallopian tubes designed to provide permanent birth control by causing a benign tissue in-growth that blocks the fallopian tubes. A successfully placed Essure micro-insert disrupts or prohibits the process of egg fertilization. Based on clinical trial data filed with the FDA in June 2004, Essure has been demonstrated to be 99.80% effective at three years of follow-up. As of January 2005, we had accumulated sufficient patient follow-up data from the

Phase II and Pivotal clinical trials and have filed a PMA supplement for a four and five year effectiveness claim consistent with the three year claim.

The Essure placement procedure is typically performed as an outpatient procedure and is intended to be a less invasive and a less costly alternative to tubal ligation, the leading form of birth control in the United States and worldwide. Laparoscopic tubal ligation and tubal ligation by laparotomy typically involve abdominal incisions and/or punctures, general or regional anesthesia, four to ten days of normal recovery time and the risks associated with an incisional procedure. The Essure placement procedure does not require cutting or penetrating the abdomen, which has lowered post-operative pain due to the incisions/punctures, and is typically performed in an outpatient setting without general anesthesia. In the Pivotal trial of Essure, the total procedure time averaged 35 minutes, with an average of 13 minutes of hysteroscopic time to place the Essure micro-insert. A patient is typically discharged approximately 45 minutes after the Essure placement procedure. No overnight hospital stay is required. Furthermore, Essure is effective without drugs or hormones.

We believe Essure also appeals to women who have completed childbearing but who are using either temporary birth control methods or no birth control method. A woman's tolerance to an implanted Essure was ascertained in our Phase II clinical study follow-up to four years was rated as "good" to "excellent" in 99% of women at all visits through November 2003. Among women from our Pivotal trial who have worn the micro-inserts for up to three years, at least 97% rated their comfort with Essure as "good" to "excellent" at visits conducted through November 2003. Satisfaction was rated "somewhat" to "very satisfied" in at least 98% of visits through two years. At three-year follow-up (reporting as of November 2003), 92% of women rated their overall satisfaction as "somewhat" to "very satisfied." Excluding the day of the Essure placement procedure, 92% of the patients in the Pivotal trial who were employed returned to work in one day or less. The safety and recovery profile of Essure is one of the reasons that we believe it may be a preferred alternative to currently available methods of permanent birth control.

We believe that physicians are receptive to Essure because it is a less invasive permanent birth control option to offer their patients. We also believe physicians find the Essure procedure relatively easy to perform after completing our training program. We believe hospitals are able to utilize their facilities more cost effectively with the Essure placement procedure compared with tubal ligation. We expect payors will continue to experience cost reductions resulting from the elimination of overhead and procedural costs related to anesthesia and post-operative hospital stays associated with tubal ligations. Payors may also benefit from the reduction of unplanned pregnancies associated with non-permanent methods of birth control used by patients who have chosen to avoid the drawbacks of traditional permanent birth control methods but who may elect to use Essure. Additionally, payors should also benefit from the reduction of costs of complications associated with the tubal ligation procedure.

We maintain two websites located at www.conceptus.com and www.essure.com. We make available free of charge on or through our websites, our annual report on Form 10-K, our quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material, or furnish it to, the SEC. Information contained on our websites is not incorporated by reference into and does not form a part of this Form 10-K.

Penetration

We are attempting to introduce a novel product into the contraception market, which is dominated by procedures that are well established among physicians and patients and are routinely taught to new physicians. As a result, we believe that recommendations and endorsements by physicians will be essential for market acceptance of our product. We believe that physicians will not use a product unless

they determine, based on clinical data and other factors, that it is an attractive alternative to other means of contraception and that it offers clinical utility in a cost-effective manner. Physicians are traditionally slow to adopt new products and treatment practices, partly because of perceived liability risks. Our biggest challenge is to speed up the adoption process to make the Essure procedure the standard of care for permanent birth control.

Our strategy in the near term is to focus on the earlier adopters who have already been trained by our professional education group. We intend to help those doctors to market their practices so that they will perform more Essure procedures on a monthly basis. We intend to increase our call frequency to those doctors by our field representatives, ensure that physicians understand the favorable reimbursement CPT code recently established, strengthen referral programs to get women who are interested in the Essure procedure to those doctors, and continue with our marketing programs to increase Essure awareness among women and the medical community. As of December 31, 2004, we have 1,681 physicians in the United States either trained or in training on the Essure procedure. We have also built strategic alliances with other businesses to help to promote Essure and to train new doctors.

In early March 2004, Planned Parenthood Federation of America, or PPFA, approved Essure for use in qualifying Planned Parenthood Affiliates across the United States. PPFA has nearly 900 clinics under 123 PPFA affiliates that serve nearly 5 million people a year. PPFA tested the Essure procedure in clinics in Oregon and Pennsylvania, evaluating the ability of a typical clinic setting to successfully offer the procedure. Standards for the use of Essure in PPFA affiliates were then developed along with guidelines for the introduction of the procedure into Planned Parenthood clinic settings. We believe that PPFA's thorough evaluation demonstrated that Essure can safely and effectively be offered in a clinic setting and this approval is of vital importance to our goal of making sure all women have access to Essure, including those who do not have private insurance coverage.

Essure is currently being marketed in multiple countries. In 2001, we were approved to affix the CE Mark to Essure, indicating that Essure is certified for sale throughout the European Union, subject to compliance with local regulations such as registration with health ministries and/or particular requirements regarding labeling or distribution. In 1999, Essure was listed with Australia's Therapeutic Goods Administration, or the TGA, which allowed us to market and sell Essure in Australia. In Canada, we received clearance from Health Canada to market Essure in Canada in November 2001. In October 2004, the French Medical Device Reimbursement Authority "Comite economique de produit sante" (CEPS) granted reimbursement status for the Essure procedure in France, an important step for successful commercialization of the product.

In December 2004, we decided to terminate our direct subsidiary operations in Australia and convert to an independent distributor. This decision was largely a cost reduction measure in lieu of the small size of the Australian market and our inability to manage a direct operation to a cash-flow positive position. A distribution agreement was entered into with a third party distributor and the transition was completed in January 2005. In January 2004, we completed the sale of our French subsidiary, Conceptus SAS, for a nominal amount to an investor group comprised of our former French management team and signed long-term exclusive distribution agreements with the former subsidiary.

Reimbursement

Market acceptance of Essure depends in part upon the availability of reimbursement within prevailing healthcare payment systems. We believe that physician advocacy of our product will be required to continue to obtain reimbursement. By December 2004, we received positive reimbursement decisions for Essure from private insurers covering a total of 154 million covered lives, which represents 73% of all the insured, non-Medicare population of the United States. We intend to continue our effort to educate payors of the cost-effectiveness of our product, and to establish further programs to help physicians to navigate reimbursement issues.

In 2004, we received several positive responses from government and private agencies relating to reimbursement, which we believe will help us to speed up the acceptance of Essure by doctors and patients. We have also received one unfavorable government response (Australian Department of Health, Medical Services Advisory Committee (MSAC) division) that we do not consider material to our future financial results or expectations for the acceptance of Essure by doctors and patients in markets that are critical to us.

In March 2004, the American Medical Association accepted our application for a Category I CPT code, which was effective January 1, 2005, subject to the completion of the AMA application process. Category I codes are reserved for those procedures that have demonstrated clinical efficacy, widespread useand known costs, and have FDA approval. Although CPT codes are administered at the federal level by the Centers for Medicare and Medicaid Services ("CMS"), they are almost universally relied upon by both Medicaid (at the state levels) and private payors. A CPT code specific to the Essure procedure is expected to ease reimbursement coding for our physicians and hospital customers, and we expect there will be fewer incidents of doctors being reimbursed incorrectly or having claims denied inadvertently. We expect that the new code, once the process to establish it at all private payors that have given a favorable coverage decision is complete, will significantly ease the burden on a physician's office in obtaining reimbursement for Essure, and accelerate the utilization of Essure by physicians. This process is not automatic following receipt of the new CPT code, however, and we anticipate continuing to focus on reimbursement issues for sometime in the future both to secure our code and payment schedule into the payors' databases, as well as to help the physician negotiate a favorable contract for payment off that schedule.

In early November 2004, the CMS released the Final Rule for the 2005 Physician Fee schedule. For the Essure CPT code, the CMS has provided for a national physician payment of $2,198.34 for procedures performed in the office and $458.94 for procedures performed in the hospital. This compares to a CPT code physician payment of $361.16 for a laparascopic tubal ligation, the current standard of care for permanent female sterilization. In addition, the CMS released the Final Rule for the 2005 OPPS, which assigns hospital outpatient reimbursement amounts. The Essure CPT code was assigned a 2005 payment level of $2,260.37 which is consistent with payments by CMS to hospitals when they perform a laparoscopic tubal ligation, normally performed in a higher cost hospital operating room. We believe these values are very favorable for the Essure procedure and will help in establishing increased utilization of the device amongst doctors.

Our Market

A 1995 National Survey of Family Growth performed by the Centers for Disease Control and Prevention, or CDC, the most current available statistics on United States reproductive health, estimated that 64% of the 60.2 million United States women of reproductive age (15-44) use some form of birth control. The most common form of birth control in the United States according to this 1995 CDC survey was tubal ligation, followed by oral contraceptives, condom and vasectomy.

According to the 1995 CDC survey, 39% of women who use any form of birth control rely on permanent birth control methods, such as tubal ligation and vasectomy. In 1971, vasectomy, a male sterilization procedure, outnumbered tubal ligation by more than three to one. As a result of the adoption of a less invasive laparoscopic procedure in 1971, tubal ligation procedures currently outnumber vasectomies by 75% annually. Published reports estimate that 700,000 tubal ligation procedures are performed each year in the United States, and the prevalence increases with age and number of children. Approximately 90% of United States women who have had tubal ligation have two or more children and 65% are between the ages of 35 and 44 at the time of procedure. Despite the decrease in vasectomies since 1971, we estimate that there are still approximately 400,000 vasectomy procedures performed each year in the United States.

In addition to permanent birth control procedures, the 1995 CDC survey estimated that approximately 21 million United States women use temporary methods of birth control, such as oral contraceptives, implants and injectables. Included in this group are approximately seven million women, who have two or more children, which we believe makes them more likely to consider permanent forms of birth control. Furthermore, researchers in a 1999 article published in Family Planning Perspectives theorized that women may not be completely satisfied with long-term use of temporary methods of birth control. The Family Planning Perspectives article reported that 44% of women using temporary birth control change methods for a method-related reason within 12 months, increasing to 61% by 24 months. For these reasons, we believe our market includes not only women who desire permanent birth control, but potentially also women who have completed childbearing but are using either temporary birth control methods or no birth control method at all because no viable non-incisional alternative to tubal ligation has been available until now.

Based on data from the CDC's 1995 National Survey of Family Growth, the following chart summarizes birth control methods used by women using contraception between the ages of 30-44 in the United States:

	Age 30-34	**Age 35-39**	**Age 40-44**
Fertile women	8.0 million	8.2 million	7.3 million
Method:			
Tubal ligation	30%	41%	50%
Pill	29%	11%	6%
Condom	18%	17%	12%
Vasectomy	10%	18%	20%
All others	13%	13%	12%

Worldwide, there is a larger market for permanent birth control. The most current and available report on worldwide birth control statistics is a 1998 United Nations report on birth control methods used in 1993 by reproductive couples. The report indicated that tubal ligation, the leading birth control method worldwide, was used by 32% of reproductive couples, followed by intrauterine devices, or IUDs, at 22%, oral contraceptives at 14% and condom at 7%.

Other Available Permanent Birth Control Methods

Tubal Ligation. Tubal ligation is the most common form of birth control. It combines high effectiveness with no required user compliance and a very low risk of long-term side effects. However, the difficulty in accessing the fallopian tubes makes it necessary to perform incisional surgery to perform the procedure. The two most common methods of tubal ligation are laparoscopic tubal ligation and tubal ligation performed by mini-laparotomy or laparotomy. Each method of tubal ligation has a one-year effectiveness rate of approximately 99.5%.

Laparoscopic tubal ligation, the least invasive method of tubal ligation, requires one to two punctures to be made in the abdomen and carbon dioxide gas to inflate the abdomen to improve visibility and access for the surgeon. The fallopian tubes are then ligated by cutting or cauterizing, or by mechanical occlusion using clips or rings. Because laparoscopic tubal ligation requires penetration of the abdomen, 93% of laparoscopic tubal ligations are performed under general anesthesia. The typical surgical procedure takes approximately 45 minutes and is followed by four to five hours of recovery time in a hospital setting. Women typically return to normal activities four to six days after a laparoscopic tubal ligation. Tubal ligation by laparotomy is a more invasive method of tubal ligation due

to a more extensive incision and is associated with a higher rate of complications and longer hospital stays and recovery periods.

In 1992, the CDC reported the result of a large, prospective trial conducted between 1978 and 1988 of women undergoing tubal ligation by either laparoscopy or laparotomy, and reported that major complications occurred in 1.6% to 5.7% of the cases, depending on the surgical approach. The most frequent major complication with laparoscopy was unintended major surgery due to unexpected bleeding, hematoma formation or stomach/bowel perforation. The major complications reported with laparotomy were fever morbidity and re-hospitalization due to pelvic abscess, pulmonary abscess, pulmonary embolus and bowel obstructions.

In addition to the CDC study, published reports of randomized trials involving the three FDA-approved devices for tubal occlusion, Filshie Clip, Hulka Clip and the Tubal Ring, cited overall complication rates of 11.2% to 24.0%, depending on the surgical approach. The complications reported in these studies included surgical injuries, primary incision complications and infections. Incision complications were the most frequent and could be eliminated with a non-incisional approach. The complication rates in these studies were higher than reported in the CDC published reports because the CDC study focused only on major complications.

In addition to the complications reported in the public research literature, a report entitled Summary of Safety and Effectiveness for the Filshie Clip PMA, which is available on the FDA's website, also noted the following complications: pelvic pain (35.7%), menstrual pattern changes (12.2%), back/shoulder pain (6.0%), nausea/vomiting (4.3%) and headache (3.0%).

Vasectomy. Vasectomy is a highly effective method of male birth control that is performed in a doctor's office with local anesthesia and typically takes about 20 minutes. The vas deferens is ligated or resected and the cut ends are typically cauterized or clipped. Patients are observed for approximately 20 minutes before release and are encouraged to use an ice pack for approximately 4 hours to reduce swelling. Support devices are recommended for two days. Before relying on the vasectomy for birth control, men are encouraged to be tested 12 weeks after the procedure for the presence of sperm and to use alternate forms of birth control during the 12 week period. Side effects of vasectomy include bleeding, infection and chronic pain syndrome.

Other Available Temporary Birth Control Methods

Oral contraceptives and drug delivery systems. Birth control pills and other hormone delivery systems offer temporary birth control to women. Birth control pills contain female hormones and require a daily pill-taking regimen in order to stop the ovaries from releasing eggs. According to Contraceptive Technology, 17th revised edition, the birth control pill has a "perfect use" failure rate of 0.1% but a "typical use" failure rate of 5.0% in the first year of use. This method has a relatively high failure rate because of imperfect user compliance, an inherent problem with many methods of temporary birth control. Many physicians will not prescribe birth control pills to women over the age of 35 who smoke cigarettes because of the potential for serious side effects. Some of the risks associated with the pill are an increased risk of heart attack, stroke and blood clots.

Other forms of temporary hormonal birth control include injectable hormones, such as Depo-Provera and Lunelle, implantable hormones, such as Implanon, vaginal rings, such as NuvaRing, and patches, such as OrthoEvra. All work to inhibit ovulation and/or inhibit sperm from entering the uterus. All have high effectiveness rates, but some, such as the ring and the patch, still require a high level of user compliance, and injectables require periodic re-injections. All have undesirable side effects, such as menstrual cycle changes, weight gain, headache, nausea and breast tenderness. Those containing estrogen, such as Lunelle, NuvaRing and OrthoEvra, may increase the risk of blood clots, heart attack and stroke.

Condoms and diaphragms. Condoms are male contraceptives that may also protect against sexually transmitted diseases. Diaphragms are soft, flexible, cup-shaped products that are placed inside of a woman's vagina and over the cervix in order to prevent the sperm from entering the uterus and fertilizing the egg. Although condoms and diaphragms have very limited side effects, these methods have relatively high first-year failure rates primarily due to imperfect user compliance. According to Contraceptive Technology, 17th revised edition, the first-year "typical use" failure rates are 14% for condoms and 20% for diaphragms.

Intrauterine devices (IUDs). IUDs are small devices that are placed in a woman's uterus to prevent fertilization of the egg. They contain either copper, as in Paragard, or hormones, as in Mirena, which is also known as an intrauterine system. According to Contraceptive Technology, 17th revised edition, IUDs have a first year failure rate of 0.1% to 0.8%. However, the use of IUDs among United States women has been low in recent years, representing only approximately 1% of contraceptive users. Potential side effects from IUDs include menstrual cycle changes, infection, cramping, expulsion and uterine perforation.

The Essure Product

We developed Essure in response to what we perceived as a market need for a permanent, less invasive and less costly alternative to tubal ligation.

The Essure micro-insert is designed to be placed into each fallopian tube during a single procedure using a hysteroscope, an instrument that allows visual examination of the cervix and uterine cavity, and our minimally invasive tubal access delivery system. The delivery system is a disposable plastic handle with a thumb-wheel that is connected to our proprietary guidewire and catheter system. The micro-insert is constructed of a stainless steel inner coil, a dynamic outer coil made from a nickel titanium alloy, called Nitinol, and a layer of polyethylene terephthalate, or polyester fibers, wound between the inner and outer coils. All of these materials have been used in the body for a variety of different applications, including cardiovascular surgery, for many years. Nitinol, a shape-memory metal, has been used in cardiovascular and peripheral vascular stents. Polyester fiber, proven to promote tissue in-growth, has been used in a variety of other medical applications, including artificial heart valves and vascular grafts. Stainless steel has been used in numerous long-term medical applications. An Essure micro-insert is deployed into each of the woman's fallopian tubes using a hysteroscope. Using the hysteroscope for guidance, the delivery catheter is guided through the uterus and the opening of the fallopian tube. Once the physician has properly positioned the delivery system in the fallopian tube, the physician releases the micro-insert. When released, the micro-insert automatically expands to the contours of the fallopian tube. Over a three-month time frame, the polyester fibers within the micro- insert elicit a localized, benign tissue in-growth that occludes, or blocks, the fallopian tubes, thereby preventing pregnancy.

On July 17, 2003, we announced introduction of a new delivery catheter for the Essure system, the "coil catheter," in the United States, Australia and Canada. A clinical study, performed in Australia, demonstrated a higher placement rate with the coil catheter than with the previous delivery catheter. In the clinical study, 101 of 103 patients achieved bilateral placement. These placements were performed by 5 investigators, most of whom had extensive experience with Essure. This translates to a statistical bilateral placement rate, at appropriate confidence levels, of 95%. The Essure system is being marketed with this claim in Australia, Canada and the European Union. Any claim in the United States that would change the 86% first procedure bilateral placement rate, which was based on the original delivery catheter studies in the Pivotal Trial, would be subject to approval by the FDA. In March 2005, we filed a PMA supplement with the FDA that intends to obtain approval to early terminate our post-approval study and recognize the findings from that study on our label. It is uncertain as to whether or not the FDA will approve the early termination of this study.

Based on clinical trial data filed with the FDA as of June 2004, Essure has been demonstrated to be 99.80% effective at three years of follow-up. As of January 2005, we have accumulated sufficient patient follow-up data from the Phase II and Pivotal clinical trials for a four and five-year effectiveness claim and have filed a PMA supplement with the FDA that is consistent with the three-year claim.

Essure has proven to have high patient satisfaction in our clinical trials. Clinical data submitted to the FDA in our Annual Report to PMA shows that Phase II study patients' tolerance to wearing Essure up to four years was rated as "good" to "excellent" in 99% of women at all visits through November 2003. Among women from our Pivotal trial who have worn the micro-inserts up to three years, at least 97% reported their comfort with Essure as "good" to "excellent" at all visits. Satisfaction was rated "somewhat" to "very satisfied" in at least 98% of visits through two years. At three-year follow-up (reporting as of November 2003), 92% of women reported their overall satisfaction as "somewhat" to "very satisfied." Excluding the day of the Essure placement procedure, 92% of women in our clinical trials who were employed returned to work in one day or less.

We did not conduct a clinical trial to compare Essure to laparoscopic tubal ligation. We believe, however, based on current data from our Pivotal trial and published reports on laparoscopic tubal ligation, that the Essure placement procedure has the following key advantages over laparoscopic tubal ligation:

	Essure Procedure	**Tubal Ligation**
Procedure	Transcervical > Non-incisional	Incisional > Abdominal incision or puncture
Typical anesthesia	Local, IV sedation	General
Average endoscopic procedure time	13-18 minutes	Not measured
Average total procedure time	35 minutes	Approximately 30-45 minutes
Average post-op recovery time	45 minutes	4-5 hours
Where performed	Outpatient/hospital, surgi-center or doctor's office	Inpatient/hospital or surgi-center
Average return to regular activities*	1-2 days	4-6 days

* *Excluding the day of procedure*

We believe that Essure and the Essure placement procedure offer the following important benefits to patients, physicians, hospitals and payors:

Benefits to patients

No risks associated with incisions and use of general or regional anesthesia.

Rapid return to regular activities of one to two days as compared to four to six days for laparoscopic tubal ligation.

Three-year effectiveness rate of 99.80%.

No risks associated with hormones used with hormone-based contraception.

No recurring management of contraception usage as compared to non-permanent contraception methods, such as the birth control pill, implants and injectables.

Benefits to physicians and hospitals

Short and relatively easily performed procedure.

No risks associated with incisions and use of general or regional anesthesia. The majority of Essure placement procedures are currently performed in hospital operation rooms or surgery centers using conscious sedation (such as IV sedation) combined with a local anesthesia (such as a paracervical block). General anesthesia is not typically used unless required by hospital protocol, or if the physician intends to perform some concomitant procedure that requires general anesthesia, or if requested by the patient. We believe over time, as the experience and comfort level of the physicians increase, the majority of Essure procedures will be done in an ambulatory surgical center or physician office with less anesthesia.

May be performed in a less resource-intensive environment. Essure procedures are currently performed in various settings including hospital operating rooms, ambulatory surgery centers and physician offices.

Elimination of costs related to the use of general or regional anesthesia and post-operative hospital stays.

Benefits to payors

Elimination of costs related to the use of general or regional anesthesia and post-operative hospital stays. Currently, the majority of Essure placement procedures are performed using conscious sedation, such as IV sedation with a local anesthesia. General anesthesia is not typically used unless required by hospital protocol, if requested by the patient, or based on the experience and comfort level of the physician.

Elimination of the costs associated with an operating room.

Potential to reduce unplanned pregnancies, which are costly to payors.

Patient Considerations

There are, however, certain key factors that a woman must consider when she selects Essure.

The woman must be certain that she desires permanent birth control, because Essure is not reversible.

Like all methods of birth control, the Essure procedure is not 100% effective. We expect that patients will report pregnancies from time to time. There have been pregnancies related to improper placement of the Essure device, failure to follow proper Conceptus protocol by either physicians or patients and luteal phase pregnancies (pregnancies occurring prior to Essure micro-insert placement). One or more of these may also be due to product failure.

For three or more months after the Essure placement procedure, a temporary method of birth control must be used in combination with Essure.

Three months post-procedure, U.S. patients are required to return for a hysterosalpingogram, or HSG, which calls for contrast dye to be injected into the uterus to confirm occlusion of both fallopian tubes and verify satisfactory micro-insert location. Outside of the U.S., patients are

required to return for a pelvic X-ray at three months post-procedure with a subsequent HSG if device location on the initial radiographic image appears suspicious.

Not all women who undergo the Essure placement procedure will achieve successful placement of both micro-inserts. Approximately 1 out of every 7 women in the Essure Pivotal and Phase II clinical studies did not achieve successful placement of both micro-inserts during the first placement procedure. Some of these women who chose to undergo a second placement procedure achieved successful placement of both micro-inserts during the second procedure, and subsequently were able to rely on Essure for contraception. We have subsequently introduced a new delivery catheter for the Essure system, the "coil catheter", which demonstrated a higher placement rate in our clinical study performed in Australia. In the clinical study, 101 of 103 patients achieved bilateral placement which translated to a statistical bilateral placement rate, at appropriate confidence levels, of 95%. In March 2005, we filed a PMA supplement with the FDA that intends to obtain approval to early terminate our post-approval study and recognize the findings from that study on our label. It is uncertain as to whether or not the FDA will approve the early termination of this study.

The Essure procedure is newer than other procedures and therefore does not yet have long-term safety and effectiveness data as compared to other procedures.

Removal of the Essure micro-inserts requires surgery; and removal is not intended for procedure reversal since Essure is not reversible.

As with all medical procedures, there are risks associated with Essure and the Essure placement procedure. Because there are no abdominal incisions or punctures and general or regional anesthesia is typically not required, the risks associated with the Essure placement procedure are more typical of hysteroscopic procedures and are of a lesser severity than those of procedures that require invasion of the abdominal cavity. This is typified by the minor nature of most of the adverse events reported in our clinical trials to date. The most frequent risk with the Essure placement procedure is the inability to rely on the micro-insert for contraception, due primarily to lack of micro-insert placement and less frequently to misplacement of the micro-insert. Based on data gathered in our clinical trials, adverse events, which prevented reliance on Essure for contraception, were reported as follows: failure to place 2 micro-inserts in first procedure (14%), initial tubal patency (3.5%), expulsion (2.2%), perforation of fallopian tube (1.5%), or other unsatisfactory device location (0.6%). All of the patients in the Pivotal and Phase II clinical studies who experienced tubal patency at the 3-month HSG were found to have bilateral occlusion at a repeat HSG performed at approximately 6 months after Essure placement. In addition, all of the patients in the Pivotal clinical study who chose to undergo a second Essure placement procedure following a micro-insert expulsion achieved successful micro-insert placement and were subsequently able to rely on Essure for contraception. The majority of women report mild to moderate pain immediately after the Essure placement procedure. The most frequent adverse events and side effects reported as a result of the hysteroscopic procedure to place the micro-inserts were as follows: cramping (29.6%), pain (12.9%), nausea/vomiting (10.8%), dizziness/fainting (8.8%) and spotting/vaginal bleeding (6.8%). Hypervolemia, an increase in blood volume, occurred in <1% of cases. During the first year of reliance on Essure for contraception (approximately 15 months after micro-insert placement), the following episodes were reported as at least possibly related to the Essure micro-inserts: back pain (9.0%), abdominal pain (3.8%), and dyspareunia (painful intercourse) (3.6%). All other events occurred in less than 3% of women. In addition, most women reported spotting for an average of three days post-procedure, and one-third reported pain on the day following the procedure, with little pain reported on subsequent days. Also, occurrences of back/abdominal/other pain, headache, gas/bloating and transient menstrual changes were reported. Persistent pain was not reported by any women, and persistent menstrual changes were reported in less than 2% of women, with virtually equal percentages of women reporting heavier than normal menstrual flow and lighter than normal menstrual flow.

Our Clinical Progress

We commenced a Phase II clinical study of safety and preliminary effectiveness of Essure in November 1998 and a Pivotal, or Phase III, trial of Essure in May 2000. The number of women in whom at least one of two Essure micro-inserts were placed totaled 682 between the two clinical trials. At three month follow-up, 647 women began relying on Essure as method of permanent birth control. The clinical endpoints of the study include safety, effectiveness and patient satisfaction.

Based on clinical trial data, Essure has been demonstrated to be 99.80% effective at three years of follow-up. As of January 2005, we have accumulated sufficient patient follow-up data from the Phase II and Pivotal clinical trials for a four and five year effectiveness claim and we have filed a PMA supplement with the FDA for a four and five year effectiveness claim consistent with the three-year claim.

The following table summarizes placement procedure data from our two clinical trials as of October 2002:

	Pivotal trial	**Phase II study**
Number of women undergoing a placement procedure	518	227
% of women with micro-inserts placed in both fallopian tubes after 1st attempt	86%	86%
% of women with micro-inserts placed in both fallopian tubes after 2nd attempt	90%	88%
Average hysteroscopic procedure time for placement of micro-inserts	13 minutes	18 minutes
"Good" to "Excellent" rating of patient tolerance of procedure	88%	89%
Adverse event rates preventing reliance on Essure	3.0%*	3.0%

* *Does not include the nine women who were able to rely on Essure after a successful second placement procedure.*

In April 2002, based on data from our trials, we submitted our PMA application to the FDA, which was granted an expedited review. In November 2002, we received formal notification from the FDA for the approval of Essure.

As a condition of the PMA approval, we are required by the FDA to follow our Phase II and Pivotal clinical trial patients for a five-year period following reliance on Essure for contraception. The information from these long-term studies will provide relevant information for our U.S. commercialization, as well as allow us to publish data at the conclusion of the follow-up period. In addition, we are required by the FDA to conduct a post-approval study to evaluate placement rates among newly trained physicians. This study involves the first 20 cases performed by 40 physicians in major metropolitan areas after physician training is completed. As of February 1, 2005, over 450 Essure placement procedures have been performed by participating physicians. Results will not be reported until appropriate statistical analyses are performed though we hope that we will have data to support an improvement in the placement rate with the FDA. In March 2005, we filed a PMA supplement with the FDA that intends to obtain approval to early terminate our post-approval study and recognize the findings from that study on our label. It is uncertain as to whether or not the FDA will approve the early termination of this study.

Our clinical trials are still ongoing, and the clinical trial statistics presented may change as longer term follow-up data from the women participating in the trials is gathered, audited and analyzed, or if the FDA requests that calculations be performed in a different manner than presented in our PMA application.

Other studies and regulatory activities

On October 30, 2003, we announced the signing of an exclusive U.S. co-promotional agreement with GYNECARE, Worldwide division of Ethicon, Inc., involving Essure and the GYNECARE THERMACHOICE Uterine Balloon Therapy System, a treatment for menorrhagia (heavy menstrual bleeding) in pre-menopausal women. ThermaChoice is a minimally invasive, outpatient treatment for menorrhagia due to benign causes in pre-menopausal women for whom childbearing is complete. The device uses a balloon catheter with heated fluid to ablate the endometrial lining of the uterus during an 8-minute therapy cycle. The procedure can be performed under local anesthesia in less than 30 minutes. An endometrial ablation ("EA") procedure is a treatment option advised only for women who are finished with their childbearing. Although women undergoing EA must be finished with childbearing, intrauterine ablation should not be considered a means of sterilization. Sterility *may* occur after ablation, but cannot be guaranteed in the uterus or in the fallopian tubes since ovulation still takes place as before, and the uterine lining may be receptive to a pregnancy. Pregnancy in general should not be elected after an ablation because it can be dangerous for both the fetus and mother including possible complications such as uterine rupture, placenta increta/accreta, and intra-uterine growth restriction. Because of the potential problems with future pregnancies, it is generally recommended that other methods of contraception be considered in women who undergo ablations. Many physicians encourage women to consider permanent birth control, such as laparoscopic tubal sterilization, at the time of endometrial ablation if the possibility of future pregnancy exists. In order to promote use of the Essure device in a concomitant procedure with the GYNECARE Thermachoice system, we conducted a study and filed a PMA supplement with the FDA in order to modify a warning label in the Essure physician labeling. On July 27, 2004, we announced that the FDA had approved labeling changes allowing concomitant use of Essure with Johnson & Johnson's GYNECARE THERMACHOICE Uterine Balloon Therapy system. We intend for this agreement with GYNECARE to provide us with the ability to increase awareness, gain market presence and credibility, accelerate our ability to train doctors, as well as expand our market opportunity by driving adoption among a group of physicians not previously targeted by our marketing programs. The success of the joint marketing campaign will depend upon the effectiveness of our GYNECARE sales force training programs, market demand for Essure in conjunction with the THERMACHOICE treatment and the efforts and commitment of GYNECARE to this new program. We cannot be certain how successful this program will be, if at all.

As a condition of FDA approval, Conceptus and GYNECARE agreed to provide the FDA with investigational data from a prospective study of 50 women to assess whether the THERMACHOICE EA procedure causes intrauterine scarring and/or adhesions that could prevent or interfere with an effective HSG at three-months post-Essure placement. In addition, the study will assess tubal occlusion three months after concomitant Essure/THERMACHOICE procedures. The study is to be conducted at no fewer than three investigational sites. A final report should be submitted to the FDA within three months of completion of the study. Information provided in this report will be used to assess the effectiveness of concomitant Essure/THERMACHOICE procedures. Data presented in this report may be used to develop additional statements for inclusion in Essure labeling.

SALES AND MARKETING

On November 6, 2002, we received FDA approval to market Essure in the United States. The achievement of this major milestone enabled us to begin an aggressive marketing and sales campaign in the United States. We are distributing Essure in the United States through our direct sales force.

Our sales and marketing strategy is to market Essure primarily to gynecologists while building interest and awareness among consumers and general practitioners. Through the use of public relations and targeted advertising, we intend to increase awareness of Essure among consumers, general practitioners and the broader medical community. In April 2003, we presented Essure at the annual

conference of the American College of Obstetricians and Gynecologists (ACOG). In early June 2003, we commenced a direct mail campaign to 500,000 women in the Atlanta and Chicago areas, with the goal of encouraging these women to contact our call center for additional information. In turn, our call center has the ability to offer a referral to a practicing Essure physician in a consumer's area. We also conducted regional advertisement in a variety of magazines, such as *Parents* and *Self*. Since then we have continued to attend meetings for the American Association of Gynecologic Laparoscopists (AAGL) and ACOG organizations and women's health care societies. We also continue to conduct a variety of marketing programs to develop awareness and promote the product.

In an effort to expand our business rapidly and effectively, we have established marketing and distribution relationships with other companies. On October 30, 2003, we announced the signing of our exclusive U.S. co-promotional agreement with GYNECARE, involving Essure and the GYNECARE THERMACHOICE Uterine Balloon Therapy System. The co-promotional agreement between Conceptus and GYNECARE will offer physicians the option of combining the ThermaChoice and Essure treatment, both of which can be used in a minimally invasive procedure and on an outpatient basis.

Under the terms of the agreement, a group of physician consultants specifically hired and trained by Conceptus have become preceptors in the Essure procedure. This group of physician preceptors will then train ThermaChoice physician users in the Essure procedure over a two-year period, commencing on and subject to the approval of a Conceptus PMA supplement. This group of physician consultants is separate and in addition to our existing sales and training team, who will continue to train additional physicians. During January 2004, we trained 80 GYNECARE sales representatives, and have designated 20 trainers, who are physicians previously trained on Essure. The designated trainers have helped us to train physicians who wish to perform Essure procedure in combination with ThermaChoice procedure. This agreement includes certain performance clauses that if not met, could lead to the termination of the agreement by Conceptus in July 2005.

During 2004, we began a direct-to-consumer ("DTC") campaign in the Chicago area that incorporated direct mail, print media and radio advertising. We have opened two new websites for physicians and patients and have established a call center for patients that are seeking additional information about Essure and who wish to be referred to physicians that are trained to perform the Essure procedure. Physicians that we refer our patients to are those that have chosen to participate in our Essure Accredited Practice program aimed at providing an optimal patient experience.

The Chicago DTC campaign ran from the third week in August 2004 through the end of February 2005 with an ongoing maintenance level of advertising expected through the remainder of 2005. Through December 31, 2004 we have spent $2.0 million on advertising and consulting expense for this campaign and expect to have spent a total of $2.5 million by the end of February 2005. Because of the long decision process in selecting permanent birth control, it will take some time to assess the success of the Chicago DTC campaign. The initial results of the Chicago campaign are being reviewed and analyzed by us now. The initiation of any future programs in other regions will depend, in part, on the final results of the Chicago campaign, which may not be available until later in 2005.

In order to focus our resources domestically, we decided to market and sell our product in Australia through a third party distributor which resulted in closing down our direct operations in January 2005. In January 2004, we completed the sale of our wholly-owned French subsidiary for a nominal amount to an investor group comprised of our former French management team, and signed a long-term exclusive distribution agreement for Essure with the acquiring group for the European, Middle East and African markets. The sale agreement includes a long-term call option that is intended to enable Conceptus to repurchase the French company. The contract was amended in September 2004 to include the territories of Mexico, Central America and South America. The sale transaction of our French subsidiary did not have any material impact to our financial statements. Both distribution

arrangements are meant to allow us to conserve our resources by eliminating the funding requirements of developing those markets so that we can focus on the larger U.S. market.

PHYSICIAN TRAINING

We have identified, educated and trained qualified gynecologists in the Essure placement procedure through a combination of presentations at major medical conferences, hands-on simulation and proctored procedures with a clinician experienced in our Essure placement procedure. In order to complete training, we proposed and the FDA agreed that we have a professional trainer in attendance during a physician trainee's initial cases, usually three to five, to observe appropriate technique and to sign off the physician for the procedure.

In early 2003, we targeted large-group gynecological practices in the United States with the goal of training, inclusive of preceptorship, approximately 700 physicians by the end of 2003. During the second quarter of 2003, we started to focus on one-on-one training sessions for new physicians who have pre-scheduled Essure cases. This is to accelerate the training process and to control training costs. As of December 31, 2004, we have a total of 1,681 doctors that have either completed or are in the process of completing preceptorship. Our accomplishment in obtaining the number of physicians trained provides us with a strong referral base within major metropolitan areas we have targeted, and we believe also creates the leverage to help us gain additional reimbursement coverage.

We understand that a strong base of trained physicians does not necessarily correlate to an increase in revenue proportionately. Another important factor is the average procedures performed per physician per month, or utilization. During 2004, our overall utilization rates declined minimally from an average of 0.8 procedures per month at the beginning of the year to 0.7 procedures per month at the end of the year. This was caused primarily by decreases in the utilization rates of physicians in preceptorship which is believed to be caused by physicians not being adequately reimbursed for their services by third party payors and subsequently slowing down their usage. Certified physician utilization increased during the year from 0.8 procedures per month at the beginning of the year to 1.0 procedures per month at the end of the year. In order to accomplish our objective, we have built marketing programs which include staff training, patient and referring physician awareness seminars and mailings, billing models for reimbursement, media outreach kits, hospital marketing tools and advertising, including radio in select areas. We will also increase the frequency of call patterns by our field sales and training force to our existing physician base. Since there is a trade-off in the amount of time that the field sales and training forces can devote to preceptoring new physicians and increasing the utilization by existing physicians, we are not certain of our ability to increase utilization.

REIMBURSEMENT

Obtaining physician fee and device reimbursement for Essure will be an important step toward successful commercialization of Essure in the United States and internationally. Regardless of the country and its type of reimbursement system, physician advocacy of our product, together with studies demonstrating clinical and cost effectiveness will be required to obtain adequate reimbursement.

In 2005, we will continue to focus on gaining additional insurance coverage of the Essure procedure, which despite our success in 2004, remains a significant barrier to stronger growth. Doctors have told us they are reluctant to perform the Essure procedure given the uncertainty of reimbursement. Gaining reimbursement is a difficult and lengthy process over which we do not have complete control. Physician demand and patient awareness also act to exert pressure on insurance carriers to consider reimbursement. We have established tactical programs, such as hot lines to aid our physicians in navigating reimbursement issues, to facilitate the process and ultimately convince major payors of the benefits of Essure for patients, physicians and the payor community.

Market acceptance of Essure depends in part upon the availability of reimbursement within prevailing healthcare payment systems. We believe that physician advocacy of our product will be required to continue to obtain reimbursement. By December 2004, we received positive reimbursement decisions for Essure from private insurers covering a total of 154 million covered lives, which represents 73% of all the insured, non-Medicare population of the United States. We intend to continue our effort to educate payors of the cost-effectiveness of our product, and to establish further programs to help physicians to navigate reimbursement issues.

In 2004, we received several positive responses from government and private agencies relating to reimbursement, which we believe will help us to speed up the acceptance of Essure by doctors and patients. Please refer to the Reimbursement discussion in Business Overview section. We have also received one unfavorable government response (Australian Department of Health, Medical Services Advisory Committee (MSAC) division) that we do not consider material to our future financial results or expectations for the world-wide acceptance of Essure by doctors and patients.

United States

Health care providers in the United States typically rely on third-party payors, specifically private health insurers, and government programs such as Medicare and Medicaid, to reimburse all or part of the cost of procedures in which medical devices are used. Access to these funds is based on coding systems that are specific to procedure type and typically separate physician fees and fees paid to the facility. In most cases, facility fees include payment for the medical device and are generally paid at rates negotiated between the providers (e.g., hospitals) and third-party payors. We have hired a group of reimbursement specialists who are actively working with physicians, facilities and payors to establish reimbursement for Essure. Payor reimbursement affects the pace of physician adoption of the Essure procedure because facilities habitually check with payors to determine the patient's applicability of coverage and the payor's policy of reimbursement for the costs of a new procedure. We expect that once a facility has established a track record of claims paid by third-party payors, the pace of adoption for subsequent physicians will be more rapid than that of the initial physicians.

International

Reimbursement systems vary significantly by country and sometimes by region, and reimbursement approvals must be obtained on a country-by-country basis. Many international markets have government-managed health care systems that determine reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems.

In 2004, we received several positive responses from government and private agencies relating to reimbursement, which we believe will help us to speed up the acceptance of Essure by doctors and patients. We have also received one unfavorable government response (Australian Department of Health, Medical Services Advisory Committee (MSAC) division) that we do not consider material to our future financial results or expectations for the world-wide acceptance of Essure by doctors and patients. The overall market for female sterilization in Australia at less than 30,000 cases per year is very small. However, the public insured population in Australia is much larger than the private and self-insured population that currently does pay for the procedure. Consequently we believe that our market penetration in Australia will remain limited by the MSAC decision until such time as we are able to submit sufficient long-term data to obtain public funding. We are in the process of determining exactly what long-term clinical data MSAC will accept.

In Europe, consultants are assisting us in developing a strategic plan to obtain reimbursement in a number of European countries, and a clinical reimbursement study has been conducted in France and the UK. A submission was filed in France with the Medical Devices Department of the Economic

Committee for Health Products ("Comite economique de produit sante" CEPS) in January 2004. In October 2004, the French Medical Device Reimbursement Authority "Comite economique de produit sante" (CEPS) granted reimbursement status for the Essure procedure in France, an important step for successful commercialization of the product.

MANUFACTURING

We have limited experience manufacturing our product in the volumes that will be necessary to achieve significant commercial sales. To achieve our production volume objectives, we decided to outsource our manufacturing activity to a third party contract manufacturer and in June 2003, we entered into a three-year contract manufacturing agreement with Accellent (formerly known as Venusa Ltd) for the manufacture of our product. Accellent's manufacturing facilities, located in Mexico and the United States, were approved by the FDA in April 2004 and we transitioned almost all of our commercial production to Accellent by the end of 2004. We intend to maintain only limited manufacturing activity in our facility in San Carlos, California.

Our agreement with Accellent provides that they will continue to use our qualified suppliers of materials and components, unless we agree otherwise. We conduct periodic quality audits of our key suppliers. Most components, including nickel titanium alloy, guidewires, the inner release catheter tubing and stainless steel wires, are available from more than one source and we intend to qualify at least two sources for certain components. One component, the delivery catheter tubing, was available from only one supplier in early 2003. This tubing was manufactured by our supplier using its proprietary intellectual property. In 2003, we finished the clinical testing of an internally developed cathether that does not require a third party license. Currently, we do not have any single source component except for the polyester fiber. The polyester fiber causes the necessary tissue in-growth, is made to our specifications and currently has only one qualified source. However, we have accumulated a quantity of this material that exceeds our anticipated production needs for the next several years. We are in the process of qualifying a second source for this fiber.

Our manufacturing facility and Accellent's manufacturing facilities are subject to periodic inspection by regulatory authorities. Our quality management system is subject to FDA Part 820 Quality System Regulations. These regulations require that we conduct our product design, testing, manufacturing and quality control activities in conformance with these regulations and that we maintain our documentation and records of these activities in a prescribed manner. Our manufacturing facility is licensed by the California Department of Health Services, Food and Drug Branch and is registered with the FDA. In addition our manufacturing facility has received EN/ISO 13485 Quality Management Systems certification and our quality system is in compliance with the European Union Medical Device Directive 93/42/EEC, allowing us to affix the CE Mark to our products after assembling appropriate documentation. EN/ISO 13485 Quality Management Systems standards have been developed to harmonize standards for the design, manufacturing and distribution of medical devices quality operations have been developed to ensure with worldwide regulatory requirements that companies know the standards of quality on a worldwide basis.

RESEARCH AND DEVELOPMENT

Our research and development activities are performed by a product development, regulatory/clinical research staff of 16 employees. Research and development expenses for 2004, 2003, and 2002 were approximately $4.1 million, $6.0 million and $8.2 million, respectively. We intend to continue to focus our research and development efforts on the development of new or alternative product designs and enhancements along with management of the on-going clinical trials. It is R&D's goal to launch one to two product enhancements over the next three years intended to result in a lower cost of goods, improved ease of use of the Essure system and simplified packaging systems.

INTELLECTUAL PROPERTY

Our policy is to protect our proprietary position aggressively by, among other things, filing United States and foreign patent applications to protect technology, inventions and improvements that are important to the development of our business. In addition to the patent protection we have obtained in our license from Target Therapeutics, a division of Boston Scientific Corporation, (see license details at end of Intellectual Property section) we have filed device and method patents for the use of our product in new clinical applications and have pursued patents for several of our other inventions and developments. As of February 24, 2005, we had 10 U.S. patent applications, 25 U.S. patent applications which have been issued to us, and 20 foreign and/or international patent applications are pending, with 29 issued foreign patents. Our issued patents include claims relevant to transcervical fallopian tube occlusion devices and methods, guidewire manipulation, a guidewire design, fallopian tube visualization, electrosurgical instruments and a delivery mechanism for a tubal occlusion device. The pending applications describe various aspects of our proprietary tubal access platform technology, including claims specific to our Essure tubal occlusion device. In January 2001, the United States Patent and Trademark Office, or PTO, issued a patent to us granting a number of claims directed to intrafallopian devices, including devices that are anchored by resilient coils. On March 4, 2003, the PTO issued a patent to us with method claims directed to expansion of a device inserted into a tubal ostium with subsequent tissue ingrowth, along with claims to conception-inhibiting devices having coils. These patents describe and claim a variety of techniques to enhance the effectiveness of these devices, including the use of polyester fibers attached to the device, and also discloses methods for deployment of these devices using a transcervical delivery system.

On January 20, 2004 the PTO issued patent #6,679,266 to us titled *Contraceptive transcervical fallopian tube occlusion devices and their delivery* with method claims directed at non-surgical methods of sterilizing a female by inserting an instrument assembly into the patient's fallopian tube and delivering electrical energy from the instrument to inner walls of the fallopian tube and leaving behind a device that is anchored within the fallopian tube by imposing a secondary shape on tubal wall, the secondary shape having a larger cross-section than the fallopian tube. Additionally, the patent stated the efficacy of the device may be enhanced by forming the structure at least in part from copper or a copper alloy.

On February 3, 2004 the PTO issued patent #6,684,884 to us titled *Contraceptive transcervical fallopian tube occlusion devices and methods* with device and method claims directed at intrafallopian devices and non-surgical methods for their placement to prevent conception. The device being anchored within the fallopian tube by a resilient structure which has a helical outer surface, together with a portion of the resilient structure which is biased to form a secondary shape, the secondary shape having a larger cross-section than the fallopian tube. Optionally, permanent sterilization is effected by passing a current through the resilient structure to the tubal walls. The efficacy of the device is enhanced by forming the structure at least in part from copper or a copper alloy.

On March 16, 2004 the PTO issued patent #6,705,323 to us titled *Contraceptive transcervical fallopian tube occlusion devices and methods* with device, method and system claims directed at at an intrafallopian tissue ingrowth contraceptive device for use in a fallopian tube comprising transcervically introducing a resilient structure into a target region of a fallopian tube; imposing an anchoring force against a tubal wall by resiliently engaging the tubal wall with the structure; the structure having an outer surface which is adapted to engage the tubal wall so as to prevent expulsion of the contraceptive device; and a material which can incite ingrowth of the tubal tissue therein, the ingrowth material attached to the retention structure. The use of copper in the intrafallopian device of the present invention improves its efficacy as a contraceptive method. Additionally, there are claims for applying current through the resilient structure to anchor in the tubal wall.

On March 23, 2004 the PTO issued patent #6,709,667 to us titled *Deployment actuation system for intrafallopian contraception* with claims directed at an invention which provides improved medical

devices, systems, and methods. The invention provides intrafallopian contraceptive systems having a handle adapted for manipulation and actuation by a single hand of a healthcare provider. Advantageously, this leaves the other hand free to grasp and manipulate a hysteroscope, allowing the healthcare provider to orient the system toward the tubal ostium and effect its deployment while optically viewing and verifying the deployment. Deployment may, alternatively, be directed under a variety of imaging modalities, including ultrasound, fluoroscopy, or possibly even with tactile guidance.

On July 20, 2004 the PTO issued patent #6,763,833 to us titled *Insertion/deployment catheter system for intrafallopian contraception* with claims directed at contraceptive methods, systems, and devices to improve the ease, speed, and reliability with which a contraceptive device can be deployed transcervically into an ostium of a fallopian tube. A distal portion of the contraceptive device will function as a guidewire, facilitating advancement of the device the tubal ostium; a proximal portion of the device remains covered by a deployment sheath until the device is in position. The deployment sheath is withdrawn proximally, and the device is expanded to a large profile configuration engaging the surrounding tissues by exposing a surface, which is well adapted for retaining the device within the tube.

We obtained an exclusive license in the field of reproductive physiology to technology developed by Target Therapeutics. In addition, we have granted to Target Therapeutics an exclusive license to our technology in certain fields of interventional medicine outside of reproductive physiology. Our exclusive license of Target Therapeutics's technology encompasses certain technology developed by Target Therapeutics as of February 1, 1996. We do not have any preferential rights to technology developed by Target Therapeutics after that date. The license from Target Therapeutics includes patents which relate to the design of its micro-catheters (the initial patent for which expires in June 2006), certain aspects of guidewire design and other important aspects of micro-catheter, guidewire and micro-coil technologies. If these Target Therapeutics patents were invalidated, our proprietary position in the marketplace would be severely compromised. In addition, should any of our Target Therapeutics technology be found to infringe upon a third party's patent rights, it may affect our ability to develop, market and sell additional products in the future. Finally, Target Therapeutics has the right to terminate our license if we materially breach the terms of the license. If the Target Therapeutics license were terminated, it might affect our ability to develop, market and sell additional products in the future.

We believe that we are free to make and sell our product, and that our product and its intended use does not infringe any valid patent rights of any other party. However, a third party, Ovion, Inc., brought to our attention a patent and certain claims from a pending patent application owned by it. Ovion indicated it believes that the claims of its patent and application cover Essure and its use. On October 23, 2003, we entered into a settlement agreement with Ovion pursuant to which we received a sole, worldwide license to Ovion's patent rights relative to the Essure system, and Ovion may not grant any additional such licenses to other parties. The settlement agreement provided for the payment of a royalty to Ovion that will be equal to 3.25% of the cumulative net sales of Essure in excess of $75.0 million for a period of no longer than ten years. In addition, the settlement agreement provided for a cash payment of $2.0 million in the fourth quarter of 2003 as a prepaid royalty, and a license fee of $2.0 million payable in our common stock in equal installments in the first and second quarters of 2004. Ovion was not granted any rights to our intellectual property pursuant to the settlement agreement. The settlement agreement was approved by the U.S. District Court for the Northern District of California on November 6, 2003.

Although we have reached a settlement agreement with Ovion, we still believe that some or all of Ovion's claims should be included within our own patents, and we requested that the PTO declare an interference. An interference is a proceeding within the PTO to determine which party was the first to invent, and which party is thereby entitled to ownership of, the claims. We believe that we filed our patent applications for Essure before Ovion filed the application that issued as its patent, and that we are entitled to any patentable claims now appearing in their patent that cover our product. We do not

know whether the PTO will declare an interference, whether we invented our product prior to Ovion's date of invention, or whether we will prevail in an interference proceeding if it is declared by the PTO. Future royalties might be avoided by a favorable interference ruling before the patent office, which might occur if interference is declared and if we are found to have priority of invention.

GOVERNMENT REGULATION

The research, development, manufacture, labeling, distribution and marketing of our product are subject to extensive and rigorous regulation by the FDA and, to varying degrees, by state and foreign regulatory agencies.

United States Regulation

The manufacture and sale of our product are subject to extensive regulation by numerous governmental authorities, principally the FDA as well as state and foreign agencies. In particular, the FDA regulates the research, clinical testing, manufacturing, safety, labeling, storage, record keeping, advertising, distribution, sale and promotion of medical devices in the United States. The FDA requires that all medical devices introduced to the market either be preceded by a pre-market notification clearance under Section 510(k) of the Federal Food, Drug & Cosmetic Act, or an approved PMA. A PMA application is approved when the FDA has determined the company has submitted clinical trial data and manufacturing quality assurance information to prove it is safe and effective for its labeled indications, or for devices that are not of the same type or substantially equivalent to a device in commercial distribution prior to 1976. Essure is regulated by the FDA and received FDA approval for commercialization in the United States on November 6, 2002. If we or our third party manufacturer, Accellent, do not comply with applicable regulatory requirements, we may be subject to, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, withdrawal of approvals and criminal prosecution.

The FDA imposes numerous requirements with which medical device manufacturers must comply in order to maintain regulatory approvals. FDA enforcement policy strictly prohibits the promotion of approved medical devices for uses other than those for which the device is specifically approved by the FDA. We and our third party manufacturer, Accellent, will be required to adhere to applicable FDA and other regulations regarding Quality Systems, including testing, control and documentation requirements. Ongoing compliance with the Quality System Regulations and other applicable regulatory requirements will be monitored through periodic inspections by federal and state agencies, including the FDA and the California Department of Health Services, as well as foreign health authorities. In July 1994, our San Carlos facility was inspected by the California Department of Health Services, and we were subsequently granted a California medical device manufacturing license. In February 1997, our facility was inspected by the California Department of Health Services, and we were granted a California drug manufacturing license. In March 1997, we were inspected by the FDA, with no action indicated and we became ISO 9001 certified in December 2000. In July 2002, we successfully passed another FDA inspection and, partly as a result, received our PMA approval in November 2002. As part of the conditions of approval, we are required to provide data annually to the FDA in order to gather long-term safety and effectiveness data on the Essure System. We are also required to conduct a post approval study in the United States with certain newly trained physicians to evaluate placement rates. We are required to provide information to the FDA on death or serious injuries which our medical devices have allegedly caused or with which they have been associated, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. If the FDA believes that a company is not in compliance with the law or regulations, it can institute proceedings to detain or seize products, issue a recall, enjoin future violations and assess civil and criminal penalties against the company, its officers and its employees. We are also subject to regulation by the Occupational Safety and Health Administration and by other government entities. Regulations

regarding the manufacture and sale of our product are subject to change. We cannot predict what impact, if any, such changes might have on our future ability to manufacture, market and distribute Essure.

International regulation

Sales of medical devices outside of the United States are subject to international regulatory requirements that vary widely from country to country. The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing may differ significantly from FDA requirements. Essure is listed with Australia's Therapeutic Goods Agency. The European Union has promulgated rules which require manufacturers of medical products to obtain the right to affix to their products the CE Mark, an international symbol of adherence to quality assurance standards and compliance with applicable European Union Medical Device Directives. We received permission to affix the CE Mark to Essure in February 2001. In Canada, we received clearance from Health Canada to market Essure in Canada in November 2001. Some countries in which we currently operate or contemplate to operate either do not currently regulate medical devices or have minimal registration requirements. However, these countries may develop more extensive regulations in the future that could delay or prevent us from marketing Essure in these countries.

COMPETITION

We compete against other surgical procedures for permanent birth control, mechanical devices and other contraceptive methods, including existing methods of reversible birth control for both women and men.

We are aware of one company that is in the early stage of developing a non-incisional permanent birth control device, and other companies may develop products that could compete with Essure in the future.

The medical device industry is characterized by rapid and significant technological change. The length of time required for product development and regulatory approval plays an important role in a company's competitive position. As a result, our success will depend in part on our ability to respond quickly to medical and technological changes through the development and commercialization of new products. Competitive factors may render Essure obsolete or noncompetitive or reduce demand for Essure.

PRODUCT LIABILITY AND INSURANCE

The manufacture and sale of medical products involve an inherent risk of exposure to product liability claims and product recalls. We currently maintain product liability insurance with coverage limits of $10.0 million per occurrence and an annual aggregate maximum of $10.0 million, which we believe is comparable to that maintained by other companies of similar size serving similar markets. However, there can be no assurance that product liability claims in connection with clinical trials or sale of our product will not exceed such insurance coverage limits, which could have a material adverse effect on us, or that such insurance will continue to be available on commercially reasonable terms or at all. Insurance is expensive and in the future may not be available on acceptable terms, if at all. A successful product liability claim or series of claims brought against us in excess of our insurance coverage or a recall of our product could have a material adverse effect on our business, financial condition and results of operations.

EMPLOYEES

As of December 31, 2004, we have 112 full-time employees, consisting of 6 in product development, 3 in process engineering, 12 in manufacturing, 59 in sales and marketing, 7 in clinical/regulatory affairs, 8 in quality assurance and 17 in general and administrative functions. We generally depend on a number of key management, sales and marketing and technical personnel. The loss of the services of one or more key employees could delay the achievement of our development and marketing objectives. Our success will also depend on our ability to attract and retain additional highly qualified management, sales and marketing and technical personnel to meet our growth goals. We face intense competition for qualified personnel, many of whom are often subject to competing employment offers, and we do not know whether we will be able to attract and retain such personnel.

None of our employees are represented by a labor union or covered by a collective bargaining agreement, and we believe our employee relations are good.

EXECUTIVE OFFICERS OF THE COMPANY

Information required by this item, insofar as it relates to directors and officers, will be contained in the Company's Definitive Proxy Statement in connection with our 2005 Annual Meeting of Stockholders, which we anticipate will be filed no later than 120 days after the end of our fiscal year pursuant to Regulation 14A, under the captions "Election of Directors," "Management". Information required by this item as to compliance with Section 16(a) of the Securities Exchange Act of 1934 will be contained in the Company's Definitive Proxy Statement under the caption "Section 16(a) Beneficial Owner Reporting Compliance," and is hereby incorporated by reference into this report.

ITEM 2. PROPERTIES

We are headquartered in San Carlos, California where we lease two buildings occupying approximately 36,400 square feet of office, research and development, and manufacturing space under leases that expire on June 30, 2005 and December 31, 2005, respectively. Additionally, as of December 31, 2004, we also lease sales and marketing offices in Australia on a month-to-month basis, which totals no more than 1,000 square feet of office space. We believe that our current facilities are adequate for our immediate needs and that we will be able to renew our leases or obtain additional space as needed.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our financial position, results of operations or cash flows.

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

No matters were submitted to a vote of stockholders of the Company during the fourth quarter of the fiscal year ended December 31, 2004.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock has been traded on the Nasdaq National Market under the symbol CPTS since the effective date of our initial public offering on February 1, 1996. The following table presents the high and low closing sale prices for our common stock as reported on the Nasdaq National Market for the period indicated.

	High	Low
Year Ended December 31, 2004:		
Fourth Quarter	$ 11.21	$ 8.09
Third Quarter	$ 11.90	$ 8.08
Second Quarter	$ 14.16	$ 9.97
First Quarter	$ 13.06	$ 8.87
Year Ended December 31, 2003:		
Fourth Quarter	$ 13.74	$ 9.53
Third Quarter	$ 17.34	$ 13.10
Second Quarter	$ 14.98	$ 8.60
First Quarter	$ 11.94	$ 6.98

As of February 28, 2005, there were 158 stockholders of record and the last reported sale price of our common stock on February 28, 2005 was $7.86.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future. We intend to retain any future earnings for reinvestment in our business. Any future determination to pay cash dividends will be at the discretion of the board of directors and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as the board of directors deems relevant.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following table presents selected consolidated financial data of Conceptus, Inc. This historical data should be read in conjunction with the attached consolidated financial statements and the related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing in Item 7 of this Form 10-K. The selected consolidated statement of operations data for the years ended December 31, 2004, 2003 and 2002 and the consolidated balance sheet data as of December 31, 2004 and 2003 are derived from our audited consolidated financial statements and the related notes, which are included elsewhere in this Form 10-K. The selected consolidated statement of operations data for the years ended December 31, 2001 and 2000 and the consolidated balance sheet data as of December 31, 2002, 2001 and 2000 are derived from our audited consolidated financial statements and the related notes, which are not included in this Form 10-K.

	Years Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Net sales	$ 11,612	$ 7,700	$ 1,650	$ 401	$
Cost of goods sold	7,112	6,587	3,142	1,456	
Gross profit (loss)	4,500	1,113	(1,492)	(1,055)	
Operating expenses:					
Research and development	4,067	6,048	8,230	7,983	10,739
Selling, general and administrative	27,075	35,256	23,417	9,776	5,012
Total operating expenses	31,142	41,304	31,647	17,759	15,751
Operating loss	(26,642)	(40,191)	(33,139)	(18,814)	(15,751)
Recovery of legal defense costs					586
Interest and other income, net	573	663	629	740	712
Net loss	$ (26,069)	$ (39,528)	$ (32,510)	$ (18,074)	$ (14,453)
Basic and diluted net loss per share	(1.05)	(1.83)	(1.71)	(1.33)	(1.37)
Shares used in computing basic and diluted net loss per share	24,754	21,565	18,968	13,561	10,559

	December 31,				
	2004	2003	2002	2001	2000
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short term investments*	$ 32,271	$ 30,863	$ 70,734	$ 33,803	$ 12,493
Working capital	32,165	27,751	68,272	31,623	9,282
Total assets	42,177	41,850	77,295	37,778	14,106
Long-term clinical liabilities		193	217	486	810
Accumulated deficit	(183,329)	(157,260)	(117,732)	(85,222)	(67,148)
Total stockholders' equity	36,994	33,737	70,714	33,175	9,959

* *Includes restricted cash of $69,000 at December 31, 2004, 2003, 2002 and 2001*

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

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes thereto. This discussion contains forward-looking statements that involve risks and uncertainties such as limited operating and sales history; the uncertainty of market acceptance of our product; dependence on obtaining and maintaining reimbursement; effectiveness and safety of our product over the long-term; our ability to obtain and maintain the necessary governmental clearances or approvals to market our product; our ability to develop and maintain proprietary aspects of our technology; our ability to manage our expansion; our limited history of manufacturing our product; our dependence on single source supplies, third party manufacturers and co-marketers; intense competition in the medical device industry; the inherent risk of exposure to product liability claims and product recalls and other factors referenced in this Form 10-K. Our actual results could differ materially from those expressed or implied in these forward-looking statements as a result of various factors, including those discussed in "Risk Factors" and elsewhere in this Form 10-K.

OVERVIEW

We develop, manufacture and market Essure®, an innovative and proprietary non-incisional permanent birth control device for women that was approved for marketing in the United States in November 2002 by the United States Food and Drug Administration, or FDA. Essure is a soft and flexible micro-insert delivered into a woman's fallopian tubes designed to provide permanent birth control by causing a benign tissue in-growth that blocks the fallopian tubes. A successfully placed Essure micro-insert prohibits the egg from traveling through the fallopian tubes and therefore prevents fertilization.

The Essure Procedure

The Essure placement procedure is typically performed as an outpatient procedure and is intended to be a less invasive and a less costly alternative to tubal ligation, the leading form of birth control in the United States and worldwide. Laparoscopic tubal ligation and tubal ligation by laparotomy typically involve abdominal incisions and/or punctures, general or regional anesthesia, four to ten days of normal recovery time and the risks associated with an incisional procedure. The Essure placement procedure does not require cutting or penetrating the abdomen, which lowers the likelihood of post-operative pain due to the incisions/punctures, and is typically performed in an outpatient setting without general or regional anesthesia. In the Pivotal trial of Essure, the total procedure time averaged 35 minutes, with an average of 13 minutes of hysteroscopic time to place the Essure micro-insert. A patient is typically discharged approximately 45 minutes after the Essure placement procedure. No overnight hospital stay is required. Furthermore, Essure is effective without drugs or hormones. There is a three-month waiting period after the procedure during which the woman must use another form of birth control while tissue in-growth occurs. At 90 days following the procedure, the patient completes a follow-up examination called a hysterosalpingogram (HSG), which can determine whether the device was placed successfully and whether the fallopian tubes are occluded.

We believe that Essure is also an attractive alternative to tubal ligation for physicians, hospitals and payors. Essure is a less invasive permanent birth control option for physicians to offer to their patients; hospitals are able to utilize their facilities more cost effectively with the Essure placement procedure compared with tubal ligation, and payors are able to experience cost reductions resulting from the elimination of overhead and procedural costs related to anesthesia and post-operative hospital stays associated with tubal ligations. We also believe Essure is a viable alternative to other temporary methods of birth control being used when there is no intention of having children in the future. In addition, payors may also benefit from the reduction of unplanned pregnancies associated with

non-permanent methods of birth control used by patients who have chosen to avoid the drawbacks of traditional permanent birth control methods but who may elect to use Essure.

Published reports estimate that 700,000 tubal ligation procedures are performed each year in the United States and 13 million procedures worldwide. We intend to tap into this market and establish the Essure procedure as the standard of care for permanent birth control.

Essure is currently being marketed in multiple countries. In November 2002 we received approval from the FDA to market Essure in the United States. In 2001, we were given approval to affix the CE Mark to Essure, indicating that Essure is certified for sale throughout the European Union, subject to compliance with local regulations such as registration with health ministries and/or particular requirements regarding labeling or distribution. In 1999, Essure was listed with Australia's Therapeutic Goods Administration, which allows us to market and sell Essure in Australia. In Canada, we received clearance from Health Canada to market Essure in Canada in November 2001. We have distributors in Australia, Canada, New Zealand and France, which covers Europe, Middle East, Africa, Mexico, Central America and South America.

Effectiveness of Essure

Based on clinical trial data filed with the FDA in November 2003, Essure has been demonstrated to be 99.80% effective at three years of follow-up. As of January 2005, we have accumulated sufficient patient follow-up data from the Phase II and Pivotal clinical trials to file a PMA supplement with the FDA for a four and five year effectiveness claim consistent with the three year claim.

Penetration

Doctors are required to be preceptored for between 3 and 5 cases by a certified trainer before they can perform procedures independently. As of December 31, 2004, Conceptus has trained or is in the process of training 1,681 physicians in the United States on the Essure procedure. This represents an increase of 889 physicians over the number of physicians at December 31, 2003. The level of sales for Essure, particularly in this early period of adoption, is highly dependent on the number of physicians trained to perform the procedure.

Reimbursement of Essure

Market acceptance of Essure also depends in part upon the availability of reimbursement within prevailing healthcare payment systems. We believe that physician advocacy of our product will be required to continue to obtain reimbursement. As of December 31, 2004, we received positive reimbursement decisions for Essure from private insurers covering a total of 154 million covered lives, which represents 73% of all the insured, non-Medicare population of the United States. We intend to continue our effort to educate payors of the cost-effectiveness of our product, and to establish further programs to help physicians to navigate reimbursement issues.

In early November 2004, the Centers for Medicare and Medicaid Services ("CMS") released the Final Rule for the 2005 Physician Fee schedule. For the Essure CPT code, the CMS has provided for a national physician payment of $2,198.34 for procedures performed in the office and $458.94 for physician payment when the procedure is performed in the hospital. This compares to a CPT code physician payment of $361.16 for a laparascopic tubal ligation, the current standard of care for permanent female sterilization. In addition, the CMS released the Final Rule for the 2005 OPPS, which assigns hospital outpatient reimbursement amounts. The Essure CPT code was assigned a 2005 payment level of $2,260.37, which is consistent with payments by CMS to hospitals when they perform a laparoscopic tubal ligation, normally performed in a higher cost hospital operating room. We believe these values are very favorable for the Essure procedure and will help in establishing increased utilization of the device amongst doctors. We expect that the new code, once the process to establish it

at all private payors that have given a favorable coverage decision is complete, will significantly ease the burden on a physician's office in obtaining reimbursement for Essure, and accelerate the coverage of Essure by private insurance companies and Medicaid. This process is not automatic following receipt of the new CPT code, however, and we anticipate continuing to focus on reimbursement issues for sometime in the future both to secure our code and payment schedule into the payors' databases, as well as to help the physician negotiate a favorable contract for payment off that schedule.

In mid-August 2004, the Australian Department of Health, Medical Services Advisory Committee (MSAC) division recommended against public funding for the Essure procedure, citing insufficient evidence for safety, effectiveness and cost effectiveness. The overall market for female sterilization in Australia at less than 30,000 cases per year is very small. However, the public insured population in Australia is much larger than the private and self-insured population that currently does pay for the procedure. Consequently we believe that our market penetration in Australia will remain limited by the MSAC decision until such time as we are able to submit sufficient long-term data to obtain public funding. We are in the process of determining exactly what long-term clinical data MSAC will accept. They have indicated that they are looking for 5 years of efficacy, which we will not be able to provide for at least one more year. As a result, in December 2004 we made the decision to terminate our direct subsidiary operations in Australia and convert to an independent distributor. This decision was largely a cost reduction measure in lieu of the small size of the Australian market and our inability to manage a direct operation to a cash-flow positive position. A distribution agreement has been entered into and the transition has been completed in January 2005.

Utilization of Essure

Essure is a novel product in the contraception market, which is dominated by procedures that are well established among physicians and patients and are routinely taught to new physicians. As a result, we believe that recommendations and endorsements by physicians will be essential for market acceptance of our product. Physicians are traditionally slow to adopt new products and treatment practices, partly because of perceived liability risks. Our biggest challenge is to speed up the adoption process to make the Essure procedure the standard of care for permanent birth control. The following discussion summarizes our program in the United States to increase adoption of the Essure procedure.

Overall utilization, which is the average number of procedures performed per physician per month, declined minimally from an average of 0.8 procedures per month at the beginning of 2004 to 0.7 procedures per month at the end of the year. This was caused primarily by decreases in the utilization rates of physicians in preceptorship which is believed to be caused by physicians not being adequately reimbursed for their services by third party payors and subsequently slowing down their usage. Certified physician utilization increased during the year from 0.8 procedures per month at the beginning of the year to 1.0 procedure per month at the end of the year. The increase in our utilization rate by certified physicians over the year is directly attributable to our tactical reimbursement efforts aimed at educating the physician and office staff regarding payor procedures following a declined claim, including appeals and petitioning procedures. Typically a newly covered product will go through a period where claims are either inadvertently declined or are paid at the incorrect amount. In either instance, the physician is reluctant to perform additional procedures until payment has been secured for earlier cases, causing the decline in utilization for Essure. Our tactical reimbursement focus is intended to give the physician and his/her staff the tools to ensure that claims will ultimately be paid and thereby encourages the physician to continue performing the Essure procedure despite reimbursement issues. This tactical reimbursement group is generally targeting specific accounts with the aim of eventually meeting with all of our accounts so as to provide them with the knowledge of how to file and follow up on claims on a payor by payor basis.

On July 27, 2004, we announced that the FDA had approved labeling changes allowing concomitant use of Essure with Johnson & Johnson's GYNECARE THERMACHOICE Uterine

Balloon Therapy system. In October 2003, we signed a co-promotion agreement with the GYNECARE division that will permit the GYNECARE sales force to market Essure. We intend for this agreement with GYNECARE to provide us with the ability to increase awareness, gain market presence and credibility, accelerate our ability to train doctors, as well as expand our market opportunity by driving adoption among a group of physicians not previously targeted by our marketing programs. The success of the joint marketing campaign will depend upon the effectiveness of our GYNECARE sales force training programs, market demand for Essure in conjunction with the THERMACHOICE treatment and the efforts and commitment of GYNECARE to this new program. We cannot be certain how successful this program will be, if at all.

As a condition of FDA approval, Conceptus and GYNECARE agreed to provide the FDA with investigational data from a prospective study of 50 women to assess whether the THERMACHOICE EA procedure causes intrauterine scarring and/or adhesions that could prevent or interfere with an effective HSG at three-months post-Essure placement. In addition, the study will assess tubal occlusion three months after concomitant Essure/THERMACHOICE procedures. A final report should be submitted to the FDA within three months of completion of the study. Information provided in this report will be used to assess the effectiveness of concomitant Essure/THERMACHOICE procedures.

In addition, we are expanding our sales territories and channels of distribution that will also impact penetration and utilization. With the addition of two national account managers and three sales territories, we will have increased our sales coverage by 15%, from 19, as of December 31, 2003, to 22 direct sales representatives as of December 31, 2004. From time to time, we may engage regional distributors of women's gynecology products to market and sell our products.

In late July 2004 we announced that we initiated an extensive direct to consumer advertising campaign in the Chicago, Illinois metropolitan area which commenced in August 2004 and was extended for 6 months and involve radio, direct mail and print media (magazine) advertisements aimed at increasing consumer awareness. Depending on the success of this marketing effort, we will be evaluating additional major metropolitan markets in which to conduct a similar advertising campaign in 2005. This program was directly responsible for the increase in selling, general and administration expense during the last half of 2004. Applying this program to additional markets will therefore result in further increases in our expenses.

We have experienced significant operating losses since inception and, as of December 31, 2004, had an accumulated deficit of $183.3 million. We expect our operating losses to continue at least through the calendar year 2005 as we continue to expend substantial resources in the selling and marketing of Essure in the United States. Due to the unpredictable nature of these activities, we do not know whether we will achieve or sustain profitability in the future. We will continue to be in a net loss position until sufficient revenues can be generated to offset expenses. In February 2004, we completed a private placement of common stock to generate enough cash to help fund our operations. In the future, depending upon a variety of factors, we will likely need to raise additional funds through bank facilities, debt or equity offerings or other sources of capital.

CRITICAL ACCOUNTING ESTIMATES AND POLICIES

The consolidated financial statements include accounts of the Company and all wholly owned subsidiaries. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions in certain circumstances that affect amounts reported in the accompanying consolidated financial statements and related footnotes. In preparing these financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. The primary estimates underlying the Company's financial statements include reserves for obsolete and slow moving inventory, allowance for doubtful accounts receivable, product warranty, impairment reserves for long-lived assets, income taxes and contingent liabilities. Application of these

accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates.

Inventories. Inventories are stated at the lower of cost or market, cost being determined on the first-in, first-out method. Reserves for potentially excess and obsolete inventories are provided based on historical experience and current product demand. We have not experienced any significant write-off of potentially excess and obsolete inventories in the past. However, this could change as we increase inventory purchases to satisfy product demand. If sales expectations and inventory purchases become mismatched and are not adjusted timely, we may experience material write-offs in the future.

In addition, we evaluate our inventory on a quarterly basis to ensure that our inventory valuation does not exceed net realizable value. Although unlikely, if we experience a significant drop in our average selling price that is below our actual cost of goods, we may incur significant write-downs of inventory.

Revenue Recognition. Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. We obtain written purchase authorizations from our customers for a specified amount of product at a specified price and consider delivery to have occurred at the time of shipment. We have several international distributors in Europe, Australia, Canada and New Zealand. Our revenue recognition policy for distributors is consistent with our policy for direct customers. We entered into written distribution contracts with our distributors with fixed terms and price and consider delivery to have occurred at the time of shipment. We do not currently accept product returns from customers or distributors. We may in the future decide to accept returns from customers or distributors, which will significantly change our revenue recognition policy and materially impact our financial statements. We may be required to defer all of our revenues until sufficient historical data is established to support an adequate return reserve. We may receive non-recurring payments from contractual arrangements which are deferred and recognized as revenue when earned based on an appropriate basis and time frame such as when services are performed or the term of the contract.

Accounts Receivable. We perform ongoing credit evaluations of our customers and adjust credit limits based upon payment history and the customer's current credit worthiness, as determined by our review of their current credit information. We continuously monitor collections and payments from our customers and maintain an allowance for doubtful accounts based upon our historical experience and any specific customer collection issues that we have identified. Our exposure to credit losses may change as we increase our receivables. Changes in customer type and mix, as well as domestic and international economic climate, will also impact potential credit losses. We may decide to change our bad debt reserve methodology in the future to better estimate credit losses. While our credit losses have historically been within our expectations and the allowance established, we might not continue to experience the same credit loss rates that we have in the past.

Warranty Accrual. We offer warranties on our product and record a liability for the estimated future costs associated with warranty claims, which is based upon historical experiences and our estimate of the level of future costs. Warranty costs are reflected in the statement of operations as a cost of goods sold. Warranty expense will increase as and if we increase our net sales. Warranty reserve rates may change when we change manufacturing process or change our third-party manufacturing contractor. Although our warranty expenses have historically been within our expectations and the accrual established, we may not continue to experience the same warranty expense rate that we have in the past.

Impairment of Long-Lived Assets. We account for the impairment of long-lived assets in accordance with Statement of Financial Accounting Standard, or SFAS, No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." We evaluate the carrying value of our long-lived assets,

consisting primarily of our property and equipment and the Essure license acquired from a patent litigation settlement in 2003 (See Note 10 to Financial Statements), whenever certain events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Such events or circumstances include a prolonged industry downturn, a significant decline in our market value or significant reductions in projected future cash flows.

Significant judgments and assumptions are required in the forecast of future operating results used in the preparation of the estimated future cash flows, including profit margins, long-term forecasts of the amounts and timing of overall market growth and our percentage of that market, groupings of assets, discount rates and terminal growth rates. In addition, significant estimates and assumptions are required in the determination of the fair value of our tangible long-lived assets, including replacement cost, economic obsolescence, and the value that could be realized in orderly liquidation. Changes in these estimates could have a material adverse effect on the assessment of our long-lived assets, thereby requiring us to write down the assets. Our net long-lived assets as of December 31, 2004 and December 31, 2003 included property and equipment of $1.3 million and $2.0 million, respectively, and other identifiable intangible assets of $1.8 million and $2.0 million, respectively.

Functional Currency. We have a wholly owned foreign subsidiary in Australia. In preparing our consolidated financial statements, we are required to translate the financial statements of the foreign subsidiary from the currency in which they keep their accounting records to U.S. dollars. Our subsidiary maintains accounting records in its local currency and the functional currency is determined to be the U.S. dollar. The functional currency is determined based on management's judgment and involves consideration of all relevant economic facts and circumstances affecting the subsidiary. Generally, the currency in which the subsidiary transacts a majority of its transactions, including billing, financing, payroll, and other expenditures would be considered the functional currency but any dependency upon the parent and the nature of the subsidiary's operations must also be considered. Since the U.S. dollar is deemed to be the functional currency for our subsidiary, any gain or loss associated with the translation of the subsidiary's financial statements is included in the consolidated statement of operations. If in the future, we determine that there has been a change in the functional currency of our subsidiary from U.S. dollars to its local currency, any translation gains or losses arising after the date of change would be included within accumulated other comprehensive income. The determination of functional currency is subject to judgment by the management.

Income Taxes. We account for income taxes under SFAS No. 109, "Accounting for Income Taxes." Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes. This process involves estimating our actual current tax exposure together with assessing temporary differences that may result in deferred tax assets. Management judgment is required in determining any valuation allowance recorded against our deferred tax assets. Any such valuation allowance would be based on our management estimates of taxable income and the period over which our deferred tax assets would be recoverable.

Contingent Liabilities We account for contingencies in accordance with SFAS No. 5, "Accounting for Contingencies." SFAS No. 5 requires that we record an estimated loss from a loss contingency when information available prior to issuance of our financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and the amount of the loss can be reasonably estimated. Accounting for contingencies such as legal and income tax matters requires us to use our judgment. While we believe that our accruals for these matters are adequate, if the actual loss from a loss contingency is significantly different than the estimated loss, our results of operations may be over or understated.

RESULTS OF OPERATIONS

Years Ended December 31, 2004 and 2003

Net Sales

Net sales were $11.6 million in 2004, of which 85% were from United States, 11% were from France, 3% were from Australia and 1% were from Asia and Canada. Net sales were $7.7 million in 2003, of which 77% were from United States, 14% were from Europe, 7% were from Australia and 2% were from Asia and Canada.

The following table summarizes the above information related to net sales by geographic region in tabular format:

	Year Ended	
	December 31, 2004	**December 31, 2003**
Net Sales (in thousands)	$11,612	$7,700
United States	85%	77%
Europe	11%	14%
Australia	3%	7%
Others	1%	2%

Net sales are attributed to region based on the shipping location of the external customers.

The increase in net sales of $3.9 million or 51% is the result of continued commercialization of Essure in the United States. Our worldwide average selling price decreased from $830 in 2003 to $763 in 2004 as a direct result of terminating the company's direct operations in Europe and subsequently selling through a distributor, which has a lower selling price.

In early 2003, we targeted groups of gynecological practices with the goal of training, inclusive of preceptorship, approximately 700 physicians by the end of 2003 and ended the year having trained 792 physicians. As of December 31, 2004, we have a total of 1,681 doctors that have either completed or are in the process of completing preceptorship. Our accomplishment in obtaining the number of physicians trained is very important because it not only provides us with a strong referral base within major metropolitan areas we have targeted, but it will also create the leverage to help us gain additional reimbursement coverage.

We understand that a strong base of trained physicians does not necessarily correlate to an increase in revenue proportionately. Another important factor is the average procedure performed per physician per month, or utilization. During 2003 and 2004, our utilization rates declined from a high of over three procedures per month per physician at the beginning of this period to a utilization of 0.7 procedure per month per physician at the end of the period. We believe this decline is primarily related to the reimbursement environment for gaining coverage of a new medical technology such as Essure which creates a level of frustration among physicians and facilities when either not all patients are covered by a third-party payor or when claims submissions are delayed or denied inadvertently by payors. This frustration can cause physicians, who otherwise are positive about the technology, to temporarily stop performing the procedure until the reimbursement environment is more assured.

We have been working diligently with third-party payors to make sure they understand the benefits of Essure. To date, United States physicians and facilities using Essure have been reimbursed for the procedure under existing Current Procedural Terminology, or CPT codes. In March 2004, the American Medical Association accepted our application for a level one CPT code effective January 2005.

Category I codes are reserved for those procedures that have demonstrated clinical efficacy, widespread use and have Food and Drug Administration (FDA) approval. By having a CPT code specific to the Essure procedure, it is expected that coding for reimbursement will become considerably easier for doctors and facilities and that there will be fewer incidents of doctors being reimbursed incorrectly. In early November 2004, the Centers for Medicare and Medicaid Services ("CMS") released the Final Rule for the 2005 Physician Fee schedule. For the Essure CPT code, the CMS has provided for a national physician payment of $2,198.34 for procedures performed in the office and $458.94 for physician payment when the procedure is performed in the hospital. This compares to a CPT code physician payment of $361.16 for a laparascopic tubal ligation, the current standard of care for permanent female sterilization. In addition, the CMS released the Final Rule for the 2005 OPPS, which assigns hospital outpatient reimbursement amounts. The Essure CPT code was assigned a 2005 payment level of $2,260.37 which is consistent with payments by CMS to hospitals when they perform a laparoscopic tubal ligation, normally performed in a higher cost hospital operating room. We believe these values are very favorable for the Essure procedure and will help in establishing increased utilization of the device amongst doctors. We expect that the new code, once the process to establish it is complete, will significantly ease the burden on a physician's office in obtaining reimbursement for Essure, and accelerate the coverage of Essure by private insurance companies and Medicaid.

In January 2005, we announced our expected net sales for 2005 to be approximately $17.0 million to $18.0 million, which represents more than 45% growth from 2004. This increase in revenues includes the effect of the 17% price increase we announced in January 2005 for customers in the United States. We expect net sales from the United States will continue to be the major contributor of our global net sales. We have established three primary goals to achieve our revenue growth. We expect to complete the implementation of the new CPT code, increase sales coverage and physician utilization of the Essure procedure and work with our strategic partners. We believe our revenue growth in 2005 will be significantly influenced by how successful we are in achieving those objectives.

Gross Profit

Cost of goods sold increased by $0.5 million to $7.1 million in 2004 as compared to $6.6 million in 2003. Gross profit increased $3.4 million to $4.5 million from $1.1 million in 2003. Our gross profit percent was 39% and 14% for the year 2004 and 2003, respectively. Our gross profit percent was 51% in the fourth quarter of 2004 as compared to 17% in the fourth quarter of 2003 and it has increased from 11% in the first quarter of 2004 to 51% in the fourth quarter of 2004. The improvement in gross profit percentage was primarily due to an increase in production volume. During 2004, we transitioned our manufacturing activities to a third party manufacturer in Mexico. This outsourcing effort decreased our production costs and increased gross profit. In April 2004, we received FDA approval for the process at the third party manufacturer. Although we expect lower production costs and the price increase in the United States to improve our gross profit in 2005, our anticipated gross profits will fluctuate in correlation to revenue growth as production costs remain sensitive to production volume.

Operating Expenses

Research and development expenses, which include clinical, regulatory and product development, decreased by $1.9 million to $4.1 million in 2004 as compared with $6.0 million in 2003. The decrease is primarily due to completion of activities pertaining to the PMA application process and completion of certain research and development projects. A decrease in headcount resulted in a reduction of $1.1 million of payroll related expense. Other factors that contributed to the decrease were a $0.2 million decrease in travel expenses, a decrease of $0.4 million in clinical expenses related to the completion of the PMA application process and a $0.2 million decrease in consulting expenses. Research and development costs in 2005 are expected to be slightly higher than 2004 levels as we

complete our Pivotal and Phase II clinical trials and continue to invest in product development of new or alternative product designs.

Selling, general and administrative expenses decreased by $8.2 million to $27.1 million in 2004 as compared to $35.3 million in 2003. The decrease was primarily attributable to a $2.8 million decrease in international sales expense as a result of the sale of the subsidiary in France in early 2004, a $1.8 million decrease in legal fees as a result of the settlement of the Ovion case in October 2003, a $1.2 million decrease in payroll related expenses for marketing and U.S. physician training, a $1.4 million decrease in expenses as a result of severance for former officers and recruitment of a new CEO in 2003, a $1.1 million decrease in expense for demonstration units due to the shift toward reusable demonstration units and a shift from large group to a smaller individual training program, a $0.5 million decrease in advertising and a $0.5 million decrease in travel expenses. These decreases were partially offset by an increase of $1.1 million in consulting and audit expenses for Sarbanes-Oxley compliance. In 2005, we expect to have limited international expenditures since we completed the divestiture of our French subsidiary in January 2004 and the closure of our direct operations in Australia in January 2005. We recorded expenses of approximately $200,000 in December 2004 related to the close down of our Australia operations, which included $183,000 of severance costs and $22,000 for impairment of fixed assets. All severance costs were completely paid out at end of January 2005 and we expect the disposal of fixed assets to be completed by March 2005.

Selling, general and administrative expenses are expected to increase in 2005 as compared to 2004 due to additional spending on the direct to consumer campaign, sales force expansion and increased costs related to Sarbanes Oxley compliance.

Other Income and Expenses

Interest and other income of $0.6 million decreased by $0.1 million in 2004 as compared to $0.7 million in 2003. The decrease is due to lower average cash and cash equivalent balances. We invest our excess cash in high quality, short-term commercial paper, government securities and money market funds. Interest and other expense for 2004 and 2003 and the change in expense from the prior year was insignificant.

Income Taxes

As a result of our net loss of $26.1 million, we incurred no income tax expense in 2004. As of December 31, 2004, we had net operating loss carry forwards for federal and state income tax purposes of approximately $167.6 million and $85.0 million, respectively. In addition, at December 31, 2004, we had federal and state research credit carry forwards of approximately $2.2 million and $2.1 million, respectively. The net operating loss and credit carry forwards described above will expire at various dates beginning in the years 2005 through 2024, if not utilized. Use of the net operating losses and credits may be subject to a substantial annual limitation by the Internal Revenue Service. The annual limitation may result in the expiration of net operating losses and credits before we can use them to reduce future earnings, if any. Because of the Company's lack of earnings history and anticipated future net loss, the deferred tax assets have been fully offset by a valuation allowance.

Restricted Stock

The Company granted 312,020 shares of restricted stock to its employees and directors during 2004, of which 72,000 shares have been repurchased by the Company in accordance with the provisions of the grant. Estimated future restricted stock expense, assuming no change in repurchased shares or attainment of performance goals, is expected to be $0.7 million, $0.7 million, $0.2 million for the years 2005, 2006 and 2007, respectively. Of the total restricted stock expense of $2.2 million, $0.4 million is

related to research and development and $1.8 million is related to selling, general and administrative expenses. There was no restricted stock expense in fiscal 2003.

Years Ended December 31, 2003 and 2002

Net Sales

Net sales were $7.7 million in 2003, of which 77% were from United States, 14% were from Europe, 7% were from Australia and 2% were from Asia and Canada. Net sales were $1.7 million in 2002, of which 47% were from Europe, 42% were from Australia, 6% were from Asia and Canada and 5% were from United States.

The following table summarizes the above information related to net sales by geographic region in tabular format:

	Year Ended	
	December 31, 2003	**December 31, 2002**
Net Sales (in thousands)	$7,700	$1,650
United States	77%	5%
Europe	14%	47%
Australia	7%	42%
Others	2%	6%

The increase in net sales of $6.1 million or 367%, is the result of commercialization of Essure in the United States. Shortly after FDA approval of Essure in the United States in November 2002, we began an aggressive launch of Essure in the United States and as a result, dramatically increased net sales generated within the United States. In addition to increased number of units sold, the increase in average selling price also contributed to the increase in net sales. Our worldwide average selling price increased from an average of $460 in 2002 to an average of $830 in 2003 because of the higher selling price in the United States, which was approximately $980 per unit throughout 2003.

As of December 31, 2003, we had a total of 792 doctors that had either completed or were in the process of completing preceptorship. During 2003, our utilization rates declined from a high of over three procedures per month per physician in the first quarter to a utilization of slightly less than one procedure per month per physician in the fourth quarter of 2003. We believe this decline was primarily related to the reimbursement environment for gaining coverage of a new medical technology such as Essure which creates a level of frustration among physicians and facilities when either not all patients are covered by a third-party payor or when claims submissions are delayed or denied inadvertently by payors. This frustration can cause physicians, who otherwise are positive about the technology, to temporarily stop performing the procedure until the reimbursement environment is more assured. We worked diligently with third-party payors to make sure they understood the benefits of Essure.

Gross Profit

Cost of goods sold increased by $3.5 million to $6.6 million in 2003 as compared to $3.1 million in 2002. Our gross profit was negative in the fourth quarter of 2002 as compared to 17% in the fourth quarter of 2003 and it increased from 0% in the first quarter of 2003 to 17% in the fourth quarter of 2003. The increase was primarily due to increase in production volume and increase in our average selling price. We were also in the process of transitioning almost all of our manufacturing activities to a third party manufacturer in Mexico in late 2003.

Operating Expenses

Research and development expenses, which include clinical, regulatory and product development, decreased by $2.2 million to $6.0 million in 2003 as compared with $8.2 million in 2002. The decrease was primarily due to a $0.7 million decrease in payroll related expenses resulting from the transfer of research and development personnel to assist with improving our manufacturing process; a $0.7 million decrease as a result of the transfer of Quality Assurance to cost of sales, since the activities of this group were manufacturing related, a $0.4 million reduction in travel expenses and bonuses, a $0.2 million decrease in expensed materials and a decrease of $0.2 million in consulting expense as a result of the completion of certain research and development projects such as the coil catheter study.

Selling, general and administrative expenses increased by $11.9 million to $35.3 million in 2003 as compared to $23.4 million in 2002. The $11.9 million expenditure increase was due to United States commercialization. The increases primarily were attributable to a $4.8 million increase in domestic selling, marketing and U.S. physician training and strategic reimbursement expenditures; a $3.3 million increase in payroll related expenses for U.S. sales; a $1.8 million increase in legal fees mainly attributable to the settlement of the Ovion lawsuit; a $1.4 million increase in expenses related to the hiring and relocation of our chief executive officer; a $1.2 million increase in general and administrative infrastructure expenses to support the overall growth in the areas of sales, physician training and reimbursement and a $1.1 million increase in advertising and public relation expenses. Internationally, expenditures decreased by $1.7 million as we focused our resources on the development of Essure in the United States.

Other Income and Expenses

Interest and other income of $0.7 million decreased by $0.2 million in 2003 as compared to $0.9 million in 2002. The decrease is due to lower average cash balances and average interest rates paid on our invested funds. We invest our excess cash in high quality, short-term commercial paper, government securities and money market funds. Interest and other expenses decreased by $0.3 million due to a one-time settlement charge recorded in 2002 in connection with a 1997 distribution agreement related to our discontinued product.

RECENT ACCOUNTING PRONOUNCEMENTS

In December 2004, the Financial Accounting Standards Board ("FASB") issued ("SFAS") No. 123(R), "Share-Based Payments" (revised 2004). The provisions of SFAS 123(R) would require us to measure all stock-based compensation awards using a fair value method and record such expense in the consolidated financial statements, including grants of employee stock options. In addition, the adoption of SFAS 123(R) will require additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS 123(R) is effective for all public companies for interim and annual periods beginning after June 15, 2005. We will adopt SFAS 123(R) effective July 1, 2005. Although we have not yet determined whether the adoption of FAS 123(R) will result in amounts that are similar to the current pro forma disclosures under SFAS 123, we are evaluating the requirements for FAS 123(R) and expect the adoption to have a significant adverse impact on our statement of operations and net loss per share.

LIQUIDITY AND CAPITAL RESOURCES

We have experienced significant operating losses since inception and as of December 31, 2004, had an accumulated deficit of $183.3 million. We have financed our operations since inception primarily through equity financings. In February 2004, we completed a private placement of approximately 3.0 million shares of common stock at $8.50 per share. Our net proceeds from the private placement were approximately $23.9 million, after deducting offering costs and commissions. The proceeds are

being used to fund operations to help us reach profitability. Once we reach profitability, we expect to finance our operation through cash received from sales of our product. We raised $23.9 million in 2004 to help fund our operations. In the future, depending upon a variety of factors, we will likely need to raise additional funds through bank facilities, debt or equity offerings or other sources of capital.

As of December 31, 2004, we had cash, cash equivalents, restricted cash and short-term investments of $32.3 million compared with $30.9 million of cash, cash equivalents, restricted cash and short-term investments at December 31, 2003. The increase in these balances as of December 31, 2004 was due to the $23.9 million of cash received from the private placement and $2.7 million received from the exercise of stock options, offset by $24.7 million of cash used in operating activities and $0.5 million of capital expenditures. We expect cash used by operating activities to decrease in 2005 as we increase net sales and continue to control operating expenses.

Operating Activities

Net cash used in operating activities was $24.7 million in 2004, $40.9 million in 2003 and $31.1 million in 2002. The net cash used in operating activities in 2004 was primarily related to our net loss of $26.1 million adjusted for non-cash related items of $2.3 million relating primarily to depreciation and amortization, stock compensation expenses and changes in inventory reserves and allowance for doubtful accounts in addition to a $0.5 million decrease in inventory, a $0.4 million decrease in other assets, an increase of $0.5 million in accrued liabilities and an increase in deferred revenue of $0.1 million. The increase in accounts receivable of $0.4 million and other current assets of $0.5 million and decrease of $1.3 million in accrued compensation and $0.2 million of clinical trial liabilities also contributed to cash used by operating activities. The decrease in accrued compensation was primarily due to severance packages recorded in 2003 and paid out in 2004. Net cash used in operating activities in 2003 and 2002 were primarily our net loss adjusted for non-cash related items such as depreciation, amortization, stock option expenses and bad debt allowance. Increase in inventories and accounts receivables, offset by increases in accounts payable and other accrued liabilities also contributed to cash used in operating activities for 2003 and 2002. The increases in net loss, inventories, accounts receivable, accounts payable and other accrued liabilities in 2003 and 2002 were related to our expansion in all areas as we transitioned from an early-stage, pilot manufacturing company to commercialization.

The increases in accounts receivable of $0.4 million in 2004 and $1.1 million in 2003 were due to increases in year to year net sales. We monitor our accounts receivable turnover closely to ensure that receivables are collected timely and have established a credit and collection policy to facilitate our collection process and reduce our credit loss exposure. Our worldwide days sales outstanding improved to 53 days in 2004 from 62 days in 2003. The improvement is primarily because a greater percentage of our accounts receivable are domestic customers, and previously, most of our customers were international; domestic receivable have shorter standard payment terms than international customers. We are still at the early stage of marketing our product and accounts receivables has not been our major source of capital. We expect to grow our business and increase our revenues, and to primarily rely on accounts receivables as the capital resources to fund our operations.

Investing Activities

Net cash used in investing activities was $5.7 million in 2004. Short-term investments of $38.2 million purchased in 2004 plus capital expenditures of $0.5 million were offset by sales and maturities of $33.0 million of short-term investments. Net cash provided by investing activities in 2003 was $8.2 million. The increase in net cash provided by investing activities in 2003 consisted primarily of the maturation of short-term investments of $36.3 million offset by the purchase of short-term investments of $27.2 million and $0.9 million of capital expenditures. Net cash used in investing activities in 2002 was $34.0 million. This consisted of purchases of short-term investments of

$64.0 million plus capital expenditures of $2.0 million, offset by sales and maturities of short-term investments of $32.0 million.

Our capital expenditures in 2004, 2003 and 2002 were $0.5 million, $0.9 million and $2.0 million, respectively. In 2004 and 2003, capital expenditures were primarily related to website development as part of our marketing campaign to increase consumer awareness; and software management tool development to help us to gather meaningful data for management analysis and to gain a better understanding of our customers and our market. In 2002, the primary objective of those capital expenditures were to expand and improve our manufacturing facility to transition from pilot manufacturing to commercial manufacturing. In 2005, we expect our capital investment to continue in the area of website development and management tool development for better tracking and gathering of data so that management can have meaningful data for analysis and decision making.

Financing Activities

Net cash provided by financing activities was $26.6 million in 2004 compared with $1.9 million in 2003. Net cash provided by financing activities was $69.9 million in 2002. In 2004, the net cash provided by financing activities consisted primarily of a private placement of common stock, from which we received net proceeds of $23.9 million. An additional $2.7 million consisted of proceeds from the exercise of stock options. The net cash provided by financing activities in 2003 consisted of net proceeds from the exercise of stock options. The net cash provided by financing activities in 2002 consisted primarily of the net proceeds from the follow-on public offering completed in June and July 2002, in which we sold 4.6 million shares of common stock at $16.00 per share.

CASH REQUIREMENTS, CONTRACTUAL OBLIGATIONS AND COMMITMENTS

We have operating lease obligations on our current building facilities and equipment. Estimated net lease payments due within a year and years 1-3 total $0.4 million and $0.1 million, respectively. We also have long-term obligations related to our Phase II clinical study and Pivotal trial. Additionally, we have a $69,000 standby letter of credit commitment in connection with an equipment lease that expires in 2006. The letter of credit is renewable every year.

The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2004:

	Payments due by period		
	Total	Less than 1 year	1-3 years
Operating lease obligations	$ 546,000	$ 446,000	$ 100,000
Clinical trial obligations	440,000	157,000	283,000
Total	$ 986,000	$ 603,000	$ 383,000

On October 23, 2003, we entered into a settlement agreement with Ovion pursuant to which we received a sole, worldwide license to Ovion's patent rights relative to the Essure system for ten years, and Ovion may not grant any additional such licenses to other parties. In exchange for such license, we were required to pay a license fee of $2.0 million payable in our common stock in equal installments in the first and second quarters of 2004. In January 2004, we paid $1.0 million in common stock to Ovion, and we made another payment of $1.0 million in common stock to Ovion in April 2004. In addition, the settlement agreement provided for a cash payment of $2.0 million in the fourth quarter of 2003 as a prepaid royalty. We are obligated to pay 3.25% of the accumulative revenue derived from sale of the Essure products in excess of $75.0 million as royalty for a period of ten years starting from the date of settlement. In accordance with the terms of the settlement agreement, our prepaid royalties will be fully amortized when cumulative net sales of Essure reach $136.5 million, thereby resulting in an

effective royalty rate of 1.47%. We are amortizing the prepaid royalties to cost of goods sold over our net sales using this effective rate. Prepaid royalties as of December 31, 2003 was the unamortized balance of $2.0 million.

We expect to have negative cash flows from operations into at least 2006 and we estimate that our existing capital resources will be sufficient to meet our cash requirements through at least the next twelve months. If our revenue growth in 2005 meets our current expectation of $17.0 million to $18.0 million and we achieve our forecasted expenses, we expect to exit 2005 with approximately $10.0 million of cash on hand. We raised $23.9 million in 2004 to help fund our operations. In the future, depending upon a variety of factors, we will likely need to raise additional funds through bank facilities, debt or equity offerings or other sources of capital.

The successful achievement of our business objectives may require additional financing and therefore, we may in the future seek to raise additional funds through bank facilities, debt or equity offerings or other sources of capital. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. Additional funding may not be available when needed or on terms acceptable to us. If we are unable to obtain additional capital, we may be required to delay, reduce the scope of or eliminate our research and development programs or reduce our sales and marketing activities. Our future liquidity and capital requirements will depend upon many factors, including, among others:

resources devoted to establish sales, marketing and distribution capabilities, including DTC programs;

the rate of adoption by doctors and patients of the Essure procedure; and

the insurance payor community's acceptance of and reimbursement for the Essure procedure.

Off-Balance Sheet Arrangements. As part of our ongoing business, we do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities ("SPEs"), which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of December 31, 2004, we were not involved in SPE transactions.

TRENDS, RISKS AND UNCERTAINTIES

In addition to the other information in this Form 10-K, the following factors should be considered carefully in evaluating Conceptus and our business. This Form 10-K contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below and elsewhere in this Form 10-K.

We have a limited history of operation with Essure and have incurred significant operating losses since inception. We expect to incur significant operating losses for the foreseeable future and we may never achieve or maintain profitability.

We have a limited history of operation with Essure and have incurred significant operating losses since our inception in 1992, including operating losses of $26.6 million for fiscal 2004, $40.2 million in fiscal 2003, and $33.1 million in fiscal 2002. We expect to continue to incur significant operating expenses and net losses as we continue sales and marketing efforts in the United States. Our net losses will continue until sufficient revenues can be generated to offset these expenses. We may not be able to generate these revenues, and we may never achieve profitability. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock.

We are presently a one-product company and if our product fails to gain market acceptance, our business will suffer.

We are attempting to introduce a novel product into the contraception market, which is dominated by procedures that are well established among physicians and patients and are routinely taught to new physicians. As a result, we believe that recommendations and endorsements by physicians will be essential for market acceptance of our product. We do not know whether physicians and patients will accept our product or whether we will be able to obtain their recommendations or endorsements in sufficient amounts to be profitable. We believe that physicians will not use a product unless they determine, based on clinical data and other factors, that it is an attractive alternative to other means of contraception and that it offers clinical utility in a cost-effective manner. Physicians are traditionally slow to adopt new products and treatment practices, partly because of perceived liability risks. We are dependent on Essure, which is currently our only commercial product. If Essure does not achieve significant market acceptance among physicians, patients and healthcare payors, even if reimbursement levels are sufficient and necessary United States and international regulatory approvals are maintained, we may never achieve significant revenues or profitability.

Our future liquidity and capital requirements are uncertain.

As we commercialize Essure on a wide-scale basis, we may require additional financing and therefore may in the future seek to raise additional funds through bank facilities, debt or equity offerings or other sources of capital. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. Additional funding may not be available when needed or on terms acceptable to us. If we are unable to obtain additional capital, we may be required to delay, reduce the scope of or eliminate our selling and marketing activities. We expect to have negative cash flows from operations into at least calendar 2006. Our future liquidity and capital requirements will depend upon many factors, including, among others:

the rate of product adoption by doctors and patients;

obtaining government and third-party reimbursement for Essure;

the resources devoted to increasing manufacturing capacity to meet commercial demands;

our ability to reduce our cost of sales;

the resources devoted to developing and conducting sales and marketing and distribution programs; and

the progress and cost of product development programs.

If the effectiveness and safety of our product are not supported by long-term data, we may not achieve market acceptance and we could be subject to liability.

The Pivotal trial of Essure was designed to support a PMA application and to have five years of post-market follow-up. In addition, patients in the Phase II study will be followed to five years. The long-term results of using Essure will not be available for several years. If long-term studies or clinical experience indicate that Essure is less effective or less safe than our current data suggest, we may not achieve or sustain market acceptance and/or we could be subject to significant liability.

Our Co-Promotion Agreement with GYNECARE may not be successful.

On October 30, 2003, we announced the signing of an exclusive U.S. co-promotion agreement with GYNECARE for marketing Essure in the United States in combination with the GYNECARE THERMACHOICE Uterine Balloon Therapy endometrial ablation system. With the FDA's approval of marketing and labeling claims regarding compatibility of the Essure procedure and the

THERMACHOICE device in July 2004, marketing has commenced. However, the success of the joint marketing campaign will depend upon the effectiveness of our GYNECARE sales team training programs, market demand for Essure in conjunction with the THERMACHOICE treatment, the efforts and commitment of GYNECARE to this new program and the results of the required 50 patient post-approval clinical study. This agreement includes certain performance clauses that if not met, could lead to the termination of the agreement by Conceptus in July 2005.

We have limited sales and marketing experience and minimal distribution capabilities, and if we are unable to develop our sales and marketing capabilities or be successful in our co-marketing agreement with GYNECARE, we may be unsuccessful in commercializing Essure.

In order to market, sell and distribute Essure, we will need to maintain and continue to develop a sales force and marketing group with relevant experience and to develop the relationship with GYNECARE for co-marketing the Essure device to the endometrial ablation market. Developing a marketing and sales force is expensive and time consuming and can impact the effectiveness of our product launch. If we fail to establish adequate marketing and sales capabilities, we may be unable to commercialize Essure successfully. Furthermore, certain factors in our relationship with GYNECARE are outside of our control, such as the number of sales persons, their compensation and the number of products they are selling, which could adversely impact the revenues and market development we expect from this co-marketing agreement. This agreement includes certain performance clauses that if not met, could lead to the termination of the agreement by Conceptus in July 2005.

Our direct-to-consumer advertising campaign may not be successful.

In August 2004, we launched a six-month advertising campaign in the Chicago, Illinois metropolitan area involving radio, direct mail, and print media (magazine). Such advertising programs aimed at increasing consumer awareness for our product are expensive and may have limited success, if any. Such campaigns require consumers to make contact with an Essure physician, often involving a referral from their primary care physician and then to be provided information regarding birth control options by the physician, be pre-authorized for insurance reimbursement and then be scheduled for the procedure. Many of these steps are not within our control, and the program may not result in revenue generation commensurate with its costs.

We depend on our contract manufacturer to supply our commercial product requirements and we may experience disruption in supply if they are not in compliance with FDA and other health authority regulations.

In April 2004, we received FDA approval to begin manufacturing the Essure product at Accellent, our third-party subcontractor located in Mexico. We transitioned almost all of our internal manufacturing operations to Accellent by the end of 2004 to manufacture the components and assemble our product. If Accellent does not comply with FDA and other health authority regulations or encounters manufacturing difficulties, this could negatively impact sales of Essure.

Government or third party reimbursement for Essure may not be available or may be inadequate, which would limit our future product revenues and delay or prevent our profitability.

Market acceptance of Essure in the United States and in international markets will depend in part upon the availability of reimbursement within prevailing healthcare payment systems. Reimbursement systems in international markets vary significantly by country and sometimes by region, and reimbursement approvals must be obtained on a country-by-country basis. Many international markets have government-managed health care systems that determine reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems. Regardless of the type of reimbursement system, we believe that physician advocacy of our product will be required to obtain reimbursement. Availability and extent of continued reimbursement

will depend, at least in part, on the clinical and cost effectiveness of our product. We do not know whether reimbursement for our product will continue to be available in the United States or in international markets under either government or private reimbursement systems, or whether physicians will support and advocate reimbursement for use of our product for all indications intended by us. We may be unable to obtain or maintain reimbursement in any country within a particular time frame, for a particular amount, or at all, which would limit our future product revenues and delay or prevent our profitability.

We may not maintain regulatory approvals for Essure, our only product, which would delay or prevent us from generating product revenues, and would harm our business and force us to curtail or cease operations.

Numerous government authorities, both in the United States and internationally, regulate the manufacture and sale of medical devices, including Essure. In the United States, the principal regulatory authorities are the FDA and corresponding state agencies, such as the California Department of Health Services. The process of obtaining and maintaining required regulatory clearances is lengthy, expensive and uncertain.

We have received FDA approval to market Essure in the United States. If we lose that approval or fail to comply with existing or future regulatory requirements, it would delay or prevent us from generating further product revenues.

Sales of medical devices outside of the United States are subject to international regulatory requirements that vary widely from country to country. The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing may differ significantly from FDA requirements. Many countries in which we currently market or intend to market Essure either do not currently regulate medical devices or have minimal registration requirements; however, these countries may develop more extensive regulations in the future, which could delay or prevent us from marketing Essure in these countries.

The FDA and certain foreign regulatory authorities impose numerous requirements with which medical device manufacturers must comply in order to maintain regulatory approvals. FDA enforcement policy strictly prohibits the promotion of approved medical devices for uses other than those for which the device is specifically approved by the FDA. We will be required to adhere to applicable FDA regulations, such as the Quality System Regulation, and similar regulations in other countries, which include testing, control and documentation requirements. Ongoing compliance with the Quality System Regulation and other applicable regulatory requirements will be monitored through periodic inspections by federal and state agencies, including the FDA and the California Department of Health Services, and by comparable agencies in other countries. If we fail to comply with applicable regulatory requirements, we may be subject to, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of approvals and criminal prosecution, any of which could negatively impact our business.

Our intellectual property rights may not provide meaningful commercial protection for our product, which could enable third parties to use our technology, or very similar technology, and could impair our ability to compete in the market.

We rely on patent, copyright, trade secret and trademark laws to limit the ability of others to compete with us using the same or similar technology in the United States and other countries. However, as described below, these laws afford only limited protection and may not adequately protect our rights to the extent necessary to sustain any competitive advantage we may have. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting their proprietary rights

abroad. These problems can be caused by the absence of rules and methods for defending intellectual property rights.

We will be able to protect our technology from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent positions of companies developing medical devices, including our patent position, generally are uncertain and involve complex legal and factual questions concerning the enforceability of such patents against alleged infringement. Recent judicial decisions have established new case law and a reinterpretation of previous patent case law, and consequently we cannot assure you that historical legal standards surrounding the questions of infringement and validity will be applied in future cases. In addition, legislation may be pending in Congress that, if enacted in its present form, may limit the ability of medical device manufacturers in the future to obtain patents on surgical and medical procedures that are not performed by, or as a part of, devices or compositions that are themselves patentable. Our ability to protect our proprietary methods and procedures may be compromised by the enactment of this legislation or any other limitation or reduction in the patentability of medical and surgical methods and procedures. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may therefore diminish the value of our intellectual property.

We own, or control through licenses, a variety of issued patents and pending patent applications. However, the patents on which we rely may be challenged and invalidated, and our patent applications may not result in issued patents. Moreover, our patents and patent applications may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. We also face the risk that others may independently develop similar or alternative technologies or design around our patented technologies.

We have taken security measures to protect our proprietary information, especially proprietary information that is not covered by patents or patent applications. These measures, however, may not provide adequate protection of our trade secrets or other proprietary information. We seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants could still disclose our proprietary information and we may not be able to protect our trade secrets in a meaningful way. If we lose any employees we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by those former employees despite the existence of a nondisclosure and confidentiality agreement and other contractual restrictions designed/intended to protect our proprietary technology. In addition, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our trade secrets.

Our ability to compete effectively will depend substantially on our ability to develop and maintain proprietary aspects of our technology. Our issued patents, any future patents that may be issued as a result of our United States or foreign patent applications, or the patents under which we have license rights may not offer any degree of protection against competitive products. Any patents that may be issued or licensed to us or any of our patent applications could be challenged, invalidated or circumvented in the future.

If we cannot operate our business without infringing third-party intellectual property rights, our prospects will suffer.

Our success will depend in part on our ability to operate without infringing or misappropriating the proprietary rights of others. We may be exposed to future litigation by third parties based on claims that our product infringes the intellectual property rights of others. There are numerous issued patents in the medical device industry and, as described in the next risk factor, the validity and breadth of medical device patents involve complex legal and factual questions for which important legal principles remain unresolved. Our competitors may assert that our product and the methods we employ may be

covered by United States or foreign patents held by them. In addition, because patent applications can take many years to issue, there may be currently pending patent applications of which we are unaware that may later result in issued patents that our product may infringe. There could also be existing patents of which we are unaware that our product may inadvertently infringe. If we lose a patent infringement lawsuit, we could be prevented from selling our product unless we can obtain a license to use technology or ideas covered by that patent or are able to redesign the product to avoid infringement. A license may not be available to us on terms acceptable to us, or at all, and we may not be able to redesign our product to avoid any infringement. If we are not successful in obtaining a license or redesigning our product, we may be unable to sell our product and our business would suffer.

We have been, and may in the future, be a party to patent litigation, which could be expensive and divert our management's attention.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. We may become a party to patent infringement claims and litigation or interference proceedings declared by the United States Patent and Trademark Office (PTO), to determine the priority of inventions. The defense and prosecution of these matters are both costly and time consuming. We may need to commence proceedings against others to enforce our patents, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel.

A third party, Ovion, Inc., brought to our attention a patent and certain claims from a pending patent application owned by it. Ovion indicated it believes that the claims of its patent and application cover Essure and its use. On October 23, 2003, we entered into a settlement agreement with Ovion pursuant to which we received a sole, worldwide license to Ovion's patent rights relative to the Essure system, and Ovion may not grant any additional such licenses to other parties. The settlement agreement provided for the payment of a royalty to Ovion that will be equal to 3.25% of the cumulative net sales of Essure in excess of $75.0 million for a period of no longer than ten years. In addition, the settlement agreement provided for a cash payment of $2.0 million in the fourth quarter of 2003 as a prepaid royalty, and a license fee of $2.0 million payable in our common stock in equal installments in the first and second quarters of 2004. Ovion was not granted any rights to our intellectual property pursuant to the settlement agreement. The settlement agreement was approved by the U.S. District Court for the Northern District of California on November 6, 2003.

Although we have reached a settlement agreement with Ovion, we still believe that some or all of Ovion's claims should be included within our own patents and we have requested that the PTO declare an interference. An interference is a proceeding within the PTO to determine which party was the first to invent, and which party is thereby entitled to ownership of, the claims. We believe that we filed our patent applications for Essure before Ovion filed the application that issued as its patent, and that we are entitled to any patentable claims now appearing in their patent that cover our product. We do not know whether the PTO will declare an interference, whether we invented our product prior to Ovion's date of invention, or whether we will prevail in an interference proceeding if it is declared by the PTO. If the PTO declares an interference in our favor and we are found to have priority of invention, we may avoid having to pay Ovion future royalties on the sales of our product.

An adverse determination in new litigation or interference proceedings to which we are or may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses

on satisfactory terms, if at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling Essure.

One of the patents included in our license from Target Therapeutics, a division of Boston Scientific Corporation, has been the subject of reexamination proceedings in the PTO and an infringement lawsuit by Target Therapeutics. We are not a party to this lawsuit. The patent is directed to variable stiffness catheters for use with guidewires, as might be used in our future products. Although the PTO reaffirmed the patent with amended claims and the lawsuit was settled, the patent could be challenged or invalidated in the future. If this patent is invalidated, our ability to prevent others from using this proprietary technology would be compromised.

If we fail to manage any expansion, our business could be impaired.

We may in the future acquire one or more technologies, products or companies that complement our business. We may not be able to effectively integrate these into our business and any such acquisition could bring additional risks, exposures and challenges to our company. If we fail to manage any acquisition, our business could be impaired.

Our third-party manufacturer and we will depend upon third party and single source suppliers for raw materials and finished goods and we do not have forward contracts with many of these suppliers.

We and our third party manufacturer purchase both raw materials used in our product and finished goods from various suppliers, and we rely on a single source for one component of our product, the polyester fiber. We do not have formal supply contracts with several key vendors and, accordingly, these firms may not continue to supply us or our third party manufacturer with raw materials or finished goods in sufficient quantities, or at all. Delays associated with any future raw materials or finished goods shortages could impair our sales of Essure, particularly as our third-party manufacturer scales up its manufacturing activities in support of United States and international commercial sales of Essure.

Health care reform may limit our return on our product.

The levels of revenue and profitability of medical device companies may be affected by the efforts of government and third party payors to contain or reduce the costs of health care through various means. In the United States, there have been, and we expect that there will continue to be, a number of federal, state and private proposals to control health care costs. These proposals may contain measures intended to control public and private spending on health care as well as to provide universal public access to the health care system. If enacted, these proposals may result in a substantial restructuring of the health care delivery system. Significant changes in the United States health care system are likely to have a substantial impact over time on the manner in which we conduct our business and could have a material adverse effect on our business, financial condition and results of operations.

We may be exposed to product liability claims, and we have only limited insurance coverage.

The manufacture and sale of medical products involve an inherent risk of exposure to product liability claims and product recalls. We currently maintain product liability insurance with coverage limits of $10.0 million per occurrence and an annual aggregate maximum of $10.0 million, which we believe is comparable to that maintained by other companies of similar size serving similar markets. However, we cannot assure you that product liability claims in connection with clinical trials or commercial sales of Essure will not exceed such insurance coverage limits or that such insurance will continue to be available on commercially reasonable terms, or at all. Insurance is expensive and in the future may not be available on acceptable terms, if at all. A successful product liability claim or series

of claims brought against us in excess of our insurance coverage, or a recall of our product, could cause our stock price to fall.

We may not be able to attract and retain additional key management, sales and marketing and technical personnel or we may lose existing key management, sales and marketing or technical personnel, which may delay our development and marketing efforts.

We depend on a number of key management, sales and marketing and technical personnel. The loss of the services of one or more key employees could delay the achievement of our development and marketing objectives. Our success will also depend on our ability to attract and retain additional highly qualified management, sales and marketing and technical personnel to meet our growth goals. We face intense competition for qualified personnel, many of whom are often subject to competing employment offers, and we do not know whether we will be able to attract and retain such personnel.

We face intense competition, and if we are unable to compete effectively, demand for Essure may be reduced.

The medical device industry is highly competitive and is characterized by rapid and significant technological change. The length of time required for product development and regulatory approval plays an important role in a company's competitive position. As we commercialize Essure, we expect to compete with:

- other methods of permanent contraception, in particular tubal ligation;
- other methods of non-permanent contraception, including devices such as intrauterine devices, or IUDs, vaginal rings, condoms and prescription drugs such as the birth control pill, injectable and implantable contraceptives and patches; and
- other companies that may develop permanent contraception devices that are similar to or otherwise compete with Essure.

We are aware of a company that is in the clinical stages of development for non-incisional permanent contraception devices, and other companies may develop products that could compete with Essure. Competitive factors may render Essure obsolete or noncompetitive or reduce demand for Essure.

Our future quarterly results may fluctuate.

Our future revenues and results of operations may fluctuate significantly from quarter to quarter and will depend upon, among other factors:

- the rate at which new physicians are trained;
- actions relating to reimbursement matters;
- the rate at which we establish United States and international distributors or marketing partners and the degree of their success;
- the extent to which Essure gains market acceptance;
- the timing and size of distributor purchases; and
- introduction of competitive products.

Changes in stock option accounting rules may adversely impact our reported operating results prepared in accordance with generally accepted accounting principles, our stock price and our competitiveness in the employee marketplace.

Technology companies like ours have a history of using broad based employee stock option programs to hire, incentivize and retain our workforce in a competitive marketplace. Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123") allowed companies the choice of either using a fair value method of accounting for options, which would result in expense recognition for all options granted, or using an intrinsic value method, as prescribed by Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25), with a pro forma disclosure of the impact on net income (loss) of using the fair value option expense recognition method. We had elected to apply APB 25 and accordingly we generally do not recognize any expense with respect to employee stock options as long as such options are granted at exercise prices equal to the fair value of our common stock on the date of grant.

In December 2004, the FASB issued, SFAS 123(R) "Share-Based Payments". We will adopt this statement on July 1, 2005 which is the first interim reporting period after June 15, 2005. This statement will have a significant impact on our consolidated statement of operations as we will be required to expense the fair value of our stock options rather than disclosing the impact on our consolidated result of operations within our footnotes in accordance with the disclosure provisions of SFAS 123. This will result in lower reported earnings per share, which could negatively impact our future stock price. In addition, this could impact our ability to utilize broad based employee stock plans to reward employees and could result in a competitive disadvantage to us in the employee marketplace.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The following discusses our exposure to market risk related to changes in interest rates and foreign currency exchange rates. These exposures may change over time as business practices evolve and could have a material adverse impact on our financial results.

Interest Rate Risk: We have been exposed to interest rate risk as it applies to interest earned on holdings of short-term marketable securities. Interest rates that may affect these items in the future will depend on market conditions and may differ from the rates we have experienced in the past. A 10% change in interest rates would not be material to our results of operations. We reduce the sensitivity of our results of operations to these risks by maintaining an investment portfolio, which is primarily comprised of highly rated, short-term investments. We do not hold or issue derivative, derivative commodity instruments or other financial instruments for trading purposes.

Foreign Currency Exchange Risk: Our expenses, except for those related to Europe and Australia, were denominated in U.S. dollars. Our revenues, 3%, 23% and 95% of which were in foreign currencies in 2004, 2003 and 2002, respectively, were immaterial in relation to our overall financial position. As a result, we have relatively little exposure for currency exchange risks and foreign exchange losses have been minimal to date. We do not currently enter into forward exchange contracts to hedge exposure denominated in foreign currencies or any other derivative financial instruments for trading or speculative purposes. In the future, if we feel our foreign currency exposure has increased, we may consider entering into hedging transactions to help mitigate that risk. As of December 31, 2004, a fluctuation in exchange rates of 10% in the foreign currencies to which we are exposed would not have a material impact on our results of operations or financial condition.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements are set forth in this Annual Report on Form 10-K beginning on page 54.

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

During our two most recent fiscal years and through the date of this report, we have had no reportable events as defined in Item 304(a)(1)(v) of Regulation S-K.

ITEM 9A. CONTROLS AND PROCEDURES

(a)

Evaluation of Disclosure Controls and Procedures:

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of December 31, 2004, the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on the foregoing, our Chief Executive Officer and Chief

Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

(b)

Management's Annual Report on Internal Control Over Financial Reporting:

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2004 based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included elsewhere herein.

(c)

Changes in Internal Control Over Financial Reporting:

There has been no change in the company's internal controls over financial reporting during the company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the company's internal controls over financial reporting.

Inherent Limitations of Internal Controls

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

Certain information required by Part III is incorporated by reference from our proxy statement (the "Proxy Statement") for our annual meeting of stockholders to be held May 26, 2005, which will be filed within 120 days after the end of our fiscal year pursuant to Regulation 14A, and the information included therein is incorporated by reference to the extent detailed below.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Information required by this item, insofar as it relates to directors and officers, will be contained in the Company's Definitive Proxy Statement in connection with our 2005 Annual Meeting of Stockholders, which we anticipate will be filed no later than 120 days after the end of our fiscal year pursuant to Regulation 14A, under the captions "Election of Directors" and "Management". Information required by this item as to compliance with Section 16(a) of the Securities Exchange Act of 1934 will be contained in the Company's Definitive Proxy Statement under the caption "Section 16(a) Beneficial Owner Reporting Compliance," and is hereby incorporated by reference into this report.

We have adopted a written code of ethics that applies to all of our employees and to our Board of Directors. A copy of the code is available on our website at www.conceptus.com.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information under the caption "Executive Compensation" in the Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the information under the caption "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans" in the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference from the information under the caption "Certain Relationships and Related Transactions" in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the information under the caption "Principal Accountant Fees and Services" in the Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)

The following documents are filed as part of this Report:

(1)

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2004 and 2003

Consolidated Statements of Operations for the Years Ended December 31, 2004, 2003 and 2002

Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2004, 2003 and 2002

Consolidated Statements of Cash Flows for the Years Ended December 31, 2004, 2003 and 2002

Notes to Consolidated Financial Statements

(2)

Financial Statement Schedule

The following financial statement schedule of Conceptus, Inc. for the years ended December 31, 2004, 2003, and 2002 is filed as part of this Form 10-K and should be read in conjunction with Conceptus, Inc.'s Consolidated Financial Statements.

Schedule II Valuation and Qualifying Accounts

Other schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(3)

Exhibits (numbered in accordance with Item 601 of Regulation S-K)

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Registrant. Incorporated by reference to the Registrant's Registration Statement on Form SB-2, as amended (File No. 33-99890-LA), which became effective on February 1, 1996.
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Registrant. Incorporated by reference to the Registrant's Registration Statement on Form S-3 (File No. 333-89266) filed on June 4, 2002.
3.3	Bylaws of Registrant. Incorporated by reference to the Registrant's Registration Statement on Form SB-2, as amended (File No. 33-99890-LA), which became effective on February 1, 1996.
3.4	Amendment to the Bylaws of the Registrant. Incorporated by reference to Exhibit 3.4 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003.

Exhibit Number	Description
10.1	Form of Indemnification Agreement for directors and officers. Incorporated by reference to the Registrant's Registration Statement on Form SB-2, as amended (File No. 33-99890-LA), which became effective on February 1, 1996.
10.2*	Amended and Restated 1993 Stock Plan. Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.
10.3*	1995 Employee Stock Purchase Plan. Incorporated by reference to the Registrant's Registration Statement on Form SB-2, as amended (File No. 33-99890-LA), which became effective on February 1, 1996.

10.4*	1995 Directors' Stock Option Plan. Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995.
10.5*	Fifth Amended and Restated 2001 Equity Incentive Plan. Incorporated by reference to Exhibit 99.1 of the Registrant's Report on Form 8-K filed on January 11, 2005.
10.6*	Amended and Restated 2002 Non-Qualified Stock Option Plan. Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.
10.7*	Form of Senior Management Amended and Restated Change of Control Agreement.
10.8*	Change of Control Agreement dated as of April 27, 2004 by and between Registrant and Gregory Lichtwardt.
10.9*	Change of Control Agreement dated as of May 13, 1997 by and between Registrant and Kathryn A. Tunstall. Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997.
10.10*	Master Consulting Agreement with Florence Comite dated September 10, 1997. Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.
10.11	Relocation bonus agreement dated April 25, 2002 between the Registrant and Stan Van Gent. Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.
10.12	Promissory note dated April 25, 2002 between the Registrant and Stan Van Gent. Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.
10.13	Promissory note dated May 22, 2002 between the Registrant and Stan Van Gent. Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.
10.14	Supplier Agreement dated March 29, 1995 between the Registrant and Advanced Cardiovascular Systems, Inc. Incorporated by reference to the Registrant's Registration Statement on Form SB-2, as amended (File No. 33-99890-LA), which became effective on February 1, 1996.
10.15	License Agreement dated December 28, 1992 between the Registrant and Target Therapeutics Inc. Incorporated by reference to the Registrant's Registration Statement on Form SB-2, as amended (File No. 33-99890-LA), which became effective on February 1, 1996.
10.16	Settlement and License Agreement between Ovion, Inc., William S. Tremulis and Jeffrey P. Callister and Conceptus, Inc. dated November 6, 2003. Incorporated by reference to the Registrant's Amendment to its Annual Report on Form 10-K/A for the year ended December 31, 2003.
10.17	Lease agreement dated November 14, 2000 with Dani Investment Partners. Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.
10.18	Offer and Acceptance of Lease Extension with Dani Investment Partners dated September 12, 2003. Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003.

10.19 Lease Agreement with Three Sisters Ranch Enterprises dated April 15, 1997. Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended April 30, 1997.

10.20 First Amendment to Lease Agreement with Three Sisters Ranch Enterprises. Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.

10.21 Second Amendment to Lease Agreement with Three Sisters Ranch Enterprises. Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.

10.22 Third Amendment to Lease Agreement with Three Sisters Ranch Enterprises. Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.

10.23 Fourth Amendment to Lease Agreement with Three Sisters Ranch Enterprises. Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.

10.24 Fifth Amendment to Lease Agreement with Three Sisters Ranch Enterprises. Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003.

10.25 Preferred Shares Rights Agreement, dated as of February 27, 1997, between the Registrant and ChaseMellon Shareholder Services, L.L.C., including the Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B and C, respectively. Incorporated by reference to Exhibit 1 filed in response to Item 2 of the Registrant's Report on Form 8-K filed on February 28, 1997.

10.26+ Exclusive U.S. Co-Promotion Agreement, dated as of October 30, 2003, by and between the Registrant and Gynecare Worldwide Division of Ethicon, Inc. Incorporated by reference to Exhibit 1 of the Registrant's Report on Form 8-K filed on March 1, 2004.

10.27+ Share Purchase and Call Option Agreement, dated as of January 17, 2004, by and between Mr. Yves Guillemain d'Echon et al. and the Registrant. Incorporated by reference to Exhibit 2 of the Registrant's Report on Form 8-K filed on March 1, 2004.

10.28 Contract Manufacturing Agreement, dated as of June 20, 2003, between the Registrant and Venusa, Ltd. (now Accellent, Inc.) Incorporated by reference to Exhibit 10.26 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003.

10.29* Letter Agreement by and between the Company and Gregory E. Lichtwardt dated November 12, 2003. Incorporated by reference to Exhibit 10.29 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003.

10.30* Employment Agreement between Mark M. Sieczkarek and Conceptus, Inc. executed September 30, 2004. Incorporated by reference to Exhibit 10.1 of the Registrant's Report on Form 8-K filed on October 5, 2004.

10.31* Letter Agreement between Ric Cote and Conceptus, Inc. executed March 25, 2004. Incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on 10-Q for the Quarter Ended March 31, 2004.

10.32*	Employment Commencement Nonstatutory Stock Option Agreement between Ric Cote and Conceptus, Inc. executed April 5, 2004. Incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-8.
10.33*	Stand-Alone Restricted Stock Purchase Agreement between Ric Cote and Conceptus, Inc. executed April 5, 2004. Incorporated by reference to Exhibit 4.3 of the Registrant's Registration Statement on Form S-8.
14.1	Code of Ethics. Incorporated by reference to Exhibit 14.1 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (See Page 79 of this Report).
31.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management contract or compensatory plan or arrangement.

\+ Confidential treatment has been requested with respect to certain portions of this Exhibit by order from the Securities and Exchange Commission or requested.

CONCEPTUS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Conceptus, Inc.

We have completed an integrated audit of Conceptus, Inc.'s 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 consolidated financial statements in accordance with the standards of the Public Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements and financial statement schedule

In our opinion, the accompanying consolidated financial statements listed in the accompanying index under Item 15(a)(1) present fairly, in all material respects, the financial position of Conceptus, Inc. (the "Company") and its subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

Internal control over financial reporting

Also, in our opinion, management's assessment, included in Management's Annual Report on Internal Control Over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Controls Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California
March 30, 2005

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

CONCEPTUS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31	
	2004	**2003**
Assets		
Current assets:		
Cash and cash equivalents	$ 2,002	$ 5,844
Short-term investments	30,200	24,950
Restricted cash	69	69
Accounts receivable, net of allowance for doubtful accounts of $62 and $164 at December 31, 2004 and 2003, respectively	2,067	1,582
Inventories, net	2,022	2,682
Other current assets	937	504
Total current assets	37,297	35,631
Property and equipment, net	1,322	2,031
Intangible assets, less accumulated amortization of $250 and $50 at December 31, 2004 and 2003, respectively	1,750	1,950
Other assets	1,808	2,238
Total assets	**$ 42,177**	**$ 41,850**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,713	$ 2,746
Accrued compensation	1,347	2,691
Other accrued liabilities	982	2,443
Deferred revenue	90	
Total current liabilities	5,132	7,880
Long-term clinical trial liabilities		193
Deferred revenue	51	40
Total liabilities	5,183	8,113
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock: $0.003 par value, authorized 3,000,000 shares; no shares issued or outstanding at December 31, 2004 and 2003		
Common stock and additional paid-in capital: $0.003 par value, 50,000,000 shares authorized, 25,729,371 and 21,817,066 shares issued and 25,657,371 and 21,817,066 shares outstanding at December 31, 2004 and 2003, respectively	221,960	190,971
Deferred stock-based compensation	(1,637)	
Accumulated other comprehensive income		26
Accumulated deficit	(183,329)	(157,260)
Treasury stock, 72,000 shares and none, at cost, at December 31, 2004 and 2003, respectively		

	December 31	
Total stockholders' equity	36,994	33,737
Total liabilities and stockholders' equity	**$ 42,177**	**$ 41,850**

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

CONCEPTUS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Years Ended December 31,		
	2004	**2003**	**2002**
Net sales	$ 11,612	$ 7,700	$ 1,650
Cost of goods sold	7,112	6,587	3,142
Gross profit (loss)	4,500	1,113	(1,492)
Operating expenses:			
Research and development	4,067	6,048	8,230
Selling, general and administrative	27,075	35,256	23,417
Total operating expenses	31,142	41,304	31,647
Operating loss	(26,642)	(40,191)	(33,139)
Interest and other income and expenses:			
Interest and other income	598	674	896
Interest and other expenses	(25)	(11)	(267)
Net loss	$ (26,069)	$ (39,528)	$ (32,510)
Basic and diluted net loss per share	$ (1.05)	$ (1.83)	$ (1.71)
Weighted-average shares used in computing basic and diluted net loss per share	24,754	21,565	18,968

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

CONCEPTUS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock & Additional Paid-In Capital		Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of January 1, 2002	16,398,786	$ 118,397	$	$	$ (85,222)	$ 33,175
Issuance of common stock for cash upon exercise of options	285,813	966				966
Issuance of common stock for cash from employee stock purchase plan	29,842	319				319
Issuance of common stock for cash pursuant to secondary public offering, net of issurance costs of $5,502	4,635,000	68,658				68,658
Issuance of stock options to consultants for services		95				95
Cumulative translation adjustments				11		11
Net loss					(32,510)	(32,510)
Balances as of December 31, 2002	21,349,441	188,435		11	(117,732)	70,714
Issuance of common stock for cash upon exercise of options	429,393	1,526				1,526
Issuance of common stock for cash from employee stock purchase plan	38,232	387				387
Issuance of stock options to consultants for services		623				623
Cumulative translation adjustments				15		15
Net loss					(39,528)	(39,528)
Balances as of December 31, 2003	21,817,066	190,971		26	(157,260)	33,737
Issuance of common stock for cash upon exercise of options	415,417	2,532				2,532
Issuance of common stock for cash from employee stock purchase plan	12,273	88				88
Issuance of common stock in connection with Ovion settlement	177,595	2,000				2,000
Private placement of common stock, net of issuance costs of $1,518	2,995,000	23,939				23,939
Issuance of stock options to consultants for services		261				261
Grants of restricted stock to employees and directors	312,020	2,169				2,169
Deferred stock-based compensation related to restricted stock grants			(2,169)			(2,169)
Amortization of deferred stock-based compensation related to restricted stock grants			532			532
Cumulative translation adjustments				(26)		(26)
Net loss					(26,069)	(26,069)
Treasury stock	(72,000)					
Balances as of December 31, 2004	25,657,371	$ 221,960	$ (1,637)	$	$ (183,329)	$ 36,994

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

CONCEPTUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,		
	2004	**2003**	**2002**
Cash flows from operating activities			
Net loss	$ (26,069)	$ (39,528)	$ (32,510)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,359	1,427	1,135
Stock compensation expense	793	623	95
Allowance for doubtful accounts	(102)	119	31
Provision for inventories	152	(26)	111
Retirement of fixed assets	63		
Changes in operating assets and liabilities:			
Accounts receivable	(383)	(1,112)	(364)
Inventories	508	(65)	(1,501)
Other current assets	(459)	316	(216)
Other assets	430	(2,053)	193
Accounts payable	(33)	(509)	1,307
Accrued compensation	(1,344)	1	1,550
Other accrued liabilities	521	21	(443)
Deferred revenue	101	40	
Clinical trial liabilities	(193)	(158)	(509)
Net cash used in operating activities	(24,656)	(40,904)	(31,121)
Cash flows from investing activities			
Purchase of investments	(38,250)	(27,162)	(64,013)
Maturities of investments	33,000	36,279	31,946
Capital expenditures	(513)	(935)	(1,959)
Net cash (used in) provided by investing activities	(5,763)	8,182	(34,026)
Cash flows from financing activities			
Issuance of common stock from company stock plans	2,620	1,913	1,285
Issuance of common stock from equity financings, net	23,939		68,658
Net cash provided by financing activities	26,559	1,913	69,943
Effect of foreign exchange rate changes on cash	18	55	68
Net (decrease) increase in cash and cash equivalents	(3,842)	(30,754)	4,864
Cash and cash equivalents at beginning of year	5,844	36,598	31,734
Cash and cash equivalents at end of year	$ 2,002	$ 5,844	$ 36,598
Supplemental Information:			
Cash paid during the period for:			
Interest	$ 14	$ 11	$
Non-cash activities			
Acquisition of license	$	$ 2,000	$

	Years Ended December 31,		
Issuance of common stock in connection with acquisition of license	$ 2,000	$	$

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

CONCEPTUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization, Ownership and Business

Conceptus, Inc. ("Conceptus" or the "Company") was incorporated in the state of Delaware on September 18, 1992 to design, develop and market minimally invasive devices for reproductive medical applications. The Company manufactures and markets Essure®, an innovative medical device and procedure designed to provide a non-incisional alternative to tubal ligation, the leading form of contraception worldwide. The Essure device is a unique and proprietary micro-insert designed to be deployed permanently into each fallopian tube using the Company's minimally invasive transcervical tubal access catheter system. Clinical studies have shown that the Essure device induces an occlusive tissue response. The Company's catheter systems are based on technology initially developed and used by Target Therapeutics, Inc. ("Target"), a business unit of Boston Scientific Corporation ("BSC"), and licensed exclusively to Conceptus in the field of reproductive physiology.

In December 2001, the Company established a wholly owned subsidiary, Conceptus SAS ("Conceptus France"), in France for the distribution and commercialization of Essure in Europe. In April 2000, the Company established a wholly owned subsidiary, Conceptus (Australia) Pty Limited, in New South Wales, Australia ("Conceptus Australia") for the distribution and commercialization of Essure in that region.

In January 2004, the Company completed the sale of its wholly owned French subsidiary for a nominal amount to an investor group comprised of its former French management team and signed a long-term exclusive distribution agreement for Essure with the acquiring group for the European, Middle East and African markets. The sale agreement includes a long-term call option that is intended to enable the Company to repurchase the French company. The contract was amended in September 2004 to include the territories of Mexico, Central America and South America. The transaction did not have any material financial impact to the Company's consolidated financial statements. In December 2004, the Company decided to close down its direct operations in Australia on January 31, 2005 and sell its product through a third party distributor. As a result, costs related to the closure were recorded in 2004 as selling, general and administrative expense and included approximately $22,000 for impaired fixed assets and $183,000 of termination benefits for the five employees, which were completely paid out on January 31, 2005. It is expected that all fixed assets will be disposed of by the end of March 2005.

The Company has a limited history of operations and has incurred significant operating losses since its inception in 1992. The Company will continue to be in a net loss position until sufficient revenues can be generated to offset expenses. In 2004, we raised $23.9 million to help fund our operations. In the future, depending upon a variety of factors, we will likely need to raise additional funds through bank facilities, debt or equity offerings or other sources of capital. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. Additional funding may not be available when needed or on terms acceptable to us. If we are unable to obtain additional capital, we may be required to delay, reduce the scope of or eliminate our research and development programs or reduce our sales and marketing activities.

2. Summary of Significant Accounting Policies

Basis of Consolidation and Foreign Currency Translation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated.

Functional Currency. The Company has a wholly owned foreign subsidiary in Australia, and also had a wholly owned subsidiary in France which it sold to an investor group in January 2004. In preparing the Company's consolidated financial statements, it is required to translate the financial statements of the foreign subsidiaries from the currency in which they keep their accounting records into U.S. dollars. The Company's two subsidiaries maintain their accounting records in their local currencies and the functional currency is determined to be U.S. dollars. The functional currency is determined based on management's judgment and involves consideration of all relevant economic facts and circumstances affecting the subsidiary. Generally, the currency in which the subsidiary transacts a majority of it transactions, including billing, financing, payroll, and other expenditures would be considered the functional currency but any dependency upon the parent and the nature of the subsidiaries' operations must also be considered. Since U.S. Dollar is deemed to be the functional currencies for the Company's subsidiaries, any gain or loss associated with the translation of those subsidiaries financial statements is included in the consolidated statement of operations. Currency gain and loss is reported under interest and other income in the consolidated statement of operations. Net currency gains recognized were $38,000 in 2004, and $80,000 in 2003. Net currency loss recognized was $41,000 in 2002.

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The primary estimates underlying the Company's financial statements include reserves for obsolete and slow moving inventory, allowance for doubtful accounts receivable, product warranty, impairment reserves for long-lived assets, income taxes and contingent liabilities. Actual results could differ from those estimates.

Concentration of Credit Risk and Other Risks and Uncertainties

The Company invests cash that is not required for immediate operating needs principally in a diversified portfolio of financial instruments issued by institutions with strong credit ratings. By policy, the amount of credit exposure to any one institution, with the exception of U.S. government backed securities, is limited.

The Company's net sales to date consist of product revenues from physicians, hospitals and distributors located in Australia, Canada, Europe, Indonesia, Singapore and the United States of America. The Company does not require collateral and provides for estimated credit losses based on customer credit assessment.

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We determine the allowance based on historical write-off experience. We review our allowance for doubtful accounts monthly. Past due balances over 90 days and over a specified amount are reviewed individually for collectibility. All other balances are reviewed on a pooled basis by type of receivable. Account balances are written off against the allowance when we feel it is probable the receivable will not be recovered. We do not have any off-balance-sheet credit exposure related to our customers.

The following table summarizes customers with greater than 10% of the Company's net sales for the years ended December 31, 2004, 2003 and 2002:

	Years Ended		
	2004	**2003**	**2002**
Customer A	11%		
Customer B			
Customer C		41%	15%
Customer D			23%
Customer E		16%	
Customer F		13%	

The following table summarizes customers with outstanding accounts receivable balance greater than 10% of the Company's total outstanding accounts receivable as of December 31, 2004 and 2003.

	2004	**2003**
Customer A	17%	
Customer B	23%	
Customer D		11%
Customer E		15%

The Company is a one-product company and its only product, Essure, received approval from the United States Food and Drug Administration ("FDA") in November 2002. Internationally, the Company received CE Mark approval to market its products from the European regulatory agency in February 2001. The Company also has regulatory clearance in Australia and Canada to distribute its product. The Company cannot be assured that necessary approvals or clearances will be obtained in other countries. If the Company is denied approval or clearance or if approval or clearance is delayed or withdrawn, it may have a material adverse impact on the Company.

The Company is subject to risks common to companies in the medical device industry including, but not limited to uncertainty of market acceptance of products, reimbursement from insurance carriers, compliance with government regulations, and protection of proprietary technology, product liability and the need to obtain additional financing. Certain components that meet the Company's requirements are available only from a limited number of suppliers. The rapid rate of technological change and the necessity of developing and manufacturing products with short life cycles may intensify these risks. The inability to obtain components as required, or to develop alternative sources, if and as required in the future, could result in delays or reductions in product shipments, which in turn could have a material adverse effect on the Company's business, financial condition, and results of operations.

Cash, Cash Equivalents and Investments

The Company considers all highly liquid investments with maturity from date of purchase of three months or less to be cash equivalents. The Company maintains deposits with two financial institutions in the U.S. and invests its excess cash in money market funds, corporate notes,

municipal bonds and government securities, which bear minimal risk. At times, these deposits may be in excess of federally

insured amounts. Short-term investments generally consist of municipal bonds, corporate notes and U.S. Treasury obligations.

Management considers all of their investments as available-for-sale. Available-for-sale investments are carried at estimated fair value, with the unrealized gains and losses, if material, reported in stockholders' equity until realized. The fair values for marketable debt investments are based on quoted market prices. At December 31, 2004 and 2003, the fair value of investments approximates cost. Realized gains and losses, computed using the specific identification cost method, were immaterial for the periods presented. Interest and dividends on investments classified as available-for-sale are included in interest and other income.

Restricted Cash

At December 31, 2004 and 2003, the Company had restricted cash of $69,000, which represents a certificate of deposit held under a letter of credit related to an equipment lease. The certificate of deposit is renewable every year with a five-year term that expires in 2006.

Inventories

Inventories are stated at the lower of cost or market. Cost is based on actual costs computed on a first-in, first-out basis. Reserves for potentially excess and obsolete inventory are made based on management's analysis of inventory levels and future sales forecast.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization of property and equipment are calculated using the straight-line method over the estimated useful lives of the respective assets, generally three years. Leasehold improvements are amortized over the lesser of the lease term or the estimated useful lives of the related assets. External direct costs of material and services consumed in website development during the application development stage are capitalized. Capitalized website costs are amortized using the straight-line method over the estimated useful life, of three years.

Intangible Assets

Intangible assets as of December 31, 2004 and 2003 is comprised of a technology license obtained as a result of the settlement of a patent litigation with Ovion, Inc. (See Note 10). The license was acquired at a cost of $2,000,000 in October 2003, which was paid in the Company's common stock, in equal installments in the first and second quarters of 2004, and has an expected useful life of ten years from the date of settlement. Amortization expense of $200,000 and $50,000 has been classified as cost of goods sold on the Company's consolidated statement of operations for the years ended December 31, 2004 and 2003 and is measured using the straight-line method. Estimated future amortization expense for each of the years ended December 31, 2005 through 2012 is $200,000 per year and $150,000 for the year ended December 31, 2013.

Other Assets

Other assets as of December 31, 2004 are principally comprised of the $1.8 million carrying value of the $2.0 million cash payment that the Company made to Ovion, Inc. as part of the settlement of a patent litigation suit (See Note 10). The settlement agreement provided for the payment of a royalty to Ovion that will be equal to 3.25% of the cumulative net sales of Essure in excess of $75.0 million for a period of no longer than ten years. In accordance with the terms of the settlement agreement, the Company's prepaid royalties will be fully amortized when cumulative net sales of Essure reach $136.5 million, thereby resulting in an effective royalty rate of 1.47%. The Company is amortizing the

prepaid royalties to cost of goods sold over its net sales using this effective rate. Prepaid royalty as of December 31, 2003 was the unamortized balance of $2.0 million.

Impairment of Long-Lived Assets

The Company accounts for the impairment of long-lived assets in accordance with Statement of Financial Accounting Standard, or SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." The Company evaluates the carrying value of its long-lived assets, consisting primarily of property and equipment and the Essure license acquired from a patent litigation settlement in 2003, whenever certain events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. When such an event occurs, management determines whether there has been impairment by comparing the anticipated undiscounted future net cash flow to the related asset's carrying value. Such events or circumstances include, but are not limited to, a prolonged industry downturn, a significant decline in market value or significant reductions in projected future cash flows.

Fair Value of Financial Instruments

For financial instruments consisting of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities included in the Company's financial statements, the carrying amounts approximate fair value due to their short maturities. Estimated fair values for short term investments, which are disclosed elsewhere, are based on quoted market prices for the same or similar instruments.

Warranty

The Company offers warranties on its products and records a liability at the time the products are sold for the estimated future costs associated warranty claims, which is based upon historical experiences and the Company's estimate of the level of future costs. Warranty costs are reflected in the statement of operations as cost of goods sold. A reconciliation of the changes in the Company's warranty liability for the years ended December 31, 2004 and 2003 follows (in thousands):

	As of December 31,	
	2004	2003
Beginning warranty accrual	$ 99	$ 28
Accruals for warranties issued during the year	189	186
Settlements made in kind during the year	(220)	(115)
Ending warranty accrual	$ 68	$ 99

Revenue Recognition

Product revenue is recognized when title and risk of ownership has been transferred, provided that persuasive evidence of an arrangement exists, the price is fixed and determinable, remaining obligations are insignificant and collectibility is reasonably assured. Revenue from product sales to distributors is recognized in the same manner as product sales to customers. Net sales generated by distributors were 15%, 12% and 53% for the years ended December 31, 2004, 2003 and 2002, respectively. The Company does not currently accept product returns from customers or distributors. Where appropriate, provision is made for estimated warranty costs relating to product sales at the time revenue is recognized. Non-recurring payments from contractual arrangements are deferred and recognized as revenue is earned based on an appropriate basis and time frame such as when services are performed or the term of the contract.

Research and Development

Research and development costs are expensed as incurred.

Advertising Costs

Advertising costs are expensed as incurred. Total advertising expenses were approximately $1,526,000, $2,000,000 and $2,000,000 in the years ended December 31, 2004, 2003 and 2002, respectively.

Stock-Based Compensation

As permitted by Statement of Financial Accounting Standard (SFAS) No. 123, "Accounting for Stock-Based Compensation," (SFAS No. 123) as amended by SFAS No. 148, "Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123," (SFAS No. 148) the Company accounts for employee stock-based compensation in accordance with Accounting Principles Board Opinion No. 25 (APB 25), "Accounting for Stock Issued to Employees," and related interpretations in accounting for its stock-based compensation plans. Accordingly, compensation costs for stock options granted to employees and directors are measured as the excess, if any, of the quoted market price of the Company's stock on the date of the grant over the amount an employee must pay to acquire the stock.

The Company granted 312,020 shares of restricted stock to its employees and directors during 2004, of which 72,000 shares have been repurchased by the Company in accordance with the provisions of the grant. The shares of restricted stock had a purchase price of $0.003 per share and the Company's repurchase right with respect to such shares lapses either in equal installments over three years or at the end of the three years, depending on the terms on the respective shares. Certain of the grants include acceleration of vesting based upon the Company's achievement of performance goals. The Company is amortizing the net total restricted stock expense of $2.2 million, calculated based on the fair value of the stock on the date of the grants, less the purchase price of the repurchased shares, over the vesting term of three years on a straight-line basis. Of the total restricted stock expense of $2.2 million, $0.4 million is related to research and development and $1.8 million is related to selling, general and administrative expenses. There was no restricted stock expense in fiscal 2003.

The following table provides a reconciliation of net loss to pro forma net loss as if compensation cost for all of the Company's employee stock option grants including grants under the Employee Stock Purchase Plan ("ESPP"), had been determined based on the fair value of the stock option at the date of grant consistent with the provision of SFAS No. 123 (in thousands, except per share data):

	Years Ended December 31,		
	2004	2003	2002
Net loss, as reported	$ (26,069)	$ (39,528)	$ (32,510)
Add: Stock based employee compensation expense included in reported net loss	532		
Less: Total stock-based employee compensation expense determined under fair value based method for all awards	(7,742)	(6,543)	(5,650)
Pro forma net loss	$ (33,279)	$ (46,071)	$ (38,160)
Basis and diluted net loss per share			
As reported	$ (1.05)	$ (1.83)	$ (1.71)
Pro forma	$ (1.34)	$ (2.14)	$ (2.01)

Stock based compensation arrangements to non-employees are accounted for in accordance with SFAS No 123 and Emerging Issues Task Force Issue No. 96-18 (EITF 96-18), "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" which requires that these equity instruments are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

Stock compensation expenses relating to non-employees was $261,000 in 2004, of which $44,000 was allocated to research and development expense and $217,000 was allocated to selling, general and administrative expense. Stock compensation expense relating to employees was $532,000 in 2004, of which $98,000 was allocated to research and development expense and $434,000 was allocated to selling, general and administrative expense.

Stock compensation expense relating to non-employees was $623,000 in 2003, of which $300,000 was allocated to research and development expense and $323,000 was allocated to selling, general and administrative expense. Stock compensation expenses relating to non-employees was $95,000 in 2002, of which $30,000 was allocated to research and development expense and $65,000 was allocated to selling, general and administrative expense. The Company did not have any stock compensation expenses for employees in 2003 and 2002.

The Company calculated the fair value of each option on the date of grant using the Black-Scholes method as prescribed by SFAS No. 123. The assumptions used are as follows:

	Years Ended December 31,		
	2004	2003	2002
Dividends			
Average risk-free interest rate	3.3%	2.5%	3.5%
Expected life (in years)	4	4	4
Volatility factor	0.7	0.9	1.0

To comply with pro forma reporting requirements of SFAS No. 123, compensation cost is also estimated for the fair value of ESPP issuances, which are included in the pro forma totals above. The fair value of purchase rights granted under the ESPP is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Years Ended December 31,		
	2004	2003	2002
Dividends			
Average risk-free interest rate	2.3%	1.4%	4.0%
Expected life (in years)	1	1	1
Volatility factor	0.5	0.6	0.5

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. The effects of applying SFAS No. 123 for recognizing compensation expense and providing pro forma disclosures in 2004, 2003 and 2002 are not likely to be representative of the effects on reported net loss in future years.

The weighted-average fair value per share of options granted was $5.28, $7.69 and $11.87 respectively, for 2004, 2003 and 2002. The weighted-average fair value of the purchase rights granted under the ESPP during fiscal 2004, 2003 and 2002 was $2.65, $3.34 and $11.58 per share, respectively.

Income Taxes

The Company accounts for income taxes under SFAS No. 109, "Accounting for Income Taxes." Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Net Loss Per Share

Basic net loss per share excludes any potential dilutive effects of options, common stock shares subject to repurchase, warrants and convertible securities. Diluted net loss per share includes the impact of potentially dilutive securities. However, due to the Company's net loss position, basic and diluted net loss per share are equivalent and are computed using the weighted average number of common shares outstanding.

The following outstanding options and restricted stock shares, which could potentially dilute basic net loss per share in the future were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive (in thousands):

	As of December 31,		
	2004	2003	2002
Outstanding options	3,549	4,216	3,716
Restricted stock	240		
ESPP shares	15		
Total	3,804	4,216	3,716

Segment Information

The Company operates in one business segment, which encompasses all the geographical regions. Management uses one measurement of profitability and does not segregate its business for internal reporting. As of December 31, 2004 and 2003, 98% of all long-lived assets were maintained in the United States of America.

Net sales by geographic region, based on shipping location of the external customer, is as follows:

	Years Ended December 31,		
	2004	2003	2002
Net sales (in thousands)	$ 11,612	$ 7,700	$ 1,650
United States	85%	77%	5%
Europe(a)	11	14	47
Australia	3	7	42
Other	1	2	6

(a) During 2004, sales in Europe were 100% in France. We are not able to provide sales information by country for 2003 and 2002.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. The Company's unrealized gains on available-for-sale securities, and cumulative translation adjustment, if

material, represent the

components of comprehensive loss that are excluded from the net loss. These components are not significant, individually or in aggregate, for the years ended December 31, 2004, 2003 and 2002.

Reclassification

Certain prior period balances have been reclassified to conform to the current year's presentation. These reclassifications had no effect on the prior years' stockholders' equity or results of operations. See Note 3.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS 123(R), "Share-Based Payments" (revised 2004). The provisions of SFAS 123(R) require the Company to measure all stock-based compensation awards using a fair value method and record such expense in the consolidated financial statements, including grants of employee stock options. In addition, the adoption of SFAS 123(R) will require additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS 123(R) is effective for all public companies for interim and annual periods beginning after June 15, 2005. The Company will adopt SFAS 123(R) effective July 1, 2005. Although the Company has not yet determined whether the adoption of FAS 123(R) will result in amounts that are similar to the current pro forma disclosures under SFAS 123, they are evaluating the requirements for FAS 123(R) and expect the adoption to have a significant adverse impact on the statement of operations and net loss per share.

3. Investments (in thousands)

	Cost and Estimated Fair Value December 31,	
	2004	**2003**
Cash and cash equivalents:		
Cash	$ 157	$ 552
Money market funds	1,845	5,292
	$ 2,002	$ 5,844
Short-term investments:		
Municipal bonds	$ 30,200	$ 24,950
	$ 30,200	$ 24,950

At December 31, 2004 and 2003, the amortized cost basis of the available-for-sale investments represents the fair value of the investments due to their short maturities. Gross realized gains and losses from the sale of securities classified as available-for-sale were not material for the years ended December 31, 2004, 2003 and 2002.

Certain auction rate securities have been reclassified from cash equivalents to short-term investments. Auction rate securities are variable rate bonds tied to short-term interest rates with maturities on the face of the securities in excess of ninety days. Auction rate securities have interest rate resets through a modified Dutch auction, at pre-determined short-term intervals, usually every seven, twenty-eight or thirty-five days. They trade at par and are callable at par on any interest payment date at the option of the issuer. Interest paid during a given period is based upon the interest rate determined during the prior auction.

Although these securities are issued and rated as long-term bonds, they are priced and traded as short-term instruments because of the liquidity provided through the interest rate reset. The Company

had historically classified these instruments as cash equivalents if the period between interest rate resets was ninety days or less, which was based on the ability to either liquidate the holdings or roll the investment over to the next reset period.

Based upon the Company's re-evaluation of these securities, the Company has reclassified its auction rate securities, previously classified as cash equivalents, as short-term investments on the accompanying consolidated balance sheet as of December 31, 2003. This resulted in a reclassification from cash and cash equivalents to short-term investments of $24,950,000 on the December 31, 2003 consolidated balance sheet. In addition, purchases of short-term investments and sales of short-term investments, included in the accompanying consolidated statements of cash flows, have been revised to reflect the purchase and sale of auction rate securities during the periods presented, which had the effect of decreasing net investing activity by $1,875,000 in 2003 and $21,075,000 in 2002. The Company accounts for its marketable securities in accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Such investments are classified as "available-for-sale" and are reported at fair value in the Company's consolidated balance sheets. The short-term nature and structure, the frequency with which the interest rate resets and the ability to sell auction rate securities at par and at the Company's discretion indicates that such securities should more appropriately be classified as short-term investments with the intent of meeting the Company's short-term working capital requirements.

4. Inventories, net (in thousands)

	December 31,	
	2004	**2003**
Raw materials	$ 250	$ 516
Work-in-process	1,073	1,420
Finished goods	699	746
Total	$ 2,022	$ 2,682

5. Property and Equipment (in thousands)

	December 31,	
	2004	**2003**
Machinery and equipment	$ 1,440	$ 1,356
Office equipment and furniture and fixtures	3,627	3,332
Leasehold improvements	1,107	1,107
	6,174	5,795
Less: accumulated depreciation and amortization	(4,852)	(3,764)
Property and equipment, net	$ 1,322	$ 2,031

6. Commitments

In 2003, the Company renewed the lease on its current facility. The extended lease term will expire on December 31, 2005. In conjunction with a renewal of the lease in 2000, the Company granted the landlord a warrant to purchase 25,000 shares of common stock at $9.00 per share. The fair value of the warrant, determined using the Black-Scholes pricing model was capitalized and amortized to rent expense over the term of the lease ending December 31, 2003. In 2001, the landlord fully exercised the warrant.

In addition, the Company has an operating lease, effective May 1997, on an additional facility, which was renewed and extended to June 30, 2005. This facility had been subleased, since October 15, 1998, under a separate sublease agreement, which expired in May 2002. In December 2001, the sublease tenant and the Company agreed to early termination of the sublease agreement upon receipt of $150,000 from the subtenant to the Company as rent abatement. The rent abatement was amortized over the remaining period of the sublease.

The Company has certain operating leases on a telephone system and copiers. These leases have terms expiring from September 2006 through April 2008.

Aggregate minimum annual rental commitments under the leases as of December 31, 2004 are as follows (in thousands):

2005	$ 446
2006	76
2007	20
2008 and thereafter	4
Total minimum rental commitment	$ 546

Rent expense was $604,000, $1,637,000 and $1,493,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

In 2003, the Company entered into a settlement agreement with Ovion Inc. (see Note 10). Pursuant to the settlement agreement, the Company was required to pay a license fee of $2.0 million payable in its common stock in equal installments in the first and second quarters of 2004. In January 2004, the Company paid $1.0 million in common stock to Ovion and made another payment of $1.0 million in common stock to Ovion in April 2004. In addition, the settlement agreement provided for a cash payment of $2.0 million in the fourth quarter of 2003 as a prepaid royalty. The Company is obligated to pay 3.25% of its accumulative revenue derived from sale of the Essure products in excess of $75.0 million as royalty for a period of ten years starting from the date of settlement.

The Company enters into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, generally the business partners or customers, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal.

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of a culpable nature; to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified; and to make good faith determination whether or not it is practicable for the Company to obtain directors and officers insurance. The Company currently has directors and officers insurance.

7. Incentive and Stock Plans

Employee Stock Purchase Plan

In November 1995, the Company's Board of Directors adopted the 1995 Employee Stock Purchase Plan (the "ESPP"). The ESPP became effective November 29, 1995. At that time, 200,000 shares were reserved for issuance under the ESPP. The ESPP permits participants to purchase common stock through payroll deductions of up to 10% of an employee's annual base earnings. The purchase price per share is equal to 85% of the fair market value per share on the participant's entry date into the offering period or, if lower, 85% of the fair market value per share on the semi-annual purchase date. In March 2004, the Board of Directors approved an amendment to the ESPP to increase the number of shares of common stock reserved for issuance by 150,000 shares. The stockholders approved this amendment in June 2004, to be effective July 1, 2004. As of December 31, 2004, 204,201 shares had been issued under the ESPP and 145,799 shares were available for future issuance. The fair value of the discount and look-back features are considered compensation for purposes of computing the Company's pro-forma earnings under SFAS No. 123 in the stock based compensation

Company Stock Option Plans

In August 2002, the Board of Directors approved the 2002 Non-Qualified Stock Option Plan ("2002 Plan") and amendments to the 2002 Plan were approved by the Board in March 2003. Under the Amended and Restated 2002 Plan, non-qualified stock options and stock purchase rights may be granted under the 2002 Plan only to the following classes of persons: (i) except as provided in (ii) below, consultants and employees who are not officers or directors of the Company, and (ii) newly hired employees (including employees who will become officers or directors of the Company) and who have not previously been employed by the Company and with respect to whom options are to be granted as an inducement essential to such employees' entering into employment contracts with the Company. The 2002 Plan was enacted to address the increased hiring done during the second half of 2002, primarily in the Company's U.S. sales, professional education and marketing functions. The maximum aggregate number of shares that may be issued upon exercise of options or stock purchase rights is 1,500,000 shares.

Under the terms of the 2002 Plan, options may be granted with different vesting terms from time to time and all options under the 2002 Plan expire ten years after grant. The options may include provisions permitting exercise of the option prior to full vesting. As of December 31, 2004 and 2003, there are no shares that were exercised prior to full vesting.

In March 2001, the Board of Directors approved the 2001 Equity Incentive Plan ("2001 Plan") allowing granting of stock options and restricted stock to employees, directors and consultants. The 2001 Plan was approved by a majority of the stockholders on May 16, 2001. In March 2002, the Board of Directors approved an amendment and restatement of the 2001 Equity Incentive Plan to increase the shares of common stock reserved for issuance to 2,000,000 shares of common stock, and to provide for automatic grants of non-qualified stock options to non-employee directors as had been provided under the 1995 Director's stock Option Plan. The stockholders approved this amendment and restatement in May 2002. In April 2004, the Board of Directors approved an amendment and restatement of the 2001 Equity Incentive Plan to increase the shares of common stock reserved for issuance to 2,500,000 shares of common stock, to reduce the size of the automatic grants of stock options to non-employee directors and to provide for automatic grants of restricted stock to non-employee directors. The stockholders approved this amendment and restatement in June 2004 (Third Amendment and Restatement). In November 2004, the Board of Directors approved an amendment and restatement of the 2001 Equity Incentive Plan to permit the administrator of the Plan to grant stock appreciation rights and restricted stock units. This Fourth Amendment and Restatement became effective immediately after approval.

Under the terms of the 2001 Plan, incentive stock options may be granted only to employees with exercise prices not less than the fair market value of the common stock on the date of grant. Options may be granted with different vesting terms from time to time but generally provide for vesting of at least 20% of the total number of shares per year. All options under the 2001 Plan expire ten years after grant, and five years in the case of a grant to a 10% stockholder. The options may include provisions permitting exercise of the option prior to full vesting. As of December 31, 2004 and 2003, there were no shares that were exercised prior to fully vesting. To the extent that the aggregate fair market value of the shares subject to a holder's incentive stock options exceeds $100,000, the excess options will be treated as non-qualified stock options.

On November 29, 1995, the Board of Directors approved the 1995 Director's Stock Option Plan ("Directors' Plan"), which allows the granting of options for up to 100,000 shares of common stock to outside directors. Stock options may be granted to outside directors with exercise prices of not less than fair market value. The options expire ten years from date of grant. Options granted under the Directors' Plan vest over one or three years. The options are only exercisable while the outside director remains a director.

In July 1993, the Board of Directors adopted the 1993 stock plan ("1993 Plan"), and amendments to the Stock Plan were adopted by the Board of Directors in March 1994, May 1995, October 1995, February 1997 and April 2000 and approved by the stockholders in March 1994, January 1996, May 1997 and May 2000 to allow granting of options up to 3,075,000 shares of common stock in the aggregate. Stock options granted under the 1993 Plan may be either incentive stock options or non-qualified stock options and can be granted to employees, distributors, consultants and directors. Incentive stock options may be granted to employees with exercise prices of no less than the fair market value and non-qualified options may be granted at exercise prices of no less than 85% of the fair market value of the common stock on the date of grant, as determined by the Board of Directors. The options expire no more than 10 years after the date of grant. Options may be granted with different vesting terms from time to time but generally provide for vesting of at least 25% of the total number of shares per year. The options may include provisions permitting exercise of the option prior to full vesting. Any unvested shares so purchased shall be subject to repurchase by the Company at the original exercise price of the option. Such repurchase rights generally lapse at a minimum rate of 25% per year from the date the option was granted. As of December 31, 2004 and 2003, there are no shares that are subject to repurchase.

In April 2004, the Board of Directors approved a nonqualified stock option grant for 125,000 shares of the Company's common stock and a grant of 36,000 shares of restricted stock for Mr. Ulric Cote as a stand-alone inducement grant in connection with his initial commencement of employment with the Company as Vice President, Sales. Stockholder approval was not required for either grant.

As of December 31, 2004, 42,345 shares remain as available for grant under the 2002 Plan, 791,391 shares remained as available for grant under the 2001 Plan, no shares remained available for grant under the 1993 Plan and 38,250 shares remained available for grant under the Director's Plan.

A summary of the activity of the Company's 1993, 2001 and 2002 Plans, the 1995 Directors' Plan and stand alone grant activity is as follows:

		Options Outstanding	
	Options Available For Grant	Options Outstanding	Weighted-Average Exercise Price
Balance at January 1, 2002	288,714	2,561,606	$ 7.08
Additional authorized	2,000,000		
Options granted	(1,588,661)	1,588,661	16.97
Options exercised		(285,813)	2.77
Options cancelled	148,795	(148,795)	14.95
Balance at December 31, 2002	848,848	3,715,659	11.33
Additional authorized	500,000		
Options granted	(1,742,650)	1,742,650	11.55
Options exercised		(429,393)	3.68
Options cancelled	812,736	(812,736)	13.82
Options expired	(94,699)		
Balance at December 31, 2003	324,235	4,216,180	11.71
Additional authorized(a)	661,000		
Options granted(a)	(886,618)	886,618	9.91
Restricted stock grants(a)	(312,020)	312,020	
Restricted stock issuances(a)		(312,020)	
Options exercised		(415,417)	5.98
Options cancelled	1,138,217	(1,138,217)	14.74
Shares repurchased	72,000		
Options expired	(124,828)		
Balance at December 31, 2004	871,986	3,549,164	$ 10.96

(a) Includes stand-alone inducement grants options and restricted stock for 161,000 shares.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2004:

	Options Outstanding			Options Vested and Exercisable	
Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Life (years)	Weighted Average Exercise Price	Options Vested and Exercisable	Weighted Average Exercise Price
$ 0.48 - $ 8.72	503,189	4.53	$ 4.06	390,184	$ 2.94
$ 8.75 - $ 8.94	445,375	9.70	8.94	23,375	8.87

	Options Outstanding			Options Vested and Exercisable	
$ 9.00 - $ 9.63	381,439	6.37	9.40	315,645	9.46
$ 9.64 - $ 9.95	641,000	8.31	9.95	211,687	9.95
$10.00 - $13.11	514,838	8.88	12.36	141,925	12.25
$13.34 - $14.20	427,017	7.72	13.84	238,620	13.83
$14.26 - $18.19	416,562	7.77	15.27	257,275	15.27
$18.37 - $22.46	219,744	6.43	19.56	171,141	19.60
$ 0.48 - $22.46	3,549,164	7.57	$ 10.96	1,749,852	$ 10.73

The weighted average exercise price for options vested and exercisable at December 31, 2003 was $10.34.

The Company has reserved 3,549,164 shares of its common stock, which may be issued with respect to outstanding options at December 31, 2004. The Company had reserved 4,216,180 shares of its common stock on December 31, 2003 and there were 2,024,782 options vested and exercisable at December 31, 2003.

The Company granted common stock of 40,000, 73,618 and 11,911 shares in 2004, 2003 and 2002, respectively, to consultants in exchange for services. In accordance with SFAS No 123 and EITF 96-18, the Company has recorded compensation expense related to these stock options. The Company periodically re-measures the fair value of the options as they vest and recognizes changes in fair value as compensation in the period.

Retirement Savings Plan

Under the Company's retirement savings plan ("401K Plan"), employees may elect to defer up to 15% of their total compensation, not to exceed the amount allowed by applicable Internal Revenue Service regulations. There were no employer contributions to the 401K Plan for the years ended 2004, 2003 and 2002.

8. Stockholder's Equity

Pursuant to the Company's certificate of incorporation, the Board of Directors will have the authority, without further action by the stockholders, to issue up to 3,000,000 shares of preferred stock, in one or more series. The Company's Board of Directors shall determine the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of any series.

As part of the settlement agreement with Ovion Inc. (see Note 10), the Company was required to pay $2.0 million in common stock for a license fee. The obligation was paid in equal installments in January and April 2004 for a total of 177,595 shares of common stock.

On February 25, 2004, the Company completed a private placement of approximately 2,995,000 shares of common stock at $8.50 per share, based upon a negotiated discount to market. The net proceeds to the Company, after fees and other offering costs totaling $1.5 million, were approximately $23.9 million.

In August 2004, the Company repurchased 72,000 shares of restricted common stock at par value in accordance with the terms of a restricted stock agreement. These shares are recorded as treasury stock.

On June 26, 2002, the Company completed a secondary offering in which it sold 4,500,000 shares of common stock for $16.00 per share. The net proceeds to the Company from the sale of the shares were approximately $66.7 million, net of underwriting discounts, commissions and other offering costs.

On July 24, 2002, the underwriters exercised the over-allotment option related to the follow-on public offering completed in June 2002, and the Company issued an additional 135,000 shares of common stock at $16.00 per share. The net proceeds to the Company from the sale of the additional shares were approximately $2.0 million after underwriting discounts and commissions and other offering costs.

9. Income Taxes

The Company has recorded no income tax expense for any of the years presented in the Consolidated Statement of Operations due to its recurring losses. As of December 31, 2004, the Company had net operating loss carryforwards for federal and state income tax purposes of

approximately $167.6 million and $85.0 million, respectively. If not utilized, these carryforwards will begin to expire beginning in 2005 through 2024 for both federal and state tax purposes. In addition, at December 31, 2004, the Company had federal and state research credit carryforwards of approximately $2.2 million and $2.1 million, respectively. If not utilized, the federal carryforward will expire in various amounts beginning in 2008. The California research credit can be carried forward indefinitely. Utilization of the net operating losses and credits may be subject to a substantial annual limitation due to the ownership change provisions of the Internal Revenue Code of 1986, as amended. The annual limitation may result in the expiration of net operating losses and credits before utilization and in the event the Company has had a change in ownership, utilization of the carryforwards could be restricted.

Deferred income taxes reflect the net effects of tax carryforward and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amount used for income tax purposes.

Significant components of the Company's deferred tax assets as of December 31, 2004 and December 31, 2003 are as follows (in thousands):

	2004	2003
Net operating loss carryforwards	$ 62,100	$ 55,700
Research credits	3,600	2,900
Capitalized research and development	4,500	1,500
Other net	1,200	1,100
Less: valuation allowance	(71,400)	(61,200)
Net deferred tax assets	$	$

Because of the Company's lack of earnings history and anticipated future losses, the deferred tax assets have been fully offset by a valuation allowance. The increase in the valuation allowance was approximately $10,200,000, $14,800,000 and $14,600,000 during 2004, 2003 and 2002, respectively.

10. Legal Proceedings

A third party, Ovion, Inc. ("Ovion"), brought to the Company's attention a patent and certain claims from a pending patent application owned by it. Ovion indicated it believed that the claims of its patent and application cover Essure and its use. On October 23, 2003, the Company entered into a settlement agreement with Ovion pursuant to which it received a sole, worldwide license to Ovion's patent rights relative to the Essure system, and Ovion may not grant any additional such licenses to other parties. The settlement agreement provided for a cash payment of $2,000,000 in the fourth quarter of 2003 as a prepaid royalty, and a license fee of $2,000,000 payable in the Company's common stock in equal installments in the first and second quarters of 2004. In addition, the settlement agreement provided for the payment of a royalty to Ovion that will be equal to 3.25% of the cumulative net sales of Essure in excess of $75,000,000 for a period of no longer than ten years. Ovion was not granted any rights to the Company's intellectual property pursuant to the settlement agreement. The settlement agreement was approved by the U.S. District Court for the Northern District of California on November 6, 2003.

Although the Company reached a settlement agreement with Ovion, it still believes that some or all of Ovion's claims should be included within its own patents, it requested that the Patent and Trademark Office ("PTO") declare an interference. An interference is a proceeding within the PTO to determine which party was the first to invent, and which party is thereby entitled to ownership of, the claims. The Company believes that it filed its patent applications for Essure before Ovion filed the application that issued as its patent, and that it is entitled to any patentable claims now appearing in their patent that cover the Essure product. The Company does not know whether the PTO will declare

an interference, whether it invented its product prior to Ovion's date of invention, or whether it will prevail in an interference proceeding if it is declared by the PTO. Future royalties might be avoided by a favorable interference ruling before the patent office, which might occur if interference is declared and if the Company is found to have priority of invention.

From time to time, the Company is involved in legal proceedings arising in the ordinary course of business. It believes there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on its financial position, results of operations or cash flows.

11. Related Parties

There were no related party transactions in 2004. During 2003 and 2002, the Company paid for consulting services provided by Dr. Florence Comite, a member of the Board of Directors. The Company paid Dr. Comite $2,500 per month in consulting fees for services rendered in 2003 and 2002.

12. Quarterly Information (unaudited)

Supplementary Data

Quarterly Results of Operations (Unaudited)

	Three Months Ended							
	December 31, 2004	September 30, 2004	June 30, 2004	March 31, 2004	December 31, 2003	September 30, 2003	June 30, 2003	March 31, 2003
	(In thousands, except per share amounts)							
Net sales	$ 3,622	$ 2,840	$ 2,769	$ 2,381	$ 2,254	$ 2,252	$ 2,040	$ 1,154
Cost of goods sold	$ 1,757	1,559	1,676	2,120	1,862	1,809	1,766	1,150
Gross profit	1,865	1,281	1,093	261(1)	392	443	274	4
Operating expenses:								
Research and development	818	1,045	905	1,299	1,260	1,521	1,656	1,611
Selling, general and administrative	7,672	6,734	6,545	6,124	8,312	7,995	9,331	9,618
Total operating expenses	8,490	7,779	7,450	7,423	9,572	9,516	10,987	11,229
Operating loss	(6,625)	(6,498)	(6,357)	(7,162)	(9,180)	(9,073)	(10,713)	(11,225)
Interest and other income and expenses	205	158	176	34	199	97	167	200
Net loss	$ (6,420)	$ (6,340)	$ (6,181)	$ (7,128)	$ (8,981)	$ (8,976)	$ (10,546)	$ (11,025)
Basic and diluted net loss per share	$ (0.25)	$ (0.25)	$ (0.25)	$ (0.31)	$ (0.41)	$ (0.41)	$ (0.49)	$ (0.52)
Weighted average shares used in computing basic and diluted net loss per share	25,391	25,304	25,185	23,099	21,739	21,635	21,499	21,383

(1) Lower gross profit in the first quarter of 2004 due to sale of high cost goods from 2003 production.

Conceptus, Inc.
Schedule II

Schedule of Valuation and Qualifying Accounts
(In thousands)

	Balance at Beginning of Period	Charges to Expenses or Other Accounts	Deductions	Balance at End of Period
Year Ended December 31, 2002				
Allowance for doubtful accounts	$ 14	31		$ 45
Reserve for inventories	$ 143	111		$ 254
Year Ended December 31, 2003				
Allowance for doubtful accounts	$ 45	119		$ 164
Reserve for inventories	$ 254	69	95	$ 228
Year Ended December 31, 2004				
Allowance for doubtful accounts	$ 164	(102)		$ 62
Reserve for inventories	$ 228	152		$ 380

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized in the City of San Carlos, California on this 31st day of March 2005.

CONCEPTUS, INC.

By: /s/ MARK M. SIECZKAREK

Mark M. Sieczkarek,
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mark Sieczkarek and Gregory E. Lichtwardt, his or her attorney-in-fact, each with the power of substitution, for him in any and all capacities, to sign any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes may do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ MARK M. SIECZKAREK	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2005
(Mark M. Sieczkarek)		
/s/ GREGORY E. LICHTWARDT	Executive Vice President, Treasurer and Chief Financial Officer	March 31, 2005
(Gregory E. Lichtwardt)		
/s/ MICHAEL A. BAKER	Director	March 31, 2005
(Michael A. Baker)		
/s/ THOMAS F. BONADIO	Director	March 31, 2005
(Thomas Bonadio)		
/s/ FLORENCE COMITE	Director	March 31, 2005
(Florence Comite)		
/s/ MARIE-HELENE PLAIS-COTREL	Director	March 31, 2005
(Marie-Helene Plais-Cotrel)		
/s/ ROBERT V. TONI	Director	March 31, 2005
(Robert V. Toni)		
/s/ KATHRYN A. TUNSTALL	Director	March 31, 2005

Signature	Title	Date
(Kathryn A. Tunstall)		
/s/ PETER L. WILSON	Director	March 31, 2005
(Peter L. Wilson)		

EXHIBIT INDEX

Exhibit Number	Description
10.7*	Form of Senior Management Amended and Restated Change of Control Agreement.
10.8*	Change of Control Agreement dated as of April 27, 2004 by and between Registrant and Gregory Lichtwardt
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (See Page 79 of this Report).
31.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management contract or compensatory plan or arrangement.

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