Sontra
MEDICAL CORPORATION

04 ANNUAL REPORT

Dear Sontra Shareholders:

Sontra was founded to advance transdermal science by developing the ultrasonic skin permeation technology licensed from the Massachusetts Institute of Technology. During 2004, we launched the first generation SonoPrep® ultrasonic skin permeation instrument and procedure tray product and our first product revenues were realized. Sontra's first product will serve as a solid foundation for the development and commercialization of many more generations and applications of the SonoPrep platform.

There were many significant accomplishments during 2004.

- Early in the year, we completed development of the SonoPrep instrument and topical anesthetic procedure tray and entered into production. The SonoPrep product launch began in September after we received FDA 510(k) clearance to market. Sontra completed four clinical studies that verified topical anesthesia was achieved in five minutes after SonoPrep treatment in over 700 adult and pediatric patients.
- We expanded our research and development competencies with the addition of transdermal drug scientists who completed development of a novel liquid crystalline transdermal gel formulation (LC-Gel™) for improved topical lidocaine delivery.
- Development of an improved Glucose Flux Biosensor (GFB) was completed and evaluated in a clinical study on 12 patients with diabetes. The GFB sensor had excellent statistical correlation ($r = 0.90$) and hypoglycemia detection was better than other commercially available continuous glucose monitoring systems.
- We expanded our development activities into topical vaccination and completed our first clinical feasibility study using a skin induration model.
- We strengthened our balance sheet through a common stock financing which provided the Company with $4 million of net proceeds for working capital.

Sontra's development activities and marketing strategies are designed to create a product and technology pipeline that secures Sontra's position as a leader in transdermal technology. We are ahead of plan to complete our independent distribution network for the SonoPrep and lidocaine procedure tray. We are performing stability assays for a new lidocaine LC-Gel formulation which we anticipate releasing before the end of 2005. Sontra product development engineers are in the later stages of development of the second generation SonoPrep instrument and procedure tray. Introduction of the LC-Gel lidocaine and next generation SonoPrep in early 2006 are expected to both accelerate product adoption and increase our gross margins significantly.

We are transitioning from R&D to product development of the Symphony Diabetes Management System. We expanded our product strategy to include a hospital intensive care glucose monitor that will be developed in parallel with the diabetes home testing and physician management products. We believe that this strategy will lead to faster FDA regulatory approvals with the first product launch anticipated in 2006.

We are continuing our proof of feasibility and optimization clinical studies in transdermal vaccine delivery. We expect these programs to result in R&D partnerships with leading vaccine suppliers and innovators during 2005.

We look forward to reporting continued progress.

Thomas W. Davison, Ph.D.
Chief Executive Officer

March 15, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-KSB

(Mark One)

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

For the fiscal year ended: December 31, 2004

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

For the transition period from to

COMMISSION FILE NUMBER 000-23017

SONTRA MEDICAL CORPORATION

(Name of small business issuer in its charter)

MINNESOTA	**41-1649949**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*
10 Forge Parkway, Franklin, Massachusetts	**02038**
(Address of principal executive offices)	*(Zip Code)*

Issuer's Telephone Number: (508) 553-8850

Securities registered under Section 12(b) of the Exchange Act: None
Securities registered under Section 12(g) of the Exchange Act: Common Stock, $.01 par value per share

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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. ☐

Issuer's revenues for its most recent fiscal year: $33,565.

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the issuer as of February 10, 2005, based upon the closing price of such stock on that date was $35,324,546.

The number of shares of the issuer's common stock outstanding as of February 10, 2005 was 22,179,904.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement (the "Definitive Proxy Statement") to be filed with the Securities and Exchange Commission relative to the issuer's 2005 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-KSB.

Transitional Small Business Disclosure Format (Check one): Yes ☐ No ☒

SONTRA MEDICAL CORPORATION

ANNUAL REPORT ON FORM 10-KSB

YEAR ENDED DECEMBER 31, 2004

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This Annual Report on Form 10-KSB contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects" and similar expressions are intended to identify forward-looking statements. The important factors discussed under the caption "Factors That May Affect Future Results" in Item 6 of this report, among others, could cause actual results to differ materially from those indicated by forward-looking statements made herein and presented elsewhere by management. Such forward-looking statements represent management's current expectations and are inherently uncertain. Investors are warned that actual results may differ from management's expectations. Sontra does not undertake any obligation to update forward-looking statements.

PART I

ITEM 1. DESCRIPTION OF BUSINESS

Overview

Sontra Medical Corporation is the pioneer of SonoPrep®, a non-invasive ultrasonic skin permeation technology for medical and therapeutic applications including transdermal diagnostics and the enhanced delivery of drugs through the skin. Our proprietary ultrasound mediated skin permeation technology is a non-invasive and painless method of enhancing the flow of fluids and molecules across the protective membrane of the stratum corneum, the outer layer of the skin.

Our strategy is to combine our ultrasonic skin permeation technology together with biosensor and synergistic transdermal drug delivery technologies to develop complete product solutions for transdermal drug delivery, diagnostics and skin treatment. We are developing a diversified product pipeline with opportunities for short-term commercialization and long-term strategic partnerships. The Company's vision is for painless and continuous transdermal diagnosis and drug delivery that will improve patient outcome and reduce health care costs. We believe these benefits will be realized with improved patient compliance to treatment, continuous diagnosis and data collection and new routes for continuous drug delivery.

To date, we have tested the feasibility of our SonoPrep technology for various applications, including glucose monitoring, transdermal drug delivery and certain anesthetic applications. We have received 510(k) marketing clearance from the FDA for our SonoPrep device for the transdermal delivery of 4% topical lidocaine and in electrophysiology applications.

Our product development programs based on our SonoPrep technology include:

- Enhanced transdermal delivery of topically applied drugs.
- Accelerated onset of action of currently approved transdermal drugs.
- Skin preparation prior to electrophysiology tests to improve electrical signals.
- Continuous non-invasive blood glucose monitoring.
- Transdermal drug delivery of large molecules and biopharmaceuticals.
- Transdermal vaccination.

We expect to develop additional products, which will require substantial expenditures, including for feasibility studies, pre-clinical studies and clinical testing. In addition, the establishment of collaborative partnerships and regulatory, manufacturing, sales and marketing activities by collaborative partners will be necessary for successful commercial production of our technologies or their incorporation into products of third parties.

Our ultrasonic skin permeation technology was developed by our co-founders Dr. Joseph Kost and Dr. Robert Langer at the Massachusetts Institute of Technology's Chemical and Bioengineering Laboratory. Sontra licensed the MIT technology and Sontra engineers and scientists reduced the technology to practice. We have an exclusive worldwide license from the Massachusetts Institute of Technology (MIT) under certain licensed patents to develop and commercialize ultrasonic skin permeation products. These licensed patents, which include eight issued patents in the United States, three issued foreign patents, two pending U.S. patents and three pending foreign patent applications, comprise a substantial portion of our patent portfolio relating to our technology.

Company Information

Sontra Medical Corporation, a Minnesota corporation, was formed through the merger of Sontra Medical, Inc. ("SMI") and ChoiceTel Communications, Inc. ("ChoiceTel") in June 2002 (the "Merger"). Following the

Merger, ChoiceTel changed its name to Sontra Medical Corporation and began operating in SMI's line of business. ChoiceTel was incorporated in Minnesota in 1989.

Our principal executive offices are located at 10 Forge Parkway, Franklin, Massachusetts 02038, and our telephone number is (508) 553-8850. Unless the context otherwise requires, the terms "Sontra," "the Company," "we," "us" and "our" refer to Sontra Medical Corporation. We make our annual reports on Form 10-KSB, quarterly reports on Form 10-QSB, current reports on Form 8-K and amendments to those reports available through our website, free of charge, as soon as reasonably practicable after we file such material with, or furnish it to the Securities and Exchange Commission. Our internet address is http://www.sontra.com. The contents of our website are not part of this annual report on Form 10-KSB, and our internet address is included in this document as an inactive textual reference only.

SonoPrep® Skin Permeation Device

The skin is the body's barrier to the outside environment that prevents body fluids from escaping and prevents protein contaminants (pyrogens), microorganisms (viruses and bacteria) and other irritating substances from entering the body. The outer layer of the skin, the stratum corneum, is a relatively thin layer of brick-shaped keratinocytes which creates the skin barrier. The interstitial space between these keratinocytes contains a highly ordered lipid bi-layer that repels water and compounds that are water-soluble, including the body fluids and vital analytes such as electrolytes, proteins and glucose. An application of ultrasonic energy disorganizes the lipid bi-layer of the stratum corneum thereby creating reversible channels in the skin through which fluids and analytes can be extracted and small and large molecules can be delivered. The transport properties of the protective stratum corneum are increased approximately 100-fold after ultrasonic skin permeation.

Our proprietary SonoPrep ultrasound-mediated skin permeation technology is a non-invasive and painless method of enhancing the flow of fluids and molecules across the protective membrane of the stratum corneum. Sontra developed the SonoPrep skin permeation device that makes the skin permeable for up to 24 hours by applying ultrasonic energy to the skin for approximately 15 seconds.

The SonoPrep device consists of a battery-operated power and control unit, an ultrasonic applicator hand piece and a single use disposable coupling medium cartridge. The SonoPrep device applies relatively low frequency (compared to diagnostic imaging) ultrasonic energy to the skin. The ultrasonic horn in the device vibrates at 55,000 times per second (55KHz) and applies the energy to the skin through a liquid coupling medium to create cavitational bubbles that expand and contract in the coupling medium and the ordered lipid bilayer of the stratum corneum. Ultrasonic cavitation disorganizes the lipid bi-layer of the stratum corneum and creates reversible channels through which fluids and analytes can be extracted. High and low molecular weight molecules can also be delivered through the skin.

The Company's SonoPrep device is easy to use and the treatment can be self-administered by the patient. The application is designed for safe use with an on-line feedback mechanism to detect permeation based on the reduction in electrical impedance and automatically shut off the ultrasonic energy when the effect is optimized. Most importantly, the permeability is reversible and the skin goes back to its normal state after approximately 24 hours. The SonoPrep device has each of the following attributes:

- Non-invasive
- Increases skin permeability approximately 100-fold
- Well controlled and long-lasting skin permeability (up to 24 hours)
- Painless and non-irritating
- Fast and easy to use
- Reversible
- Safe

Sontra has completed product development of the first generation of the SonoPrep device and has commenced manufacturing of the device and plans to introduce a second generation device in early 2006. The SonoPrep device will be employed in all of Sontra's product applications. Sontra has identified several target markets, including adult and pediatric phlebotomy and IV catheterization, central venous catheter insertion, and dermatological procedures, for the SonoPrep device. Sontra received its first FDA 510(k) marketing clearance for its SonoPrep device in February 2004 for enhancing electrophysiology signals. In August 2004, we received 510(k) marketing clearance from the FDA for the SonoPrep device and procedure tray for use with topical lidocaine. We will need to obtain additional 510(k) marketing clearances, or PMA or NDA approvals, from the FDA in order to market other products and applications.

Electrophysiology Preparation

Electro-cardiograms (EKG), electro-encephalograms (EEG) and electro-myelograms (EMG) are common electrophysiology modalities used in medical diagnosis. Three principal elements of successful tests are:

- Electrode adhesion
- Conductivity (low impedance) between the electrode and the skin
- Motion artifact and electrical interference reduction

The most important variable that needs to be controlled in order to obtain an accurate electrophysiology test result is a reduced level of skin impedance. Lower impedance means higher signals and lower signal-to-noise ratios. The standard impedance level desired in most electrophysiology measurements is 5000 Ohms. In order to achieve this level, technicians prepare the skin site by shaving, cleaning and de-fatting with alcohol and, in some applications, dermabrasion with sandpaper or tape stripping. These procedures are time consuming, often painful and not always effective.

The SonoPrep device has been demonstrated through an internal human feasibility study to reduce skin impedance consistently to 1000 Ohms. The Company believes the SonoPrep device will add value to applications where low impedance is critical to enhance signal strength and motion artifact is a concern. In February 2004, Sontra received 510(k) marketing clearance from the FDA for its SonoPrep device for use in electrophysiology applications. The Company is currently evaluating the commercial market opportunity and methods of distribution for electrophysiology applications.

SonoPrep® Topical Anesthetic System for Rapid Skin Anesthesia

In August 2004, Sontra received 510(k) marketing clearance from the FDA to market the SonoPrep device and procedure tray for use with over-the-counter (OTC) 4% topical lidocaine for dermal anesthesia prior to the insertion of needles or intravenous catheters. In September 2004, the Company launched its SonoPrep Topical Anesthetic System, which consists of the SonoPrep device and a topical anesthetic procedure tray for usage with OTC 4% topical lidocaine, and is marketing the system through independent medical device distributors. The Topical Anesthetic Procedure Tray consists of a SonoPrep coupling medium and cleaning cartridge, and a locator ring.

To achieve rapid skin anesthesia, a patient's skin is first permeated with the SonoPrep device and then topical lidocaine is applied to the permeated skin site. Sontra has demonstrated that SonoPrep can achieve skin analgesia in five minutes or less, versus the thirty to sixty minutes recommended for the existing topical anesthetics. The topical anesthetic products are used in dermatology and pediatrics procedures to numb the skin before IV insertions, blood draws and other needle sticks.

Although Sontra received this clearance, OTC 4% topical lidocaine has not been approved by the FDA for the indications covered by the Company's 510(k) marketing clearance, namely needle sticks or venipuncture.

Under federal law, the marketing of OTC 4% topical lidocaine for dermal anesthesia prior to the insertion of needles or intravenous catheters requires the FDA to approve a new drug application (NDA) with respect thereto. The Company intends to continue to market the SonoPrep Topical Anesthetic System pursuant to its 510(k) marketing clearance, and we plan to submit to the FDA an NDA seeking approval of OTC 4% topical lidocaine for dermal anesthesia prior to the insertion of needles or intravenous catheters.

Continuous Non-Invasive Glucose Monitoring System

Diabetes is a serious metabolic disorder and is the sixth leading cause of death in the United States, and those individuals afflicted with the disease are at serious risk of developing complications, such as coronary and vascular disease, retinopathy and neuropathy. The immediate and long-term effects of inadequate blood glucose control are devastating. Diabetes is the leading cause of kidney failure, adult blindness, non-traumatic amputations and nerve damage. When patients monitor their blood glucose frequently they can schedule their insulin injections to properly control their glucose levels. Clinical studies have proven that tighter glucose control through precise insulin dosing significantly reduces diabetes related complications. The Company believes that continuous non-invasive monitoring of blood glucose will greatly improve a patient's compliance to frequent testing, which has been shown to significantly reduce severe complications related to diabetes and lead to reduced health care costs.

Sontra is developing a non-invasive glucose monitoring system that continuously measures glucose levels in patients with diabetes and addresses the unmet need in the home testing market for a truly continuous and non-invasive glucose monitor. Sontra's glucose monitoring system consists of the SonoPrep skin permeation device and a glucose flux biosensor placed over the permeated skin site that continuously measures the glucose as it flows into the sensor. Because SonoPrep can permeate many different skin locations a patient will be able to place the biosensor on skin areas that are out of sight such as the abdomen, so the patient can maintain an active lifestyle. The glucose biosensor is designed to continuously measure glucose levels and transmit readings wirelessly to a glucose meter that will be designed as a watch or beeper capable of transmitting data to a night stand alarm monitor.

The glucose biosensor contains an electrochemical sensor and an osmotic extraction gel that couples with the skin and continuously draws the glucose into the sensor. The glucose that flows through the skin is consumed by the biosensor as it reacts with glucose oxidase that is contained in the biosensor. This chemical reaction produces a constant electrical signal, which is recorded by the glucose meter. Due to the enhanced permeation created with SonoPrep, the constant glucose flux detected by Sontra's glucose biosensor provides continuous glucose measurements that are analyzed every second.

Sontra completed its first Phase 1 clinical study in patients with diabetes in April 2003. The study was conducted using a prototype of the first generation SonoPrep skin permeation system and Sontra's first glucose flux biosensor and meter prototypes. Twenty glucose flux biosensors (2 per patient) were placed over ten SonoPrep treated skin sites of ten adult subjects with Type 1 or Type 2 diabetes. Data was collected for eight to nine hours. Over 5,000 data points were collected and analyzed per sensor. As a control, blood glucose was measured from an intravenous catheter or finger stick blood withdrawn every twenty minutes. Data sets comparing blood glucose measurements to data from the glucose flux biosensor had an 84 percent (r=.84) correlation to glucose measurements. The accuracy of the data from this study demonstrated the clinical feasibility of our system.

In November 2004, Sontra completed a second Phase 1 clinical trial. The study included twelve adult participants with either Type 1 or Type 2 diabetes. Each participant had three glucose flux biosensors placed on their skin, allowing over 2,000 glucose measurements to be collected over an eight-hour period at five-second intervals. Completed data showed a 90 percent (r=.90) correlation to reference blood glucose measurements.

Strategic Partnership with Bayer Diagnostics

On July 28, 2003, the Company and Bayer Diagnostics Division of Bayer Healthcare LLC ("Bayer") executed a definitive license agreement pursuant to which the Company granted to Bayer an exclusive worldwide right and license of the Company's intellectual property rights to make, have made, use, import and sell the continuous non-invasive glucose monitoring system. In consideration of the license and the Company's delivery of all information, materials and know-how related to the licensed technology, Bayer paid the Company a one-time, non-refundable license fee of $1.5 million in January 2004.

Pursuant to the terms of the license agreement, the Company and Bayer may also enter into one or more additional agreements to continue the joint development of the continuous non-invasive glucose monitoring system. Such agreements may include, among other things, a $3.0 million milestone payment to the Company after the first phase of development of the product, a royalty agreement providing for the payment by Bayer to the Company of royalties based on net sales of the product and a manufacturing and supply agreement providing Sontra with the exclusive manufacturing rights of the SonoPrep device. To date, no such additional agreements have been entered into, and there can be no assurance that the Company and Bayer will enter into any additional agreements or that Bayer will make any further payments to the Company. In the event that Bayer does not complete the development of the product necessary to obtain FDA approval, the license shall convert to a non-exclusive license. Bayer has the right to terminate the agreement at any time following the payment of the license fee. In the event that Bayer terminates the agreement following the payment of the license fee, the license shall cease to be an exclusive license and shall become a co-exclusive license pursuant to which the Company will receive royalties based on net sales of the product.

Transdermal Drug Delivery

The existing worldwide transdermal drug market consists of low molecular weight drugs. The formidable challenge of effectively permeating the skin and delivering a therapeutic dosage within the required onset time of action has currently limited the transdermal drug delivery market to low molecular weight drugs. The following drugs are being marketed in transdermal formulations:

Drug	Indication
Lidocaine	Topical Anesthesia
Fentanyl	Pain
Nitroglycerine	Anti-angina
Estradiol	Hormone Replacement
Testosterone	Hypogonadism
Clonidine	Hypertension
Scopolamine	Motion Sickness
Nicotine	Smoking Cessation

Sontra believes that its SonoPrep skin permeation technology can be positioned in the transdermal drug delivery market based on the following product attributes:

- An application of SonoPrep can significantly accelerate the onset time of action, thereby expanding the clinical indications for existing transdermal systemic drugs and topically applied local drugs where current onset times limit the clinical indications for these drugs.
- An application of SonoPrep increases skin permeation 100 times greater than untreated skin, thereby making it possible to deliver large molecule drugs.

Transdermal Vaccine Delivery

SonoPrep disrupts the stratum corneum and has the potential to precisely deliver vaccines to the viable epidermis to activate the dendritic Langerhan cells which invoke a powerful immune response. The Company is

developing a universal patch/reservoir delivery system for the transdermal delivery of vaccines. In October 2004, the Company completed a twenty patient human clinical study conducted at the University of Massachusetts that demonstrated that SonoPrep facilitated the transdermal delivery of large molecular weight antigenic proteins; tetanus toxoid and candida albicans (yeast) to induce a skin immune response. Building on this study, the Company plans to complete a second study at the University of Massachusetts using SonoPrep to deliver the hepatitis A vaccine through the skin.

Government Regulation

Sontra's SonoPrep device and procedure tray for use with topical lidocaine, and its continuous glucose monitoring product in development, are regulated as medical devices and are subject to extensive regulation by the Food and Drug Administration (FDA) and other regulatory authorities in the United States. The Federal Food, Drug, and Cosmetic Act (the "FD&C Act") and other federal and state statutes and regulations govern the research, design, development, manufacturing, preclinical and clinical testing, storage, packaging, recordkeeping, servicing, labeling, distribution and promotion of medical devices in the United States. Failure to comply with these requirements can lead to stringent sanctions, including withdrawal or recalls of products from the market, refusal to authorize government contracts, civil monetary penalties and criminal prosecution.

Generally, medical devices require FDA approval or clearance before they may be marketed. There are two review procedures by which a product may receive such approval or clearance. Some products may qualify for clearance under a pre-market notification, or 510(k) procedure, in which the manufacturer provides to the FDA a pre-market notification that it intends to begin marketing the product, and demonstrates to the FDA's satisfaction that the product is substantially equivalent to a legally marketed device. A product is considered substantially equivalent if it has the same intended use, and also has either the same technological characteristics (as defined in the FD&C Act), or if the product has different technological characteristics, the information submitted in the pre-market notification demonstrates that the product is as safe and effective, as a legally marketed device and does not raise different questions of safety and effectiveness than a legally marketed device. Marketing may commence when the FDA issues a clearance letter. If a medical device does not qualify for the 510(k) procedure, the FDA must approve a pre-market approval application, or PMA, before marketing can begin. PMA applications must demonstrate, among other matters, that the medical device is safe and effective. The PMA process is typically more comprehensive than the 510(k) process, and usually requires pre-clinical and extensive clinical studies. Further, before the FDA will approve a PMA, the manufacturer must pass an inspection demonstrating its compliance with the requirements of the FDA's quality system regulations. FDA requests for additional studies during the review period are not uncommon, and can significantly delay approvals.

In addition, a number of other FDA requirements apply to medical device manufacturers and distributors. Device manufacturers must be registered and their products listed with the FDA, and certain adverse events and product malfunctions must be reported to the FDA. The FDA also prohibits an approved or cleared device from being marketing for unapproved or uncleared uses. Our product labeling, promotion and advertising are subject to continuing FDA regulation. Manufacturers must comply with the FDA's quality system regulation, which establishes extensive requirements for quality control and manufacturing procedures. The FDA periodically inspects facilities to ascertain compliance with these and other requirements. Thus, manufacturers and distributors must continue to spend time, money and effort to maintain compliance. Failure to comply with the applicable regulatory requirements may subject us to a variety of administrative and judicially imposed sanctions, including withdrawal of an approval or clearance, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and civil and criminal penalties against the Company or its officers, directors or employees. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

In February 2004, Sontra received 510(k) marketing clearance from the FDA for its SonoPrep device for use in electrophysiology applications. In August 2004, Sontra received 510(k) marketing clearance from the FDA to market the SonoPrep device and procedure tray for use with over-the-counter (OTC) 4% topical lidocaine for

dermal anesthesia prior to the insertion of needles or intravenous catheters. In September 2004, the Company launched its SonoPrep Topical Anesthetic System, which consists of the SonoPrep device and a topical anesthetic procedure tray for usage with OTC 4% topical lidocaine, and is marketing the system through independent medical device distributors. Although Sontra received this clearance, OTC 4% topical lidocaine has not been approved by the FDA for the indications covered by the Company's 510(k) marketing clearance, namely pain relief associated with needle sticks or venipuncture. Under federal law, the marketing of OTC 4% topical lidocaine for dermal anesthesia prior to the insertion of needles or intravenous catheters requires the approval of the FDA of a new drug application (NDA) with respect thereto. The Company plans to submit to the FDA an NDA seeking approval of OTC 4% topical lidocaine for dermal anesthesia prior to the insertion of needles or intravenous catheters. The Company intends to continue to market the SonoPrep Topical Anesthetic System pursuant to its 510(k) marketing clearance; however, prior to approval of the NDA, the FDA may determine to limit, restrict or delay our ability to market the system. If the FDA ultimately does not approve the NDA, our business and results of operations would be materially adversely affected.

In order to obtain marketing clearance for its continuous non-invasive glucose monitoring system, Sontra will be required to file a PMA application that demonstrates the safety and effectiveness of the product. In addition, applications of the SonoPrep device in conjunction with drugs or vaccines will require FDA approval for each drug or vaccine for the specific indication if such approval does not already exist. The NDA process is comprehensive and includes the results of pre-clinical and extensive clinical studies before approval may be obtained, similar to the PMA process.

Research and Development

To date, our research and development efforts have been aimed at the development and commercialization of our SonoPrep technology for non-invasive diagnostic and transdermal drug delivery applications. We are also developing complete transdermal product solutions that combine our ultrasonic skin permeation technology together with synergistic biosensor and transdermal drug delivery technologies. For all of our products we will conduct human clinical trials to demonstrate the benefits of our SonoPrep device and our transdermal products.

For the years ended December 31, 2004 and 2003, our research and development expenses were approximately $3,039,000 and $2,266,000, respectively.

Sales and Marketing

We market the SonoPrep device and procedure tray for use with topical lidocaine through independent medical device distributors. For larger markets such as transdermal vaccination and glucose testing, Sontra plans to license its product to large pharmaceutical companies.

Manufacturing

We currently perform manufacturing of certain critical components and final assembly and testing of the SonoPrep device at our Franklin, Massachusetts facilities. As volumes increase, we may decide to outsource the manufacturing of the entire device.

Competition

The medical device industry in general, and the market for glucose monitoring in particular, is intensely competitive. Sontra's continuous non-invasive glucose monitoring system will compete directly with glucose monitoring products manufactured by Roche Diagnostics, LifeScan, Inc., a division of Johnson & Johnson, Bayer Corporation, MediSense, a division of Abbott Laboratories, Medtronic, Inc., Cygnus, Inc., SpectRx and TheraSense, Inc. The Company's SonoPrep device will also compete with numerous companies developing drug delivery products such as Nektar Therapeutics, Alkermes, Inc., Bioject, Inc., PowderJect Pharmaceuticals PLC,

Antares Pharma, Inc., Becton Dickinson & Co., Aerogen, Inc., ALZA Corporation, a division of Johnson & Johnson, Norwood Abbey Limited, Vyteris, Iomed and 3M Company. In the topical lidocaine market, Sontra competes with the existing topical lidocaine products manufactured by Astra and others, and also competes with Norwood Abbey, who has received clearance from the FDA to market a laser poration device.

The first product to reach the market in a therapeutic area often has a significant competitive advantage relative to later entrants to the market. Competitive products have either been approved or are being developed for most of Sontra's products. Additionally, many competitors or potential competitors of Sontra are larger than Sontra and able to commit significantly greater financial and other resources to all aspects of their business, including development, marketing, sales and distribution, and may have substantially greater experience in developing products, in obtaining regulatory approvals and in manufacturing and marketing products. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended purposes of Sontra's product concepts that are more commercially attractive than Sontra's product concepts, or that could render Sontra's technology uncompetitive or obsolete.

In the area of transdermal drug delivery, many pharmaceutical companies have the financial resources to acquire the skills necessary to develop transdermal systems. Any transdermal drug delivery products that Sontra may develop will also compete with drugs marketed in traditional dosage forms, including oral doses, injections and continuous infusion. New drugs, new therapeutic approaches or further developments or innovations in alternative drug delivery methods, such as time release capsules, liposomes and implants, may provide greater therapeutic benefits for a specific indication or may offer comparable performance at lower cost, than those that could be offered by Sontra's current transdermal drug delivery technology. Sontra expects that any products that it develops will compete primarily on the basis of product efficiency, safety, patient convenience, reliability, availability and price. However, there can be no assurance that Sontra will successfully develop technologies and products that are more effective, safer, more convenient, more reliable, more available or more affordable than those being developed by its current and future competitors.

Intellectual Property

Currently, Sontra maintains a comprehensive portfolio of intellectual property. Sontra has pursued a course of developing and acquiring patents and patent rights and licensing technology. Sontra's success depends primarily on its ability to establish and maintain the proprietary nature of its technology through the patent process and to license third-party patents and patent applications necessary to develop its products. In order to protect its proprietary technologies, Sontra also relies on a combination of trademark, copyright and trade secret protection, as well as confidentiality agreements with employees, consultants and third parties.

Sontra owns or exclusively licenses patents and patent applications that are very broad in scope, including ultrasound-enhanced transdermal drug delivery and ultrasound-enhanced transdermal analyte extraction and measurement (i.e. transdermal diagnostics), and provide significant protection from new entrants. Sontra has also patented specific elements of the technology that are keys to successful skin permeation enhancement and to establish our position in the area of ultrasound-enhanced skin permeation. Sontra has not sought patent protection for all of its technology. Sontra seeks patent coverage in the United States and in foreign countries only on aspects of its transdermal technologies that it believes will be significant and that could provide barriers to entry for its competition. We have an exclusive license from MIT on eight issued patents in the United States, three issued foreign patents, two pending U.S. patents and three pending foreign patent applications, and as of December 31, 2004, we owned four issued patents and six pending patent applications in the United States and two foreign patent and fifteen pending foreign applications. Sontra's success depends to a significant degree upon its ability to develop proprietary products and technologies and to obtain patent coverage for such products and technologies. Sontra intends to file patent applications covering any newly developed products or technologies.

Pursuant to a license agreement entered into with MIT in June 1998, Sontra has an exclusive, worldwide license to certain patent rights related to the use of ultrasound to enhance skin permeability for applications in

transdermal diagnostics and drug delivery. The term of this license extends until 2018, the expiration date of the last to expire of the patents licensed under the agreement. Under the agreement, Sontra is obligated to pay MIT annual license maintenance fees of $25,000 per year and running royalties based on the net sales of any products that are covered by the licensed patent rights. Sontra also has the right to grant sublicenses under the agreement, for which Sontra must also pay royalties to MIT for products sold by such sublicensees. MIT may terminate this license upon 90 days written notice if we fail to pay the annual license maintenance fees or running royalties, or otherwise upon an uncured material breach of the agreement.

Employees

As of February 15, 2005, Sontra had 24 full time employees, 14 of whom are engaged in research and development activities, four of whom are engaged in sales and marketing, three of whom are engaged in manufacturing activities, and three of whom are engaged in administration, finance and business development. All of Sontra's employees are covered by confidentiality agreements. No employees are covered by collective bargaining agreements.

ITEM 2. DESCRIPTION OF PROPERTY

Sontra leases approximately 13,000 square feet of manufacturing, laboratory and office space in a single facility located in Franklin, Massachusetts under a lease expiring in March 2008.

ITEM 3. LEGAL PROCEEDINGS

In December 2004, the Company entered into an agreement with the Puerto Rican Telephone Company ("PRTC") regarding alleged rate overcharges by PRTC related to the activity of ChoiceTel prior to the Merger. Pursuant to the agreement, the Company agreed to waive certain legal claims against PRTC in exchange for $250,000. The Company received the $250,000 settlement payment in January 2005.

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We currently are not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our results of operations or financial position.

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

There were no matters submitted to a vote of security holders during the quarter ended December 31, 2004.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the Nasdaq SmallCap Market under the symbol "SONT." The following table sets forth the range of high and low sale prices for our common stock for the periods indicated. The number of common shareholders of record of Sontra Medical Corporation as of February 10, 2005 was approximately 123.

	HIGH	LOW
Fiscal Year Ended December 31, 2004		
First Quarter	$3.45	$1.70
Second Quarter	$2.80	$1.80
Third Quarter	$2.63	$1.22
Fourth Quarter	$2.39	$1.65
Fiscal Year Ended December 31, 2003		
First Quarter	$4.29	$1.37
Second Quarter	$2.54	$0.83
Third Quarter	$1.98	$0.81
Fourth Quarter	$3.75	$1.33

We have never paid or declared any cash or other dividends on our common stock. We have no current plans to pay common stock dividends. We intend to retain earnings, if any, for working capital purposes. Any future determination as to the payment of dividends will depend upon our results of operations, and on our capital requirements, financial condition and other relevant factors which are in effect at that time.

On September 15, 2003, we filed with the Secretary of State of the State of Minnesota the Statement of the Powers, Designations, Preferences and Rights of the Series A Convertible Preferred Stock (the "Certificate of Designations"). As set forth in the Certificate of Designations, the issued and outstanding shares of Series A Preferred Stock bear an eight percent (8%) per annum dividend per share. The dividend accrues and is payable annually on June 30 of each year in cash or shares of our common stock at our discretion. In addition, we shall not declare or pay any dividends on our common stock unless and until all accrued dividends on the Series A Preferred Stock have been paid in full. Finally, if we declare and pay any dividends on our common stock, then, in that event, holders of shares of Series A Preferred Stock shall be entitled to share in such dividends on a pro rata basis, as if the shares had been converted into shares of our common stock pursuant to the Certificate of Designations.

Information regarding our equity compensation plans and the securities authorized for issuance thereunder is set forth in Item 11 below.

We did not repurchase any shares of common stock during the fourth quarter of fiscal 2004.

During the fourth quarter of fiscal 2004, we issued and sold an aggregate of 125,000 shares of common stock pursuant to the exercise of outstanding Common Stock Purchase Warrants. Pursuant to the terms of the warrants, the warrant holders paid the exercise price of $1.50 per share to us in connection with such exercises, for an aggregate purchase price of $187,500. The shares of common stock were issued and sold to the warrant holders in reliance on Section 4(2) of the Securities Act of 1933, as amended, as a sale by the issuer not involving a public offering. No underwriters were involved with the issuance and sale of the shares of common stock.

On October 27, 2004, we issued an aggregate of 2,088 shares of common stock in satisfaction of the annual 8% dividends payable on the outstanding shares of Series A Preferred Stock. The shares of common stock were

issued and sold to the Series A Preferred Stockholders in reliance on Section 4(2) of the Securities Act of 1933, as amended, as a sale by the issuer not involving a public offering. No underwriters were involved with the issuance and sale of the shares of common stock.

2004 Private Placement

During the fourth quarter of fiscal 2004, we completed a financing (the "Financing") with selected qualified purchasers that provided the Company with net proceeds of approximately $4.2 million pursuant to the terms of a Common Stock and Warrant Purchase Agreement, dated as of December 8, 2004 (the "Purchase Agreement"). Under the terms of the Purchase Agreement, at the initial closing of the Financing on December 8, 2004, investors purchased 2,464,713 shares of the Company's Common Stock in a private placement at a per share purchase price of $1.70 (with the exceptions noted below). The investors also received warrants (together with the Placement Agent Warrants, the "Warrants") to purchase up to 985,886 shares of Common Stock. At the second closing of the Financing on December 15, 2004, investors purchased 171,287 shares of the Company's Common Stock and Warrants to purchase up to 68,514 shares of Common Stock, on the same terms as the initial closing. The Warrants are exercisable at a per share price of $2.45 and will expire no later than the fifth anniversary of the issue date. In addition, the Company shall have the right to terminate the Warrants, upon thirty days notice, in the event that the closing price of the Company's common stock for twenty consecutive trading days is equal to or greater than $4.90 per share.

The Company agreed to pay to the placement agent for the Financing for its services (a) a cash fee of seven percent of all funds received by the Company in the Financing from all investors, excluding Warrants, and (b) warrants to purchase a number of shares of Common Stock of the Company equal to five percent of the aggregate number of shares of Common Stock issued in the Financing, on the identical terms and conditions (including a per share exercise price of $2.45) with the Warrants (the "Placement Agent Warrants"). The Company will also reimburse the placement agent for all pre-approved expenses in connection with the Financing. In addition, the placement agent received contractual rights of indemnification from the Company relating to the placement agent's participation in the Financing.

In the Financing, Michael R. Wigley, Chairman of the Board of the Company, purchased 58,825 shares of Common Stock at a per share purchase price of $2.00 (equal to the closing price of the Common Stock on the Nasdaq SmallCap Market on December 7, 2004), for an aggregate purchase price of $117,650.00. Mr. Wigley also received Warrants for the purchase of 23,530 shares of Common Stock. In addition Great Plains Companies, Inc. ("Great Plains") purchased 58,825 shares of Common Stock at a per share purchase price of $2.00 (equal to the closing price of the Common Stock on the Nasdaq SmallCap Market on December 7, 2004), for an aggregate purchase price of $117,650.00. Great Plains also received Warrants for the purchase of 23,530 shares of Common Stock. Mr. Wigley is the Chief Executive Officer and the majority shareholder of Great Plains.

The shares of Common Stock and the warrants to purchase shares of Common Stock were issued and sold in reliance on Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder, as a sale by the Company not involving a public offering. No underwriters were involved with the issuance and sale of such securities in the Financing.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion of our consolidated financial condition and results of operations should be read in conjunction with the financial statements and the related notes thereto included elsewhere in this Form 10-KSB. The matters discussed herein contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, which involve risks and uncertainties. All statements other than statements of historical information provided herein may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes", "anticipates", "plans", "expects" and similar expressions are intended to identify forward-looking statements. Factors that could cause actual results to differ materially from those reflected in the forward-looking statements include, but are not limited to, those discussed in "Risk Factors" and elsewhere in this report and the risks discussed in our other filings with the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis, judgment, belief or expectation only as of the date hereof. We undertake no obligation to publicly revise these forward-looking statements to reflect events or circumstances that arise after the date hereof.

Overview

On June 20, 2002, the Company (previously operating under the name ChoiceTel Communications, Inc.) consummated a merger with Sontra Medical, Inc. ("SMI"), pursuant to which SMI merged with and into a wholly owned subsidiary of the Company (the "Merger"). Subsequent to the consummation of the Merger, the Company changed its name to Sontra Medical Corporation and began operating in SMI's line of business.

Sontra Medical Corporation is the pioneer of SonoPrep®, a non-invasive ultrasonic skin permeation technology for medical and therapeutic applications. Our proprietary ultrasound mediated skin permeation technology is a non-invasive and painless method of enhancing the flow of fluids and molecules across the protective membrane of the stratum corneum, the outer layer of the skin.

A significant portion of the Company's research and development expenses include salaries paid to personnel and outside consultants and service providers, as well as the cost of materials used in research and development, and information technology and facilities costs. The Company expects that its research and development expenses will continue to increase as it works to complete the development of its products, obtain regulatory clearances or approvals, and conduct further research and development.

Selling, general and administrative expenses consist primarily of non-research personnel salaries and related expenses, facilities costs and professional fees. The Company expects selling, general and administrative expenses to increase as it hires additional personnel and builds its infrastructure to support future growth.

Stock-based compensation expense, a non-cash expense, represents the difference between the exercise price and fair value of common stock on the date of option grant. Certain stock-based compensation expense is remeasured each period and amortized over the vesting period of the applicable options, which is generally 42 months.

Critical Accounting Policies and Estimates

Management's Discussion and Analysis or Plan of Operation discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, management evaluates its estimates and judgments, including those related to inventory valuation, revenue recognition and stock-based compensation. Management bases its estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Management believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

Inventory Valuation. Inventories are stated at the lower of cost (first in, first out) or market. Work-in-process and finished goods consist of material, labor and overhead. Finished goods consist of completed SonoPrep units and procedure trays. Demo inventory consists of SonoPrep units owned by Sontra used for demonstration purposes. The cost of SonoPrep demo units is amortized to cost of sales over a one year period. The reserve for obsolescence represents inventory the Company expects to use in prototype manufacturing as well as possible design changes and product enhancements that may make certain raw materials and finished goods obsolete. Because we have only limited manufacturing experience with the SonoPrep units and procedure trays, through June 30, 2004 we considered all inventory to be related to prototype manufacturing. With our first product sales in the quarter ended September 30, 2004, we began capitalizing inventory based on our manufacturing experience. We expect to continue to adjust our reserve based on additional manufacturing experience, production levels and possible design changes and enhancements in the SonoPrep units.

Revenue Recognition. For product revenue, revenues are recognized when persuasive evidence of an arrangement exists in the form of a signed non-cancelable purchase order, the product is shipped, the selling price is fixed and determinable, and collection is reasonably assured. We currently sell primarily through distributors and have contracts with all such distributors. We have established credit policies that we believe allow us to determine when collectibility is reasonably assured. There are also reporting procedures in place to allow us to monitor the inventory levels at our distributors and to determine the end-user of our products.

Stock-based Compensation. We record stock-based compensation to non-employees at fair value. We do not record expense relating to stock options granted to employees with an exercise price greater than or equal to market price at the time of grant. We report pro forma net loss and loss per share in accordance with the requirements of Statement of Financial Accounting Standard ("SFAS") No. 148. This disclosure shows net loss and loss per share as if we had accounted for our employee stock options under the fair value method. The fair value of options granted to non-employees and the pro forma information discussed above is calculated using the Black-Scholes option pricing model. This option valuation model requires input of assumptions including the volatility of our stock price, the expected life of the option and the risk-free interest rate. Because our stock options have characteristics significantly different from those of traded options, and because changes in the input assumptions can materially affect the fair value estimate, the existing model may not necessarily provide a reliable single measure of fair value of our stock options.

We believe that full consideration has been given to all relevant circumstances that Sontra may be subject to, and the financial statements accurately reflect Sontra's best estimate of the results of operations, financial position and cash flows for the periods presented.

Results of Operations

Comparison of the years ended December 31, 2004 and 2003

Gross Profit

Sontra commenced the marketing launch of the SonoPrep device and procedure kit for topical lidocaine delivery in September 2004. For the year ended December 31, 2004, the Company recorded revenue of $34,000 and a gross profit of $17,000, or 50.3% of revenue. The Company expects to continue to refine its product costing and, accordingly, gross profit on future sales may differ.

Licensing revenue of $1,500,000 for the year ended December 31, 2003 consisted of a licensing payment due from Bayer Diagnostics. The Company received this payment on January 15, 2004.

Research and Development Expenses

Research and development expenses increased by $773,000 to $3,039,000 for the year ended December 31, 2004 from $2,266,000 for the year ended December 31, 2003. The increase was primarily attributable to an increase in clinical trial costs of $219,000, an increase in staffing of $234,000, and $305,000 spent on the manufacturing of SonoPrep prototypes and other manufacturing-related research and development.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $683,000 to $2,424,000 for the year ended December 31, 2004 from $1,741,000 for the year ended December 31, 2003. The increase was primarily attributable to selling and marketing costs of $355,000 associated with hiring personnel and marketing launch costs, an increase in stock-based compensation expenses of $204,000 and an increase in executive compensation of $150,000.

Interest Income

Interest income was $86,000 for the year ended December 31, 2004 compared to interest income of $27,000 for the year ended December 31, 2003. The increase in interest income is attributable to higher interest rates and a higher average balance invested.

Liquidity and Capital Resources

The Company has financed its operations since inception primarily through private sales of its common and preferred stock, the issuance of convertible promissory notes, and the cash it received in connection with the Merger. As of December 31, 2004, the Company had $9,515,000 of cash and cash equivalents on hand.

Net cash used in operating activities was $2,826,000 for the year ended December 31, 2004. The net loss for the year ended December 31, 2004 was $5,360,000 and included in this loss were non-cash expenses of $157,000 for depreciation and amortization, $309,000 for stock-based compensation and $225,000 for common stock contributed to the 401(k) plan. A decrease in accounts receivable provided $1,483,000 of cash and an increase in accounts payable and accrued expenses provided $516,000 of operating cash.

Net cash used in investing activities was $159,000 for the year ended December 31, 2004, resulting from $169,000 used to purchase property and equipment, offset by a reduction in restricted cash of $10,000.

Net cash provided by financing activities was $7,631,000 for the year ended December 31, 2004. The sale of common stock in a private placement provided $4,153,000 in cash and the exercise of warrants provided $3,285,000. In addition, the exercise of stock options provided $157,000 in cash, and adjustments related to the Merger provided $37,000.

The Company expects that the cash and cash equivalents of $9,515,000 at December 31, 2004 will be sufficient to meet its cash requirements through June 2006. The Company will be required to raise a substantial amount of capital in the future to complete the commercialization of its products.

At December 31, 2004, the Company had outstanding warrants to purchase 6,720,292 shares of common stock at exercise prices ranging from $1.20-$2.45. If all these warrants were exercised for cash the Company would received cash proceeds of $11,082,000.

The Company will be required to raise a substantial amount of capital in the future to execute in accordance with its product development, commercialization and marketing strategies. The Company's ability to fund its future capital requirements will depend on many factors, including the following:

- its ability to obtain funding from third parties, including any future collaborative partners;
- its progress on research and development programs and pre-clinical and clinical trials;
- the time and costs required to gain regulatory approvals;
- the costs of manufacturing, marketing and distributing its products, if successfully developed and approved;
- the costs of filing, prosecuting and enforcing patents, patent applications, patent claims and trademarks;
- the status of competing products; and
- the market acceptance and third-party reimbursement of its products, if successfully developed and approved.

Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements, including derivative instruments, that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Effect Of Inflation and Changes In Prices

Management does not believe that inflation and changes in price will have a material effect on the Company's operations.

Factors That May Affect Future Results

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. Forward-looking statements in this document and those made from time to time by us through our senior management are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements concerning the expected future revenues or earnings or concerning projected plans, performance, or development of products and services, as well as other estimates related to future operations are necessarily only estimates of future results and there can be no assurance that actual results will not materially differ from expectations. Forward-looking statements represent management's current expectations and are inherently uncertain. We do not undertake any obligation to update forward-looking statements. Factors that could cause actual results to differ materially from results anticipated in forward-looking statements include, but are not limited to, the following:

We have a history of operating losses, and we expect our operating losses to continue for the foreseeable future.

We have generated limited revenues and have had operating losses since our inception. Our historical accumulated deficit was approximately $23,382,561 as of December 31, 2004. It is possible that the Company

will never generate enough additional revenue to achieve and sustain profitability. Even if the Company reaches profitability, it may not be able to sustain or increase profitability. We expect our operating losses to continue for the foreseeable future as we continue to expend substantial resources to conduct research and development, feasibility and clinical studies, obtain regulatory approvals for specific use applications of our SonoPrep® technology, identify and secure collaborative partnerships, and manage and execute our obligations in strategic collaborations.

If we fail to raise additional capital, we will be unable to continue our development efforts and operations.

The Company has generated limited revenue since inception (from an historical accounting perspective), and does not expect to generate sufficient revenues to earn a profit in the near future. Our development efforts to date have consumed and will continue to require substantial amounts of capital to complete the development of our SonoPrep® technology and to meet other cash requirements in the future. Our product development programs will require substantial additional clinical trials to demonstrate the efficacy of our products before we can begin to commercialize our products under development. As we enter into more advanced product development of our SonoPrep device and our continuous non-invasive glucose monitoring system, we will need significant funding to pursue our product commercialization plans. We have generated limited revenues from our products under development. Our ability to continue our research, development and testing activities and commercialize our products in development is highly dependent on our ability to obtain additional sources of financing, including by entering into and maintaining collaborative arrangements with third parties who have the resources to fund such activities. Raising capital has become increasingly difficult for many companies. Any future equity financing, if available, may result in substantial dilution to existing shareholders, and debt financing, if available, may include restrictive covenants or may require us to grant a lender a security interest in our assets. To the extent that we attempt to raise additional funds through third party collaborations and/or licensing arrangements, we may be required to relinquish some rights to our technologies or products currently in various stages of development, or grant licenses on terms that are not favorable to the Company. Any failure by the Company to timely procure additional financing or investment adequate to fund the Company's ongoing operations, including planned product development initiatives and clinical studies, will have material adverse consequences on the Company's business operations and as a result, on our consolidated financial condition, results of operations and cash flows. If the Company is unable to raise sufficient additional financing we will not be able to continue our operations.

We have limited publicly available historical financial information, which makes it difficult to evaluate our business.

Because limited publicly available historical financial information is available on our business, it may be difficult to evaluate our business and prospects. Our business and prospects must be considered in light of the substantial risks, expenses, uncertainties and difficulties encountered by entrants into the medical device industry, which is characterized by increasingly intense competition and a high failure rate. To date, we have engaged primarily in research and development efforts, prototype development and testing, and human clinical feasibility studies. Our results of operations will depend on, among other things, the following factors:

- research and development activities and outcomes;
- results of feasibility and pre-clinical studies;
- the ability to enter into collaborative agreements;
- the timing of payments, if any, under future collaborative agreements; and
- costs related to obtaining, defending and enforcing patents.

The development and commercialization of our potential products, including the SonoPrep® device and the continuous non-invasive glucose monitoring system, require the successful development of strategic partnerships

with third parties, as well as substantial capital expenditures either by the Company or the strategic partner of the Company on research, regulatory compliance, sales and marketing and manufacturing.

Our future success is dependent upon successful collaborations with strategic partners.

Our future success is dependent upon our ability to selectively enter into and maintain collaborative arrangements with leading medical device and pharmaceutical companies, such as Bayer Healthcare LLC ("Bayer"). On July 28, 2003, Sontra and Bayer executed a definitive license agreement pursuant to which Sontra granted to Bayer an exclusive worldwide right and license of Sontra's intellectual property rights to make, have made, use, import and sell a continuous non-invasive glucose monitoring system. Pursuant to the terms of the license agreement, Sontra and Bayer may also enter into one or more additional agreements to continue the joint development of the continuous non-invasive glucose monitoring system. To date, we have not entered into any additional agreements with Bayer, and we may not be able to enter into any additional collaborative arrangements with Bayer or any other strategic partners on acceptable terms, if at all. If we are not able to collaborate with Bayer or additional partners, the business, financial condition and results of operations of the Company could be materially adversely affected.

Even if we were to enter into a collaborative arrangement, there can be no assurance that the financial condition or results of operations of the Company will significantly improve. The risks involved with collaborating with strategic partners include, but are not limited to, the following:

- such collaborative arrangements could terminate upon the expiration of certain notice periods;
- funding by collaborative partners may be dependent upon the satisfaction of certain goals or "milestones" by certain specified dates, the realization or satisfaction of which may be outside of our control;
- collaborative partners may retain a significant degree of discretion regarding the timing of these activities and the amount and quality of financial, personnel and other resources that they devote to these activities;
- disputes may arise between the Company and any future collaborative partner regarding their respective rights and obligations under the collaborative arrangements, which may be costly; and
- any future collaborative partner may not be able to satisfy its obligations under its arrangement with the Company or may intentionally or unintentionally breach its obligations under the arrangement.

Most of our products are in early stages of development, and we face risks of failure inherent in developing products based on new technologies.

Most of our products under development have a high risk of failure because they are in the early stages of development. To date, we have tested the feasibility of our SonoPrep® technology for various applications, including glucose monitoring, transdermal drug delivery and certain anesthetic applications. The Company has received 510(k) marketing clearance from the FDA for our SonoPrep® device for the transdermal delivery of 4% topical lidocaine and in electrophysiology applications. However, to develop additional products or additional uses, substantial expenditures will be required, including feasibility studies, pre-clinical studies and clinical testing, the establishment of collaborative partnerships and regulatory, manufacturing, sales and marketing activities by collaborative partners will be necessary for successful commercial production of our technologies or their incorporation into products of third parties.

Our future prospects are substantially dependent on forming collaborative partnerships, further developing our products and obtaining favorable results from pre-clinical studies and clinical trials and satisfying regulatory standards and approvals required for the market introduction of the SonoPrep® device and a continuous non-invasive glucose monitoring system. There can be no assurance that the Company or any strategic partner of the Company will not encounter unforeseen problems in the development of the SonoPrep® technology, or that we or

any such strategic partner will be able to successfully address the problems that do arise. In addition, there can be no assurance that any of our potential products will be successfully developed, proven safe and efficacious in clinical trials, meet applicable regulatory standards, be capable of being produced in commercial quantities at acceptable costs, be eligible for third-party reimbursement from governmental or private insurers, be successfully marketed or achieve market acceptance. If any of our development programs are not successfully completed, required regulatory approvals or clearances are not obtained, or potential products for which approvals or clearances are obtained are not commercially successful, our business, financial condition and results of operations would be materially adversely affected.

Failure to obtain necessary regulatory clearances or approvals will prevent the Company or our collaborators from commercializing our products under development.

The design, manufacturing, labeling, distribution and marketing of our potential products will be subject to extensive and rigorous government regulation in the United States and certain other countries. The process of obtaining and maintaining required regulatory clearances and approvals in the United States is lengthy, expensive and uncertain. In order for us to market our potential products in the United States, we must obtain clearance by means of a 510(k) pre-market notification, or approval by means of a pre-market approval ("PMA") application, or a new drug application ("NDA"), from the United States Food and Drug Administration ("FDA"). In February 2004, we received 510(k) marketing clearance from the FDA for our SonoPrep® device for use in electrophysiology applications. In August 2004, we received 510(k) marketing clearance from the FDA for the SonoPrep device and procedure tray for use with topical lidocaine. We will need to obtain additional marketing clearances or approvals from the FDA in order to market new products and new uses of existing products. In order to obtain marketing approval for our continuous non-invasive glucose monitoring system, we will be required to file a PMA application that demonstrates the safety and effectiveness of the product. If the SonoPrep device is used for the transdermal delivery of a drug for an indication for which the drug has not already been approved, an NDA would be required to be filed and approved by the FDA for such drug before marketing. The PMA and the NDA processes are more rigorous and more comprehensive than the 510(k) clearance process and can take several years from initial filing and require the submission of extensive supporting data and clinical information.

Even if we receive 510(k) clearance or PMA or NDA approval, there can be no assurance that the FDA will not impose strict labeling or other requirements as a condition of our clearance or approval, any of which could limit our ability to market our products under development. Further, if we wish to modify a product after FDA clearance or approval, including changes in indications or other modifications that could affect safety and efficacy, additional clearances or approvals could be required from the FDA. No assurance can be given that such clearances or approvals will be granted by the FDA on a timely basis, or at all. Further, we may be required to submit extensive pre-clinical and clinical data depending on the nature of the changes. Any request by the FDA for additional data or any requirement by the FDA that we conduct additional clinical studies could significantly delay the commercialization of our products and require us to make substantial additional research, development and other expenditures by the Company. Similarly, any labeling or other conditions or restrictions imposed by the FDA on the marketing of our potential products could hinder the Company's ability to effectively market these products.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of drug products and medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

We must maintain our regulatory clearances and approvals in order to continue marketing our products.

Regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to continual review and periodic inspections. We will be subject to ongoing FDA requirements, including required

submissions of safety and other post-market information and reports, registration requirements, Quality Systems regulations, and recordkeeping requirements. The Quality Systems regulations include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Our distributors, depending on their activities, are also subject to certain requirements under the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder, and state laws and registration requirements covering the distribution of our products. Regulatory agencies may change existing requirements or adopt new requirements or policies that could affect our regulatory responsibilities or the regulatory responsibilities of our distributors. We may not be able to adapt to these changes or new requirements on a timely basis, or at all.

Later discovery of previously unknown problems with our products, manufacturing processes, or our failure to comply with applicable regulatory requirements may result in enforcement actions by the FDA including, but not limited to: warning letters; patient or physician notification; restrictions on our products or manufacturing processes; product recalls or seizures; refusal to approve pending applications or supplements to approved applications that we submit; suspension or withdrawal of marketing approvals or clearances; and civil and criminal injunctions, fines and penalties.

We need to obtain further regulatory approval in connection with the usage of 4% topical lidocaine with our SonoPrep Topical Anesthetic System.

In August 2004, we received 510(k) marketing clearance from the FDA to market our SonoPrep device and procedure tray for use with over-the-counter (OTC) 4% topical lidocaine for dermal anesthesia prior to the insertion of needles or intravenous catheters. In September 2004, we launched our SonoPrep Topical Anesthetic System, which consists of the SonoPrep device and a topical anesthetic procedure tray for usage with OTC 4% topical lidocaine, and we are marketing the system through independent medical device distributors. However, OTC 4% topical lidocaine has not yet been approved by the FDA for the indications covered by the Company's 510(k) marketing clearance, namely needle sticks or venipuncture. Under federal law, the marketing of OTC 4% topical lidocaine for dermal anesthesia prior to the insertion of needles or intravenous catheters requires the approval by the FDA of a new drug application (NDA) with respect thereto. The Company plans to submit to the FDA an NDA seeking approval of OTC 4% topical lidocaine for dermal anesthesia prior to the insertion of needles or intravenous catheters.

The Company intends to continue to market the SonoPrep Topical Anesthetic System pursuant to its 510(k) marketing clearance; however, prior to approval of the NDA, the FDA may determine to limit, restrict or delay our ability to market the system, or may rescind our 510(k) marketing clearance. In addition, if the FDA does not approve the NDA, it is likely that our 510(k) marketing clearance would be rescinded, which would have a material adverse effect on our business and results of operations.

We must continue to meet the listing requirements of Nasdaq or we risk delisting.

Our Common Stock is currently listed for trading on the Nasdaq SmallCap Market. We must continue to satisfy Nasdaq's continued listing requirements, including the minimum $2.5 million shareholder equity requirement, or risk delisting which would have an adverse effect on the Company's business.

If the Company's Common Stock is delisted from the Nasdaq SmallCap Market, it may trade on the over-the-counter market, which may be a less liquid market. In such case, our shareholders' ability to trade, or obtain quotations of the market value of, shares of Sontra's Common Stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our Common Stock. In addition, the delisting of the Common Stock from the Nasdaq SmallCap Market would significantly impair our ability to raise capital in the public markets in the future.

A substantial portion of the intellectual property used by the Company is owned by the Massachusetts Institute of Technology.

We have an exclusive worldwide license from the Massachusetts Institute of Technology (MIT) under certain licensed patents to practice our ultrasound-mediated skin permeation technology. These licensed patents, which include eight issued patents in the United States, three issued foreign patents, two pending U.S. patents and three pending foreign patent applications, comprises a substantial portion of our patent portfolio relating to our technology.

While, under the license agreement, we have the right to advise and cooperate with MIT in the prosecution and maintenance of the foregoing patents, we do not control the prosecution of such patents. Instead, the Company relies upon MIT to determine the appropriate strategy for prosecuting these patents. If MIT does not adequately protect our patent rights, our ability to manufacture and market our products, currently in various stages of development, would be adversely affected.

We will need to protect the proprietary information on which our SonoPrep® technology relies.

We have an exclusive license from MIT on eight issued patents in the United States, three issued foreign patents, two pending U.S. patents and three pending foreign patent applications, and as of December 31, 2004, we owned four issued patents and six pending patent applications in the United States and two foreign patent and fifteen pending foreign applications. We can provide no assurance that patents will be issued from the patent applications, or, if issued, that they will be issued in a form that will be advantageous to the Company.

There can be no assurance that one or more of the patents owned or licensed by the Company will not be successfully challenged, invalidated or circumvented or that we will otherwise be able to rely on such patents for any reason. If any of our patents or any patents licensed from MIT are successfully challenged or our right or ability to manufacture our future products (if successfully developed and commercialized) were to be limited, our ability to manufacture and market these products could be adversely affected, which would have a material adverse effect upon our business, financial condition and results of operations.

In addition to patent protection, we rely on a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality agreements and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect the rights or competitive advantage of the Company. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by our employees. Nondisclosure and confidentiality agreements with third parties may be breached, and there is no assurance that the Company would have adequate remedies for any such breach.

If we fail to protect our intellectual property rights, our competitors may take advantage of our ideas and compete directly against the Company. There can be no assurance that competitors, many of whom have substantial resources and have made substantial investments in competing technologies, will not seek to apply for and obtain patents that limit our ability to make, use and sell our potential products either in the United States or in foreign markets. Furthermore, if our intellectual property is not adequately protected, our competitors may be able to use our intellectual property to enhance their products and compete more directly with the Company, which could prevent us from entering our products into the market or result in a decrease in our eventual market share.

We have limited manufacturing experience, which could limit our growth.

To successfully commercialize our SonoPrep skin permeation technology we will have to manufacture or engage others to manufacture the particular device in compliance with regulatory requirements. We have limited manufacturing experience that would enable us to make products in the volumes that would be necessary for us

to achieve significant commercial sales, and there can be no assurance that we will be able to establish and maintain reliable, efficient, full scale manufacturing at commercially reasonable costs, in a timely fashion. Difficulties we encounter in manufacturing scale-up, or our failure to implement and subsequently maintain our manufacturing facilities in accordance with good manufacturing practice regulations, international quality standards or other regulatory requirements, could result in a delay or termination of production. Companies, and especially small companies in the medical device field, often encounter these types of difficulties in scaling up production, including problems involving production yield, quality control and assurance, and shortages of qualified personnel.

We may be subject to litigation or other proceedings relating to our patent rights.

The medical device industry has experienced extensive litigation regarding patents and other intellectual property rights. In addition, the United States Patent and Trademark Office may institute litigation or interference proceedings against the Company. The defense and prosecution of intellectual property proceedings are both costly and time consuming.

Litigation may be necessary to enforce patents issued to the Company, to protect trade secrets or know how owned by or licensed to the Company or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings involving the Company may require us to incur substantial legal and other fees and expenses. Such proceedings would also be time consuming and can be a significant distraction for employees and management, resulting in slower product development and delays in commercialization. In addition, an adverse determination in litigation or interference proceedings could subject the Company to significant liabilities to third parties, require us to obtain licenses from third parties or prevent us from selling our products, once developed, in certain markets, or at all, which would have a material adverse effect on our business, financial condition and results of operations.

Our potential markets are highly competitive and most participants are larger, better capitalized, and more experienced than Sontra.

The industries in which our potential products may eventually be marketed are intensely competitive, subject to rapid change and significantly affected by new product introductions. Our continuous non-invasive glucose monitoring system will compete directly with glucose monitoring products manufactured by Roche Diagnostics, LifeScan, Inc., a division of Johnson & Johnson, Bayer Corporation, MediSense, a division of Abbott Laboratories, Medtronic, Inc., Cygnus, Inc., SpectRx and TheraSense, Inc. The Company's SonoPrep® device will also compete with numerous companies developing drug delivery products such as Nektar Therapeutics, Alkermes, Inc., Bioject, Inc., PowderJect Pharmaceuticals PLC, Antares Pharma, Inc., Becton Dickinson & Co., Aerogen, Inc., ALZA Corporation, a division of Johnson & Johnson, Norwood Abbey Limited, Vyteris, Iomed and 3M Company. In the topical lidocaine market, Sontra competes with the existing topical lidocaine products manufactured by Astra and others, and also competes with Norwood Abbey, who has received clearance from the FDA to market a laser poration device.

Most of these companies are already producing and marketing glucose monitoring or drug delivery products, are either publicly traded or a division of a publicly traded company, and enjoy several competitive advantages over the Company. In addition, several of our competitors have products in various stages of development and commercialization similar to our SonoPrep® device and our continuous non-invasive glucose monitoring system. At any time, these companies and others may develop products that compete directly with our proposed product concepts. In addition, many of our competitors have resources allowing them to spend significantly greater funds for the research, development, promotion and sale of new or existing products, thereby allowing them to respond more quickly to new or emerging technologies and changes in customer requirements. For all of the foregoing reasons, we may not be able to compete successfully against our current and future competitors. If any of our competitors succeeds in developing a commercially viable product and obtaining government approval, the business, financial condition and results of operations of the Company would be materially adversely affected.

We operate in an industry with significant product liability risk.

Our business will expose us to potential product liability claims that are inherent in the testing, production, marketing and sale of human diagnostic and ultrasonic transdermal drug delivery products. While we intend to take steps to insure against these risks, there can be no assurance that we will be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Our current product liability insurance provides for coverage in the amount of $2,000,000. A product liability claim in excess of our product liability insurance would have to be paid out of our cash reserves, if any, and would harm our reputation in the industry and adversely affect our ability to raise additional capital.

If we are unable to retain or hire additional key personnel, we may not be able to sustain or grow our business.

Our future success will depend upon our ability to successfully attract and retain key scientists, engineers and other highly skilled personnel. With the exception of Dr. Thomas W. Davison, our President and Chief Executive Officer, and Sean Moran, our Chief Financial Officer, our employees are at-will and not subject to employment contracts and may terminate their employment with the Company at any time. In addition, our current management team has limited experience managing a public company subject to the Securities and Exchange Commission's periodic reporting obligations. Hiring qualified management and technical personnel will be difficult due to the limited number of qualified professionals in the work force in general and the intense competition for these types of employees in the medical device industry, in particular. We have in the past experienced difficulty in recruiting qualified personnel and there can be no assurance that we will be successful in attracting and retaining additional members of management. Failure to attract and retain personnel, particularly management and technical personnel, would materially harm our business, financial condition and results of operations.

Our stock price has been volatile and may fluctuate in the future.

The trading price of our Common Stock may fluctuate significantly. This price may be influenced by many factors, including:

- our performance and prospects;
- the depth and liquidity of the market for our Common Stock;
- sales by selling shareholders of shares issued and issuable in connection with our private placements in 2003 and 2004;
- investor perception of us and the industry in which we operate;
- changes in earnings estimates or buy/sell recommendations by analysts;
- general financial and other market conditions; and
- domestic and international economic conditions.

Public stock markets have experienced, and are currently experiencing, extreme price and trading volume volatility, particularly in the technology and life sciences sectors of the market. This volatility has significantly affected the market prices of securities of many technology companies for reasons frequently unrelated to or disproportionately impacted by the operating performance of these companies. These broad market fluctuations may adversely affect the market price of our Common Stock. In addition, fluctuations in our stock price may have made our stock attractive to momentum, hedge or day-trading investors who often shift funds into and out of stocks rapidly, exacerbating price fluctuations in either direction particularly when viewed on a quarterly basis.

Securities we issue to fund our operations could dilute or otherwise adversely affect our shareholders.

We will likely need to raise additional funds through public or private debt or equity financings to fund our operations. If we raise funds by issuing equity securities, the percentage ownership of current shareholders will be reduced and the new equity securities may have rights senior to those of the shares of our Common Stock. If we raise funds by issuing debt securities, we may be required to agree to covenants that substantially restrict our ability to operate our business. We may not obtain sufficient financing on terms that are favorable to investors or us. We may delay, limit or eliminate some or all of our proposed operations if adequate funds are not available.

In addition, upon issuance of the shares of Common Stock issuable upon conversion of the outstanding shares of Series A Preferred Stock and the exercise of outstanding warrants, the percentage ownership of current shareholders will be diluted substantially.

The availability of preferred stock for issuance may adversely affect our shareholders.

Our Articles of Incorporation, as amended, authorize our Board of Directors to fix the rights, preferences and privileges of, and issue up to 10,000,000 shares of, preferred stock with voting, conversion, dividend and other rights and preferences that could adversely affect the voting power or other rights of our shareholders. An aggregate of 7,000,000 shares of Series A Preferred Stock were issued in our private placement in 2003, of which 73,334 were issued and outstanding as of December 31, 2004. The issuance of additional preferred stock or rights to purchase preferred stock may have the effect of delaying or preventing a change in control of the Company. In addition, the possible issuance of additional preferred stock could discourage a proxy contest, make more difficult the acquisition of a substantial block of the Company's Common Stock or limit the price that investors might be willing to pay for shares of the Company's Common Stock.

Anti-takeover effects of Minnesota law could discourage, delay or prevent a change in control.

As a publicly traded company, we are prohibited by the Minnesota Business Corporation Act, except under certain specified circumstances, from engaging in any merger, significant sale of stock or assets or business combination with any shareholder or group of shareholders who own at least 10% of our Common Stock.

ITEM 7. FINANCIAL STATEMENTS

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of
Sontra Medical Corporation
Franklin, MA

We have audited the accompanying consolidated balance sheets of Sontra Medical Corporation and Subsidiary as of December 31, 2004 and 2003, and the related consolidated statements of loss, changes in stockholders' equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits 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 consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Sontra Medical Corporation and Subsidiary as of December 31, 2004 and 2003, and the results of its consolidated operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ WOLF & COMPANY, P.C.

Boston, Massachusetts
January 21, 2005

SONTRA MEDICAL CORPORATION
Consolidated Balance Sheets

	As of December 31, 2004	As of December 31, 2003
Assets		
Current Assets:		
Cash and cash equivalents	$ 9,515,244	$ 4,868,933
Accounts receivable	16,821	1,500,000
Legal settlement receivable	250,000	—
Inventory, net	152,642	—
Prepaid expenses and other current assets	69,492	66,075
Total current assets	10,004,199	6,435,008
Property and Equipment, at cost:		
Computer equipment	206,970	171,272
Office and laboratory equipment	492,377	405,285
Furniture and fixtures	14,288	14,288
Manufacturing equipment	182,210	144,695
Leasehold improvements	174,698	166,289
	1,070,543	901,829
Less-accumulated depreciation and amortization	(655,242)	(498,341)
Net property and equipment	415,301	403,488
Other Assets:		
Restricted cash	38,997	48,746
Other assets	2,000	2,000
Total other assets	40,997	50,746
Total assets	$ 10,460,497	$ 6,889,242
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 358,530	$ 136,810
Accrued expenses	759,051	465,092
Total current liabilities	1,117,581	601,902
Commitments		
Stockholders' Equity:		
Series A Convertible Preferred Stock, $0.01 par value, authorized 7,000,000 shares, issued and outstanding 73,334 shares at December 31, 2004 (preference in liquidation of $76,291) and 6,495,000 shares at December 31, 2003	76,291	6,628,842
Common stock, $0.01 par value, authorized 40,000,000 shares, issued and outstanding 21,935,732 shares at December 31, 2004 and 10,102,992 shares at December 31, 2003	219,358	101,030
Additional paid-in capital	32,674,740	17,952,721
Deferred stock-based compensation	(244,912)	(372,874)
Accumulated deficit	(23,382,561)	(18,022,379)
Total stockholders' equity	9,342,916	6,287,340
Total liabilities and stockholders' equity	$ 10,460,497	$ 6,889,242

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

SONTRA MEDICAL CORPORATION
Consolidated Statements of Loss

	For the Years Ended December 31,	
	2004	2003
Revenue:		
Product revenues	$ 33,565	$ —
Licensing revenue	—	1,500,000
Total revenue	33,565	1,500,000
Cost of product revenue	16,680	—
Gross profit	16,885	1,500,000
Operating Expenses:		
Research and development	3,039,450	2,265,519
Selling, general and administrative	2,423,806	1,740,555
Total operating expenses	5,463,256	4,006,074
Loss from operations	(5,446,371)	(2,506,074)
Interest income	86,189	26,620
Net loss	(5,360,182)	(2,479,454)
Accretion of dividend and beneficial conversion feature on Series A Convertible Preferred Stock	(413,901)	(3,676,950)
Net loss applicable to common stockholders	$ (5,774,083)	$ (6,156,404)
Net loss per common share, basic and diluted	$ (0.34)	$ (0.65)
Basic and diluted weighted average common shares outstanding	16,763,798	9,467,912

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

SONTRA MEDICAL CORPORATION
Consolidated Statements of Changes in Stockholders' Equity

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Stock-Based Compensation	Subscription Receivable	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Carrying Value	Number of Shares	Carrying Value					
Balance at December 31, 2002	—	$ —	9,355,880	$ 93,559	$19,473,410	$(2,033,765)	$(17,294)	$(15,542,925)	$ 1,972,985
Issuance of Series A convertible preferred stock net of issuance costs of $771,455	7,000,000	7,000,000	—	—	(771,455)	—	—	—	6,228,545
Conversion of Series A preferred stock into common stock	(505,000)	(505,000)	505,000	5,050	499,950	—	—	—	—
Dividend paid on converted Series A preferred stock	—	(6,651)	6,651	66	6,585	—	—	—	—
Accretion of Series A preferred stock dividend	—	140,493	—	—	(140,493)	—	—	—	—
Post merger Choicetel adjustments	—	—	—	—	66,395	—	—	—	66,395
Exercise of common stock options	—	—	116,364	1,164	45,560	—	—	—	46,724
Stock issued to 401(k) plan	—	—	109,097	1,091	305,573	—	—	—	306,664
Amortization and remeasurement of options	—	—	—	—	(1,684,804)	1,660,891	—	—	(23,913)
Intrinsic value of options granted and repriced	—	—	—	—	129,600	—	—	—	129,600
Common stock issued for services	—	—	10,000	100	22,400	—	—	—	22,500
Forgiveness of stock subscription receivable	—	—	—	—	—	—	17,294	—	17,294
Net loss	—	—	—	—	—	—	—	(2,479,454)	(2,479,454)
Balance at December 31, 2003	6,495,000	6,628,842	10,102,992	101,030	17,952,721	(372,874)	—	(18,022,379)	6,287,340
Conversion of Series A preferred stock into common stock	(6,421,666)	(6,421,666)	6,421,666	64,217	6,357,449	—	—	—	—
Dividend paid on Series A preferred stock	—	(250,737)	248,371	2,484	248,253	—	—	—	—
Accretion of Series A preferred stock dividend	—	119,852	—	—	(119,852)	—	—	—	—
Post merger Choicetel adjustments	—	—	—	—	286,607	—	—	—	286,607
Exercise of common stock options	—	—	147,532	1,475	155,661	—	—	—	157,136
Stock issued to 401(k) plan	—	—	113,263	1,133	224,189	—	—	—	225,322
Fair value of options issued for services	—	—	—	—	23,832	—	—	—	23,832
Amortization and remeasurement of options	—	—	—	—	157,614	127,962	—	—	285,576
Stock issued upon exercise of warrants	—	—	2,265,908	22,659	3,261,931	—	—	—	3,284,590
Common stock issued in private placement net of issuance costs of $353,800	—	—	2,636,000	26,360	4,126,335	—	—	—	4,152,695
Net loss	—	—	—	—	—	—	—	(5,360,182)	(5,360,182)
Balance at December 31, 2004	73,334	$ 76,291	21,935,732	$219,358	$32,674,740	$ (244,912)	$ —	$(23,382,561)	$ 9,342,916

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

SONTRA MEDICAL CORPORATION
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2004	2003
Cash Flows From Operating Activities:		
Net loss	$(5,360,182)	$(2,479,454)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	156,901	154,932
Gain on sale of equipment	—	(5,461)
Stock-based compensation	309,408	105,687
Stock issued to 401(k) plan	225,322	306,664
Write off common stock loan	—	17,294
Common stock issued in exchange for services	—	22,500
Changes in assets and liabilities:		
Accounts receivable	1,483,179	(1,500,000)
Inventory	(152,642)	—
Prepaid expenses and other current assets	(3,417)	72,379
Accounts payable	221,720	(32,558)
Accrued expenses	293,959	(89,125)
Net cash used in operating activities	(2,825,752)	(3,427,142)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(168,714)	(373,922)
Sale of fixed assets	—	16,300
Decrease in restricted cash	9,749	51,254
Decrease in other assets	—	29,675
Net cash used in investing activities	(158,965)	(276,693)
Cash Flows From Financing Activities		
Cash received and adjustments to net assets related to ChoiceTel merger	36,607	66,395
Proceeds from the sale of Series A convertible preferred stock	—	6,228,545
Proceeds from the sales of common stock	4,152,695	—
Proceeds from the exercise of warrants	3,284,590	—
Proceeds from the exercise of stock options	157,136	46,724
Net cash provided by financing activities	7,631,028	6,341,664
Net Increase in Cash and Cash Equivalents	4,646,311	2,637,829
Cash and Cash Equivalents, beginning of period	4,868,933	2,231,104
Cash and Cash Equivalents, end of period	$ 9,515,244	$ 4,868,933
Supplemental Disclosure of Non Cash Financing Transactions:		
Accretion of dividend on Series A Convertible Preferred Stock	$ 119,852	$ 140,493
Conversion of Series A Convertible Preferred Stock into common stock	$ 6,421,666	505,000
Common stock issued for dividends on converted Series A Convertible Preferred Stock	$ 250,737	$ 6,651
Legal settlement receivable included in adjustments to net assets related to ChoiceTel merger	$ 250,000	$ —

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

SONTRA MEDICAL CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2004 and 2003

(1) ORGANIZATION AND BASIS OF PRESENTATION

On June 20, 2002, the Company (previously operating under the name ChoiceTel Communications, Inc. ("ChoiceTel")) consummated a merger with Sontra Medical, Inc. ("SMI"), pursuant to which SMI merged with and into a wholly owned subsidiary of the Company (the "Merger"). Subsequent to the consummation of the Merger, the Company changed its name to Sontra Medical Corporation and began operating in SMI's line of business. For accounting purposes, the Merger was treated as a capital transaction and a recapitalization, whereby the historical financial statements of SMI became the historical financial statements of the Company. Accordingly, from an historical accounting perspective, the Company's inception begins on January 29, 1996, upon the inception of SMI. The accounting treatment for the recapitalization is similar to that resulting from a business combination, except that goodwill and other intangible assets were not recorded. Because the financial statements of the Company only reflect the historical results of SMI prior to the Merger, and of the combined entities following the Merger, they do not include the historical financial results of ChoiceTel prior to the consummation of the Merger on June 20, 2002.

The accompanying consolidated financial statements include the accounts of Sontra Medical Corporation (the "Company") and its wholly-owned subsidiary, SMI. All significant inter-company balances and transactions have been eliminated in consolidation.

The Company is a medical company engaged in the development of transdermal diagnostic and drug delivery products based on its SonoPrep® ultrasonic skin permeation technology. On an historical basis since its inception, the Company has devoted substantially all of its efforts toward product research and development, raising capital and marketing products under development. The Company has incurred significant losses from operations since its inception and has primarily funded these losses through issuances of equity and convertible promissory notes.

As of September 30, 2003, the Company recognized $1,500,000 of license revenue under a license agreement with Bayer Diagnostics Division of Bayer Healthcare LLC (see Note 10) entered into on July 28, 2003. As a result, the Company is no longer considered a development stage company for financial reporting purposes.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying financial statements reflect the application of certain accounting policies as described in this note and elsewhere in the accompanying financial statements.

(a) Use of Estimates

The preparation of 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 disclosures of contingent assets and liabilities at the date of the financial statements and the amounts of revenues and expenses recorded during the reporting period. Actual results could differ from those estimates. Material estimates that are particularly susceptible to significant changes in the near term relate to the valuation of inventory, the recoverability of long-lived assets, the realizability of deferred tax assets and the fair value of equity instruments issued.

(b) Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of ninety days or less to be cash equivalents. Cash equivalents consist primarily of auction rate preferred shares and money market funds as of December 31, 2004 and 2003. Restricted cash at December 31, 2004 and 2003 represents a deposit on the Company's leased offices.

(c) Accounts Receivable

The Company provides credit terms to customers in connection with purchases of the Company's products. Credit terms, for approved customers, are generally on a net 30-day basis.

Management periodically reviews customer account activity in order to assess the adequacy of the allowances provided for potential losses. Factors considered include economic conditions and each customer's payment history and credit worthiness. Adjustments, if any, are made to reserve balances following the completion of these reviews to reflect management's best estimate of potential losses. No allowance for doubtful accounts was considered necessary at December 31, 2004 and 2003.

(d) Inventory

Inventories are stated at the lower of cost (first in, first out) or market and consist of the following at December 31, 2004:

Raw materials and work-in-process	$ 221,701
Demo inventory	9,205
Finished goods	21,736
	252,642
Less: reserve for obsolescence	(100,000)
Inventory, net	$ 152,642

Work-in-process and finished goods consist of material, labor and overhead. Finished goods consist of completed SonoPrep units, inventory used for demonstration purposes and procedure trays. The cost of SonoPrep demo units is amortized to cost of sales over a one year period. The reserve for obsolescence represents inventory the Company expects to use in prototype manufacturing as well as anticipated design changes and product enhancements that will make certain inventory obsolete.

(e) Depreciation and Amortization

The Company provides for depreciation and amortization by charges to operations for the cost of assets using the straight-line method based on the estimated useful lives of the related assets, as follows:

Asset Classification	Estimated Useful Life
Computer equipment	3 years
Office and laboratory equipment	3-5 years
Furniture and fixtures	7 years
Manufacturing equipment	5 years
Leasehold improvements	Life of lease

(f) Long-Lived Assets

In accordance with the Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment and Disposal of Long-Lived Assets*, the Company at least annually evaluates whether events or circumstances have occurred that indicate that the carrying value of these assets may be impaired. The Company believes there has been no significant impairment of its long-lived assets as of each of the balance sheet dates presented.

(g) Stock-Based Compensation

Statement of Financial Accounting Standards ("SFAS") No. 123, *Accounting for Stock-Based Compensation* encourages all entities to adopt a fair value based method of accounting for employee stock compensation plans, whereby compensation cost is measured at the grant date based on the value of the award and is recognized over the service period, which is usually the vesting period. However, it also allows an entity to continue to measure compensation cost for those plans using the intrinsic value based method of accounting prescribed by Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees*, whereby compensation cost is the excess, if any, of the quoted market price of the stock at the grant date (or other measurement date) over the amount an employee must pay to acquire the stock. Stock options issued under the Company's stock option plans generally have no intrinsic value at the grant date, and under APB No. 25 no compensation cost is recognized for them.

The Company applies APB No. 25 and related interpretations in accounting for stock options issued to employees and directors as more fully described in Note 8. Had compensation cost for the Company's stock options issued to employees and directors been determined based on the fair value at the grant dates consistent with SFAS No. 123, the Company's net loss and net loss per share would have been adjusted to the pro forma amounts indicated below:

	Twelve Months Ended December 31,	
	2004	2003
Net loss—as reported	$(5,360,182)	$(2,479,454)
Add: stock-based employee compensation under APB No. 25	230,334	105,687
Deduct: stock-based employee compensation determined under SFAS No. 123	(1,170,474)	(945,824)
Pro forma net loss	(6,300,322)	(3,319,591)
Accretion of preferred stock dividend and beneficial conversion feature of preferred stock	(413,901)	(3,676,950)
Net loss applicable to common stockholders - pro forma	$(6,714,223)	$(6,996,541)
Basic and diluted net loss per share, as reported	$ (0.34)	$ (0.65)
Basic and diluted net loss per share, pro forma	$ (0.40)	$ (0.74)

(h) Concentration of Credit Risk

SFAS No. 105, *Disclosure of Information about Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk*, requires disclosure of any significant off-balance-sheet risks and credit risk concentrations. The Company has no significant off-balance-sheet risk. Financial instruments, which subject the Company to credit risk, principally consist of cash and cash equivalents. The Company mitigates its risk by maintaining the majority its cash and equivalents with high-quality financial institutions.

(i) Financial Instruments

SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, requires disclosure about fair value of financial instruments. The estimated fair market value of the Company's financial instruments, which include cash and cash equivalents, restricted cash, accounts receivable and accounts payable, approximates their carrying value due to the short-term nature of these instruments.

(j) Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income*, requires disclosure of all components of comprehensive income (loss) on an annual and interim basis. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss is equal to net loss for all periods presented.

(k) Net Loss per Common Share

Basic and diluted net loss per share of the Company's common stock is presented in conformity with SFAS No. 128, *Earnings per Share*, for all periods presented. For the periods presented, options, warrants and convertible securities were anti-dilutive and excluded from diluted earnings (loss) per share calculations. Accordingly, basic and diluted net loss per share of common stock has been computed by dividing the net loss applicable to common stockholders in each period by the weighted average number of shares of common stock outstanding during such period.

(l) Segment Information

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, established standards for reporting information regarding operating segments and for related disclosures about products and services and geographical areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as principally one operating segment, which is development of transdermal diagnostics and drug delivery products for sale to the medical market. As of December 31, 2004 and 2003, all of the Company's assets were located in the United States.

(m) Research and Development Expenses

The Company charges research and development expenses to operations as incurred. Research and development expenses primarily consist of salaries and related expenses for personnel and consulting services. Other research and development expenses include fees paid to consultants and outside service providers, the costs of materials used in research and development, prototype manufacturing, information technology and facilities costs.

(n) Income Taxes

The Company accounts for federal and state income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes*. Under SFAS No. 109, deferred tax assets and liabilities are recognized based upon temporary differences between the financial statement and the tax basis of assets and liabilities. Deferred income taxes are

based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. SFAS No. 109 requires that a valuation allowance be recorded when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, since the Company cannot be assured of realizing the deferred tax asset, a full valuation allowance has been provided.

(o) Revenue Recognition

For product revenue, revenues are recognized when persuasive evidence of an arrangement exists in the form of a signed non-cancelable purchase order, the product is shipped, the selling price is fixed and determinable, and collection is reasonably assured.

(p) Recent Accounting Pronouncements

In December 2003, the Securities and Exchange Commission, ("SEC") issued Staff Accounting Bulletin ("SAB") No. 104, Revenue Recognition. SAB No. 104 supersedes SAB No. 101, Revenue Recognition in Financial Statements. SAB No. 104's primary purpose is to rescind accounting guidance contained in SAB No. 101 related to multiple element revenue arrangements, superseded as a result of the issuance of Emerging Issues Task Force ("EITF") No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. Additionally, SAB No. 104 rescinds the SEC's Revenue Recognition in Financial Statements Frequently Asked Questions and Answers ("FAQ") issued with SAB No. 101 that had been codified in SEC Topic No. 13, "Revenue Recognition". Selected portions of the FAQ have been incorporated into SAB No. 104. While the wording of SAB No. 104 has changed to reflect the issuance of EITF No. 00-21, the revenue recognition principles of SAB No. 101 remain largely unchanged by the issuance of SAB No. 104, which was effective upon issuance. The adoption of SAB No. 104 did not impact our consolidated financial statements.

In December 2003, the Financial Accounting Standards Board ("FASB") issued interpretation No. 46R ("FIN 46R"), Consolidation of Variable Interest Entities. FIN 46R expands upon existing accounting guidance that addresses when a company should include in its financial statements the assets, liabilities and activities of another entity. A variable interest entity is a corporation, partnership, trust or any other legal structure used for business purposes that either (a) does not have equity in investments with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. FIN 46R requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's or is entitled to receive a majority of the entity's residual returns or both. The adoption of this interpretation did not have any impact on our financial position or results of operations.

In December 2004, the FASB issued Statement of Financial Accounting Standard ("SFAS") No. 123R, Accounting for Stock-Based Compensation ("SFAS No. 123R"). SFAS No. 123R establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. SFAS No. 123R requires that the fair value of such equity instruments be recognized as an expense in the historical financial statements as services are performed. Prior to SFAS No. 123R, only certain pro forma disclosures of fair value were required. The provisions of this Statement are effective for small business issuers the first interim reporting period that begins after December 15, 2005. Accordingly, we will adopt SFAS No. 123R commencing with the quarter ending March 31, 2006. If we had included the fair value of employee stock options in our financial statements, our net loss for the years ended December 31, 2004 and 2003 would have been as disclosed in Note 2 above. Accordingly, the adoption of SFAS No. 123R is expected to have a material effect on our financial statements.

In December 2004, FASB issued SFAS No. 151 ("SFAS 151") Inventory Costs - an Amendment of ARB No. 43, Chapter 4. SFAS 151 clarifies the accounting for inventory when there are abnormal amounts of idle facility expense, freight, handling costs, and wasted materials. Under existing accounting principles, items such as idle facility expense, excessive spoilage, double freight, and re-handling costs may be "so abnormal" as to require treatment as current period charges rather than recorded as adjustments to the value of the inventory. SFAS 151 requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS 151 is not expected to have a material effect on our position or results of operations.

(3) MERGER AGREEMENT WITH CHOICETEL COMMUNICATIONS, INC.

At an annual meeting of ChoiceTel shareholders and a special meeting of SMI stockholders held on June 20, 2002, the stockholders of SMI and the shareholders of ChoiceTel approved and adopted the Agreement and Plan of Reorganization, dated as of February 27, 2002 (the "Merger Agreement"), among ChoiceTel, its wholly-owned subsidiary, CC Merger Corp., and SMI. Pursuant to the Merger Agreement, SMI merged with and into CC Merger Corp., with SMI surviving the merger as a wholly-owned subsidiary of ChoiceTel. Subsequent to the consummation of the Merger, ChoiceTel changed its name to Sontra Medical Corporation and began operating in SMI's line of business.

For accounting purposes, the Merger transaction is treated as a capital transaction and a recapitalization, whereby the historical financial statements of SMI became the historical financial statements of the combined entity. The accounting treatment for the recapitalization is similar to that resulting from an acquisition, except that goodwill and other intangible assets were not recorded.

Pursuant to the recapitalization and in consideration for the $4,794,524 of net assets that SMI received from ChoiceTel on June 20, 2002, the shareholders of ChoiceTel were deemed to have received 3,035,781 shares of the Company's common stock. SMI incurred $480,500 of merger costs which was reflected as a reduction in paid-in capital. In addition, the preferred stockholders of SMI converted their shares of Series A Preferred Stock and Series B Preferred Stock into common stock of SMI. Thereafter, 32,227,829 shares of SMI's common stock were exchanged at a ratio of .1927 for 6,210,289 shares of the Company's common stock. In addition, all options of SMI were assumed by the Company with no modifications other than to reflect the exchange ratio. Upon completion of the Merger, 9,246,084 shares of the Company's common stock were issued and outstanding, with the former ChoiceTel shareholders owning approximately 32.83% of the Company's common stock and the former SMI shareholders owning approximately 67.17% of the Company's outstanding common stock. All of the per share data for periods prior to the merger date have been retroactively adjusted by the .1927 exchange ratio to reflect the recapitalization. Since the merger date, certain adjustments were made to the net assets of ChoiceTel. These adjustments which, in the aggregate, increased net assets acquired by $154,992 have been recorded as an increase to additional paid in capital.

The Merger was intended to be a tax-free reorganization under Section 368(a)(1)(A) of the Internal Revenue Code of 1986, as amended.

(4) COMMITMENTS

Operating lease

The Company leases 12,999 square feet of office, laboratory and manufacturing space in Franklin, Massachusetts under a lease expiring March 10, 2008. Future minimum rental payments under this operating lease are approximately as follows:

	Amount
For the years ended December 31,	
2005	$161,000
2006	163,000
2007	171,000
2008	33,000
Total	$528,000

The Company's rent expense was approximately $129,000 and $134,000 for the years ended December 31, 2004 and 2003, respectively.

(5) PATENT LICENSE AGREEMENT

Effective June 30, 1998, SMI entered into a patent license agreement with the Massachusetts Institute of Technology (MIT) that granted SMI an exclusive right and license to certain existing and future MIT patents that relate to ultrasound enhancement of transdermal drug delivery.

The Company is obligated to pay MIT an annual license maintenance fee of $25,000. This license maintenance fee is payable starting January 1, 1999 and on January 1 of each year thereafter to the end of the term of the patent rights or until the agreement is terminated. In addition, the Company is obligated to pay MIT royalties up to 2% of net sales of products and processes using the licensed patents (the Licensed Products and Licensed Processes) used, leased or sold by the Company and/or its affiliates, as defined.

(6) SERIES A CONVERTIBLE PREFERRED STOCK

The Company is authorized in its Articles of Incorporation, as amended, to issue up to 10,000,000 shares of preferred stock with the rights, preferences and privileges to be fixed by the board of directors. The board of directors has authorized and designated the issuance of up 7,000,000 shares of Series A Convertible Preferred Stock with the rights, preferences and privileges as described below.

The Company completed a $7 million private placement to selected qualified purchasers of units consisting of shares of the Company's Series A Convertible Preferred Stock and warrants to purchase shares of the Company's Common Stock (the "Private Placement") in three closings on September 15, September 30, and October 15, 2003. In total, the Company received proceeds of $6,228,545, net of a placement agent fee and other offering costs. Individual investors, institutions and certain members of the Board of Directors purchased 7,000,000 shares of Series A Convertible Preferred Stock at a price of $1.00 per share. The investors also received warrants to purchase up to 7,000,000 shares of Common Stock.

Each share of Series A Convertible Preferred Stock is initially convertible into one share of Common Stock, subject to adjustment in certain events. The holders of shares of Series A Convertible Preferred Stock are entitled to receive annual 8% dividends, payable in cash or shares of Common Stock. The Company has the right to convert the shares of Series A Convertible Preferred Stock in the event that the closing price of the Common Stock for twenty consecutive trading days is equal to or greater than $3.00 per share. The Series A Convertible Preferred Stock has no voting power, except as otherwise required under the Minnesota Business Corporations Act. In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company, the holders of shares of Series A Convertible Preferred Stock are entitled to be paid an amount equal to $1.00 per share plus any accrued and unpaid dividends on such shares prior to any payment to the holders of common stock, but are not entitled to any further participation in distributions of any remaining net assets.

The warrants issued to the purchasers in the Private Placement are exercisable at a per share price of $1.50 and expire no later than the fifth anniversary of their issuance date. In addition, the Company has the right to terminate the warrants, upon thirty days notice, in the event that the closing price of the Common Stock for twenty consecutive trading days is equal to or greater than $4.00 per share. The warrants shall be exercisable during such thirty-day notice period.

In connection with the Private Placement, the placement agent received warrants to purchase an aggregate of 800,000 shares of Common Stock. Such placement agent warrants are exercisable at a per share price of $1.20 and expire no later than the fifth anniversary of their issuance date. In addition, the Company has the right to terminate the placement agent warrants, upon thirty days notice, in the event that the closing price of the Common Stock for twenty consecutive trading days is equal to or greater than $4.00 per share. The warrants shall be exercisable during such thirty-day notice period.

The Company allocated the $7,000,000 gross proceeds received to the Series A Convertible Preferred Stock and the warrants, including the placement agent warrants, based on the relative fair values as follows:

Series A Convertible Preferred Stock	$3,543,108
Warrants	3,456,892
Gross proceeds	$7,000,000

Based on the effective conversion price after the allocation of the gross proceeds, the Company recorded a beneficial conversion discount of $3,543,108 in 2003. As the Series A Convertible Preferred Stock is immediately convertible, this beneficial conversion discount was accreted immediately and reflected as a return to the Series A Preferred stockholders in the Statement of Loss for the year ended December 31, 2003 for purposes of calculating net loss applicable to common stockholders.

In conjunction with the 8% dividend on the Series A Convertible Preferred Stock, the Company accreted dividends of $119,852 and $140,493 for the years ended December 31, 2004 and 2003, respectively.

During the year ended December 31, 2004, 6,421,666 shares of Series A Convertible Preferred Stock were converted into common shares and there was a preferred dividend paid on such converted shares of $246,283 in the form of 246,283 shares of Common Stock. In December 2004, the Company paid an annual dividend of $4,454 that was paid in the form of 2,088 shares of Common Stock. At December 31, 2004, 73,334 shares of Series A Convertible Preferred Stock were outstanding.

During the year ended December 31, 2003, a total of 505,000 shares of Series A Convertible Preferred Stock converted into common shares and there was a preferred dividend paid on such converted shares of $6,651 in the form of 6,651 shares of Common Stock. At December 31, 2003, there were 6,495,000 shares of Series A Convertible Preferred Stock outstanding.

Dividends paid in conjunction with conversions of Series A Convertible Preferred Stock are paid based on a fixed common stock price of $1.00 per share. As a result, there is a beneficial conversion feature equal to the difference between the fair value of the common stock on the date the common shares are issued and the $1.00 per share conversion price. For the year ended December 31, 2004, the Company recorded a beneficial conversion related to dividends paid on converted Series A Convertible Preferred Stock of $294,049. The amount was not material for the year ended December 31, 2003.

(7) COMMON STOCK

The Company has authorized 40,000,000 shares of common stock, $0.01 par value per share, of which 21,935,732 and 10,102,992 shares were issued and outstanding, as of December 31, 2004 and 2003, respectively.

In December 2004, the Company issued 2,636,000 shares of Common Stock upon the closing of a private placement of stock that raised proceeds of $4,152,695 net of placement fee and other offering costs. In connection with the financing, the Company issued warrants to the investors to purchase 1,054,400 shares of common stock. In addition, the Company issued warrants to the placement agent to purchase 131,800 shares of Common Stock. The warrants have a five-year term and are exercisable at $2.45 per share. The Company has the right to terminate the warrants, upon thirty days notice, in the event that the closing price of the Company's common stock for twenty consecutive trading days is equal or greater than $4.90 per share.

During 2004, the Company issued 2,265,908 shares of common stock upon the exercise of warrants issued in connection with the Series A Convertible Preferred Stock Financing that provided the Company with proceeds of $3,284,590.

During 2004, 6,421,666 shares of common stock were issued upon the conversion of Series A Convertible Preferred Stock, 248,371 shares of common stock were issued upon the payment of dividends for the Series A Convertible Preferred Stock, 147,532 shares of common stock were issued for proceeds of $157,136 upon the exercise of stock options and 113,263 shares of common stock with a fair value of $225,322 were issued to the Company's 401(k) plan.

During 2003, 511,651 shares of common stock were issued upon the conversion of Series A Convertible Preferred Stock, 116,364 shares of common stock were issued for proceeds of $46,724 upon the exercise of stock options and 109,097 shares of common stock with a fair value of $306,664 were issued to the Company's 401(k) plan. In addition, the Company issued 10,000 shares with a fair value of $22,500 to a vendor for providing services. The $22,500 was charged to general and administrative expenses in 2003.

The Company has established the following reserves for the future issuance of common stock as follows:

Reserve for 401(k) plan	271,851
Reserve for exercise of warrants	7,509,749
Reserve for the conversion of and dividends on Series A Convertible Preferred Stock	378,312
Reserve for the exercise of stock options	3,313,291
Total reserves	11,473,203

(8) STOCK OPTION PLANS

In 1997, the Company adopted the 1997 Long-term Incentive and Stock Option Plan (the "1997 Plan"). Pursuant to the 1997 Plan, the Board of Directors (or committees and/or executive officers delegated by the Board) may grant incentive and nonqualified stock options to the Company's employees, officers, directors, consultants and advisors. The Company has reserved an aggregate of 1,500,000 shares of Common Stock for issuance upon exercise of options granted under the 1997 Plan. As of December 31, 2004, there were options to purchase an aggregate of 1,410,615 shares of Common Stock outstanding under the 1997 Plan, and 4,845 shares available for option grants hereunder.

In connection with the Merger, the Company assumed all outstanding options under the 1999 Sontra Medical, Inc. Stock Option and Incentive Plan (the "1999 Plan"). The Company may not grant any additional options under the 1999 Plan. The Company assumed options to purchase an aggregate of 845,172 shares of Common Stock under the 1999 Plan. As of December 31, 2004, there were options to purchase an aggregate of 478,831 shares of Common Stock outstanding under the 1999 Plan.

In March 2003, the Board of Directors adopted the 2003 Stock Option and Incentive Plan (the "2003 Plan"). The 2003 Plan was approved by the stockholders in May 2003. Pursuant to the 2003 Plan, the Board of Directors (or committees and/or executive officers delegated by the Board) may grant incentive and nonqualified stock options, restricted stock and other stock-based awards to the Company's employees, officers, directors, consultants and advisors. The Company has reserved an aggregate of 1,500,000 shares of Common Stock for issuance upon exercise of options granted under the 2003 Plan. The 2003 Plan provides that the number of shares authorized for issuance will automatically increase each January 1 by the greater of 4% of the outstanding number of shares of Common Stock on the immediately preceding December 31 or the aggregate number of shares made subject to equity-based awards during the one year prior to such January 1; or, in either case, such lesser number as may be approved by the Board. The maximum aggregate number of shares that may be authorized for issuance under the 2003 Plan for all periods is 2,500,000. As of December 31, 2004, there were options to purchase an aggregate of 1,058,333 shares of Common Stock outstanding under the 2003 Plan and 361,667 available for option grants hereunder. On January 1, 2005, the number of shares authorized for issuance under the 2003 Plan automatically increased by 877,429 shares.

Options granted generally vest 25% on the first anniversary of the vesting start date and 2.5% monthly thereafter. However, certain options granted were allowed accelerated vesting. Vested options expire after a ten-year period from the date of grant. Vesting for options under the 1997 Plan were 100% vested on the date of grant.

Stock-Based Compensation

On July 24, 2002 the Company granted under the 1997 Plan an option to purchase 50,000 shares to a member of the Scientific Advisory Board with a four year vesting schedule. On May 21, 2003 the Company granted under the 2003 Plan an option to purchase 50,000 shares to a member of the Scientific Advisory Board with a four year vesting schedule. The Company re-measures the fair value of these options each quarter using the Black-Scholes option pricing model and records the corresponding non-cash expense throughout the vesting period of these options. As a result, for the year ended December 31, 2004, the Company increased additional paid-in capital by $4,000 and decreased deferred compensation by $51,000, respectively, and recorded a non-cash compensation expense of $55,000 in the Statement of Loss. For the year ended December 31, 2003, the Company decreased additional paid-in capital and deferred compensation by $44,000 and $61,000, respectively, and recorded a non-cash compensation expense of $17,000 in the Statement of Loss.

On September 23, 2002, the Company repriced and/or exchanged certain options previously granted, pursuant to the Plans, to the Chief Executive Officer and Chief Financial Officer, which relate to a total of 850,000 shares of the Company's Common Stock. The new exercise prices for these options are between $.5189 and $2.55 per share. The Company records the compensation expense over the vesting period and re-measures the intrinsic value each period throughout the life of these options. As a result, for the year ended December 31, 2004, the Company increased additional paid-in capital by $153,000 and decreased deferred compensation by $74,000, respectively, and recorded a non-cash compensation expense of $227,000 in the Statement of Loss. For the year ended December 31, 2003, the Company decreased additional paid-in capital and deferred compensation by $1,653,000 and $1,610,000, respectively, and recorded a non-cash compensation benefit of $43,000 in the Statement of Loss. This re-measurement may result in unpredictable charges or credits to the Statement of Loss, which will depend on the fair value of the Company's Common Stock.

On May 21, 2003, the Company granted under the 2003 Plan options to purchase a total of 60,000 shares of Common Stock at an exercise price of $0.10 per share to two Board members that had provided consulting services to the Company. These options were fully vested upon grant. As a result, for the year ended December 31, 2003, the Company recorded additional paid in capital and a non-cash compensation charge to the Statement of Loss of $129,600.

During the quarter ended September 30, 2003, one employee received an option with intrinsic value on the grant date of $12,000. As a result, for the year ended December 31, 2003, the Company increased additional paid-in capital and deferred compensation by $12,000 and $10,000, respectively, and recorded a non-cash compensation expense of $2,000 in the Statement of Loss. For the year ended December 31, 2004, the Company decreased deferred compensation by $3,000 and recorded a non-cash compensation expense of $3,000 in the Statement of Loss.

During the year ended December 31, 2004, the Company granted options to purchase 15,000 shares of the Company's common stock at prices between $1.88 and $1.99 to consultants. These options were fully vested and the fair value of $23,832 was recorded as additional paid in capital and non-cash compensation in the Statement of Loss.

Information with respect to all activity under the 1997, 1999 and 2003 Plans is as follows:

	Number of Shares	Weighted Average Exercise Price
Balance December 31, 2002	2,193,818	$1.62
Granted	868,036	1.58
Cancelled	(160,179)	2.02
Exercised	(134,221)	0.91
Balance December 31, 2003	2,767,454	1.62
Granted	466,333	2.16
Cancelled	(138,476)	1.47
Exercised	(147,532)	1.07
Balance December 31, 2004	2,947,779	$1.74
Options Exercisable at December 31, 2004	1,701,572	
Options available for future grant, December 31, 2004	366,512	

All of the options issued from the 1997, 1999 and 2003 stock option plans have been previously approved by the Company's stockholders.

SFAS No. 123 requires the measurement of the fair value of stock options, to be included in the statement of operations or disclosed in the notes to financial statements (see Note 2). The Company has determined that it will continue to account for stock-based compensation for employees under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and has elected the disclosure-only alternative under SFAS Nos. 123 and 148 using the Black-Scholes option pricing model prescribed by SFAS No. 123. The assumptions used and weighted average information for the years ended December 31, 2003 and 2002 were as follows:

	2004	2003
Risk-free interest rate	4.00%	4.00%
Expected dividend yield	—	—
Expected lives	10 years	10 years
Expected volatility	136%	100%
Weighted average fair value per share of options granted	$ 1.77	$ 1.50

A summary of options outstanding at December 31, 2004, is as follows:

	December 31, 2004				
	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number	Weighted Average Remaining Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$.10 - $.52	508,831	7.48	$0.49	268,061	$0.47
$1.05 - $1.99	1,171,876	7.67	$1.55	526,295	$1.44
$2.00 - $2.55	1,267,072	7.88	$2.43	907,215	$2.45
Outstanding at end of year	2,947,779	7.72	$1.74	1,701,572	$1.82

(9) WARRANTS

At December 31, 2004, the Company had the following outstanding warrants:

	Number of Shares Exercisable	Exercise Price	Date of Expiration
Granted to investor relations company	10,000	$5.00	2/10/2005
Granted to investors and placement agent in private placement	629,457	$4.95	4/25/2005
Granted to investors in private placement	5,115,000	$1.50	9/15-10/15/2008
Granted to placement agent in private placement	419,092	$1.20	9/15-10/15/2008
Granted to investors and placement agent in private placement	1,186,200	$2.45	12/8-12/15/2009
Granted to investor in former subsidiary	150,000	$5.00	2/23/2010
Total	7,509,749		
Weighted average exercise price		$2.00	
Weighted average duration in years			3.64

(10) BAYER LICENSE AGREEMENT

On July 28, 2003, the Company and Bayer Diagnostics Division of Bayer Healthcare LLC ("Bayer") executed a definitive license agreement pursuant to which the Company granted to Bayer an exclusive worldwide right and license of the Company's intellectual property rights to make, have made, use, import and sell the continuous non-invasive glucose monitoring system. In consideration of the license and the Company's delivery of all information, materials and know-how in 2003 related to the licensed technology in 2003, Bayer agreed to pay the Company no later than January 15, 2004, a one-time, non-refundable license fee of $1.5 million. The Company recorded the $1.5 million license payment as accounts receivable and licensing revenue for year ended December 31, 2003. In January 2004, the Company collected the $1,500,000 receivable from Bayer.

Pursuant to the terms of the license agreement, the Company and Bayer may enter into one or more additional agreements to continue the joint development of the continuous non-invasive glucose monitoring system. Such agreements are expected to include, among other things, a $3.0 million milestone payment to the Company after the first phase of development of the product, a royalty agreement providing for the payment by Bayer to the Company of royalties based on net sales of the product and a manufacturing and supply agreement providing Sontra with the exclusive manufacturing rights of the SonoPrep device. In the event that Bayer does not complete the development of the product necessary to obtain FDA approval, the license shall convert to a non-exclusive license. Bayer has the right to terminate the agreement at any time following the payment of the license fee. In the event that Bayer terminates the agreement following the payment of the license fee, the license shall cease to be an exclusive license and shall become a co-exclusive license pursuant to which the Company will receive royalties based on net sales of the product.

(11) INCOME TAXES

No provision or benefit for federal or state income taxes has been recorded, as the Company has incurred a net loss for all periods presented, and has provided a valuation allowance against its deferred tax assets.

At December 31, 2004, the Company had federal net operating loss carryforwards of approximately $21,158,000, which will expire in varying amounts beginning in 2018. The Company also had research and development tax credit carryforwards of approximately $465,000 which will begin to expire in 2018 unless previously utilized. The United States Tax Reform Act of 1986 contains provisions that may limit the Company's net operating loss carryforwards available to be used in any given year in the event of significant changes in the ownership interests of significant stockholders, as defined.

Significant components of the Company's net deferred tax asset are as follows:

	December 31,	
	2004	2003
Deferred Tax Assets		
Net Operating loss carryforwards	8,146,000	$ 6,318,000
Research credit carryforward	465,000	375,000
Other temporary differences	17,000	(80,000)
Total deferred tax assets	8,628,000	6,613,000
Valuation allowance	(8,628,000)	(6,613,000)
Net deferred tax asset	$ —	$ —

In 2004, the Company's valuation allowance increased by $2,015,000. SFAS No. 109 requires that a valuation allowance be recorded when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Since the Company cannot be assured of realizing the deferred tax asset, a full valuation allowance has been provided.

(12) EMPLOYEE BENEFIT PLANS

The Company sponsors a 401(k) Plan that covers all eligible employees. Employees must be 21 years of age or older as of the plan's entry dates. In addition, employees become eligible to participate in the 401(k) Plan on the entry date occurring on or immediately after meeting the eligibility requirements, as long as they are in a group of employees eligible to participate on that entry date. Participants may contribute up to 20% of their compensation, not to exceed the maximum allowable by Internal Revenue Service regulations. Prior to June 30, 2002, the 401(k) Plan did not provide for employer matching contributions. In July 2002, the plan was amended to include a Company matching contribution equal to 100% of the participant's contribution up to the first 3% of compensation and 50% of the next 2% of compensation. In addition the Company may make profit sharing contributions at its discretion. The matching contribution and the profit sharing contribution are payable in cash or in the Company's common stock, at the discretion of the Board. For the year ended December 31, 2004, the Company contributed 113,263 shares of Company common stock to the 401(k) plan and recorded compensation expense of $225,322. For the year ended December 31, 2003, the Company contributed 109,097 shares of Company common stock to the 401(k) plan and recorded compensation expense of $306,664.

(13) LITIGATION

Based on the Company's activities in the public payphone market in Puerto Rico, commencing in August 2002, the Company had been participating in a lawsuit against GTE International Telecommunications, Inc. and Puerto Rico Telephone Company in the United States District Court for the District of Puerto Rico for violations of federal and Commonwealth antitrust laws, among others. The Company's lawsuit was joined by two other Puerto Rican payphone providers, Pan American Telephone Co., Inc. and In Touch Telecommunications, Inc. The lawsuit alleged that Puerto Rico Telephone Company and its operating company, GTE International Telecommunications, Inc., engaged in a pattern of unlawful exclusionary acts in order to maintain its monopoly position in the market for the provision of payphones to payphone location owners in Puerto Rico. In November 2003, the Company filed a notice of voluntary dismissal without prejudice with the Court, thereby withdrawing from the suit.

In December 2004, the Company entered into an agreement with the Puerto Rican Telephone Company ("PRTC") regarding alleged rate overcharges by PRTC related to the activity of ChoiceTel prior to the Merger (see Note 3). Pursuant to the agreement, the Company agreed to waive certain legal claims against PRTC in exchange for $250,000. The Company recorded the $250,000 payment as an adjustment to increase the net assets of ChoiceTel as it related to the resolution of a pre-acquisition contingency and consequently the Company recorded a receivable and additional paid in capital of $250,000 in 2004. The Company subsequently received the $250,000 settlement payment in January 2005.

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 8A. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during our fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 8B. OTHER INFORMATION

None.

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT

Incorporated by reference to the portions of the Definitive Proxy Statement entitled "Election of Directors," "Directors, Nominees for Director and Executive Officers," "The Board of Directors and its Committees," "Audit Committee Financial Expert," "16(a) Beneficial Ownership Reporting Compliance" and "Involvement in Legal Proceedings."

The Company has adopted a Code of Business Conduct and Ethics that applies to all directors, officers and employees of the Company, including the Company's principal executive officer, and its senior financial officers (principal financial officer and controller or principal accounting officer, or persons performing similar functions). A copy of the Company's Code of Business Conduct and Ethics is filed with or incorporated by reference in this report, and is also posted to the Company's website at www.sontra.com.

ITEM 10. EXECUTIVE COMPENSATION

Incorporated by reference to the portions of the Definitive Proxy Statement entitled "Executive Compensation" and "Director Compensation."

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Incorporated by reference to the portions of the Definitive Proxy Statement entitled "Securities Ownership of Certain Beneficial Owners and Management."

Equity Compensation Plan Information as of December 31, 2004

The following table sets forth certain information regarding the Company's equity compensation plans as of December 31, 2004. The Company has no equity compensation plans not previously approved by security holders.

	(a)	(b)	(c)
Plan Category	**Number of securities to be issued upon exercise of outstanding options, warrants and rights**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**
Equity compensation plans approved by security holders	2,947,779	$1.74	366,512(1)
Equity compensation plans not approved by security holders	N/A	N/A	N/A
Total	2,947,779	$1.74	366,512

(1) Consists of 4,845 shares authorized for issuance under the Company's 1997 Long-Term Incentive and Stock Option Plan and 361,667 shares authorized for future issuance under the Company's 2003 Stock Option and Incentive Plan (the "2003 Plan"). The Company initially reserved an aggregate of 750,000 shares of Common Stock for issuance upon exercise of options granted under the 2003 Plan. The 2003 Plan provides that the number of shares authorized for issuance will automatically increase each January 1 (beginning in 2004) by the greater of (i) 4% of the outstanding number of shares of Common Stock on the immediately preceding December 31, or (ii) the aggregate number of shares made subject to equity-based awards during the one year prior to such January 1; or, in either case, such lesser number as may be approved by the Board.

The maximum aggregate number of shares that may be authorized for issuance under the 2003 Plan for all periods is 2,500,000. As of December 31, 2004, there were options to purchase an aggregate of 1,058,333 shares of Common Stock outstanding under the 2003 Plan. On January 1, 2005, the number of shares authorized for issuance under the 2003 Plan automatically increased by 877,429 shares.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Incorporated by reference to the portions of the Definitive Proxy Statement entitled "Certain Relationships and Related Transactions."

ITEM 13. EXHIBITS

The Exhibits listed in the Exhibit Index immediately preceding such Exhibits are filed with or incorporated by reference in this report.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Incorporated by reference to the portions of the Definitive Proxy Statement entitled "Independent Registered Public Accounting Firm" and "Audit Committee Policy on Pre-Approval of Services of Independent Registered Public Accounting Firm."

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on February 16, 2005.

SONTRA MEDICAL CORPORATION

By: /s/ THOMAS W. DAVISON
Name: **Thomas W. Davison**
Title: **President and Chief Executive Officer**

By: /s/ SEAN F. MORAN
Name: **Sean F. Moran**
Title: **Chief Financial Officer**

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on February 16, 2005.

Signature and Title

/s/ MICHAEL R. WIGLEY
Michael R. Wigley
Chairman of the Board

/s/ THOMAS W. DAVISON
Thomas W. Davison
Chief Executive Officer,
President and Director
(Principal Executive Officer)

/s/ SEAN F. MORAN
Sean F. Moran
Chief Financial Officer
(Principal Financial and Accounting Officer)

Signature and Title

/s/ JOSEPH F. AMARAL
Joseph F. Amaral
Director

/s/ GARY S. KOHLER
Gary S. Kohler
Director

/s/ ROBERT S. LANGER
Robert S. Langer
Director

/s/ GERARD E. PUORRO
Gerard E. Puorro
Director

/s/ BRIAN F. SULLIVAN
Brian F. Sullivan
Director

EXHIBIT INDEX

Exhibit Number	Description of Document
2.1	Agreement and Plan of Reorganization by and among the Registrant, SMI and CC Merger Corp., dated February 27, 2002 is incorporated by reference to Exhibit 2.1 of the Registrant's Registration Statement on Form S-4 (File No. 333-86814).
2.2	Amendment No. 1 to Agreement and Plan of Reorganization by and among the Registrant, SMI and CC Merger Corp., dated February 27, 2002 is incorporated by reference to Exhibit 2.2 of the Registrant's Registration Statement on Form S-4 (File No. 333-86814).
3.1	Second Amended and Restated Articles of Incorporation of the Registrant is incorporated herein by reference to Exhibit 3.01 to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 000-23017).
3.2	Statement of the Powers, Designations, Preferences and Rights of the Series A Convertible Preferred Stock of the Registrant is incorporated herein by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-3 (File No. 333-109716).
3.3	Amended and Restated Bylaws of the Registrant is incorporated herein by reference to Exhibit 3.03 to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 000-23017).
4.1	Specimen Certificate of Common Stock, $.01 par value per share, of the Registrant is incorporated herein by reference to Exhibit 4.02 to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002 (File No. 000-23017).
10.1*	Director Voting Agreement, dated as of June 20, 2002, by and among Michael Wigley, Gary S. Kohler and each of the persons or entities listed on Annex A thereto is incorporated herein by reference to Exhibit 2 to Schedule 13D, dated as of June 20, 2002, filed July 1, 2002 (File No. 005-52931).
10.2*	2003 Stock Option and Incentive Plan is incorporated herein by reference to Exhibit 10.04 to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 000-23017).
10.3*	1997 Long-Term Incentive and Stock Option Plan, as amended, are incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-QSB for the period ended June 30, 2002 (File No. 000-23017).
10.4*	Sontra Medical, Inc. 1999 Stock Option and Incentive Plan is incorporated by reference to Exhibit 10.31 of the Registrant's Registration Statement on Form S-4 (File No. 333-86814).
10.5*	Employment Agreement between the Registrant and Thomas W. Davison, dated May 20, 2002, is incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-QSB for the period ended June 30, 2002 (File No. 000-23017).
10.6*	Employment Agreement between the Registrant and Sean Moran, dated June 22, 2002, is incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-QSB for the period ended June 30, 2002 (File No. 000-23017).
10.7	License Agreement, dated as of July 28, 2003, by and between the Registrant and Bayer Healthcare LLC is incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated July 28, 2003 (File No. 000-23017).
10.8	Lease Agreement between the Registrant and Forge Park Investors LLC dated January 24, 2003 is incorporated herein by reference to Exhibit 10.13 to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002 (File No. 000-23017).

Exhibit Number	Description of Document
10.9	Patent License Agreement (Exclusive) between SMI and the Massachusetts Institute of Technology dated June 30, 1998 (incorporated by reference to Exhibit 10.39 of the Registrant's Registration Statement on Form S-4; Registration No. 333-86814).
10.10*	401(k) Retirement Plan is incorporated herein by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002 (File No. 000-23017).
10.11	Form of Subscription Agreement is incorporated herein by reference to Appendix C to the Registrant's Definitive Schedule 14A filed September 8, 2003 (File No. 000-23017).
10.12	Form of Series A Unit Supplemental Agreement is incorporated herein by reference to Appendix F to the Registrant's Definitive Schedule 14A filed September 8, 2003 (File No. 000-23017).
10.13	Pre-Emptive Rights Granted to Purchasers of Series A Preferred Stock of the Registrant is incorporated herein by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K dated October 14, 2003 (File No. 000-23017).
10.14	Form of Common Stock Purchase Warrant is incorporated herein by reference to Appendix E to the Registrant's Definitive Schedule 14A filed September 8, 2003 (File No. 000-23017).
10.15	Form of Placement Agent Common Stock Purchase Warrant is incorporated herein by reference to Exhibit 99.4 to the Registrant's Registration Statement on Form S-3 (File No. 333-109716).
10.16	Common Stock and Warrant Purchase Agreement, dated as of December 8, 2004, by and among the Company and the investors listed on Schedule 1 thereto, is incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated December 8, 2004 (File No. 000-23017).
10.17	Form of Common Stock Purchase Warrant is incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated December 8, 2004 (File No. 000-23017).
14	Code of Business Conduct and Ethics of the Registrant is incorporated herein by reference to Exhibit 14 to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 000-23017).
21	Subsidiaries of the Registrant is incorporated herein by reference to Exhibit 21 to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002 (File No. 000-23017).
23.1	Consent of Wolf & Company, P.C.
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management contract or compensatory plan or arrangement filed in response to Item 13 of Form 10-KSB.

Exhibit 31.1

CERTIFICATION

I, Thomas W. Davison, certify that:

1. I have reviewed this annual report on Form 10-KSB of Sontra Medical Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report.

4. The small business issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the small business issuer and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The small business issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of small business issuer's board of directors (or persons performing the equivalent function):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: February 16, 2005

/s/ THOMAS W. DAVISON

Thomas W. Davison
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Sean F. Moran, certify that:

1. I have reviewed this annual report on Form 10-KSB of Sontra Medical Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report.

4. The small business issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the small business issuer and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The small business issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of small business issuer's board of directors (or persons performing the equivalent function):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: February 16, 2005

/s/ SEAN F. MORAN

Sean F. Moran
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-KSB of Sontra Medical Corporation (the "Company") for the fiscal year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas W. Davison, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ THOMAS W. DAVISON

Thomas W. Davison
President and Chief Executive Officer

February 16, 2005

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-KSB of Sontra Medical Corporation (the "Company") for the fiscal year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sean F. Moran, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

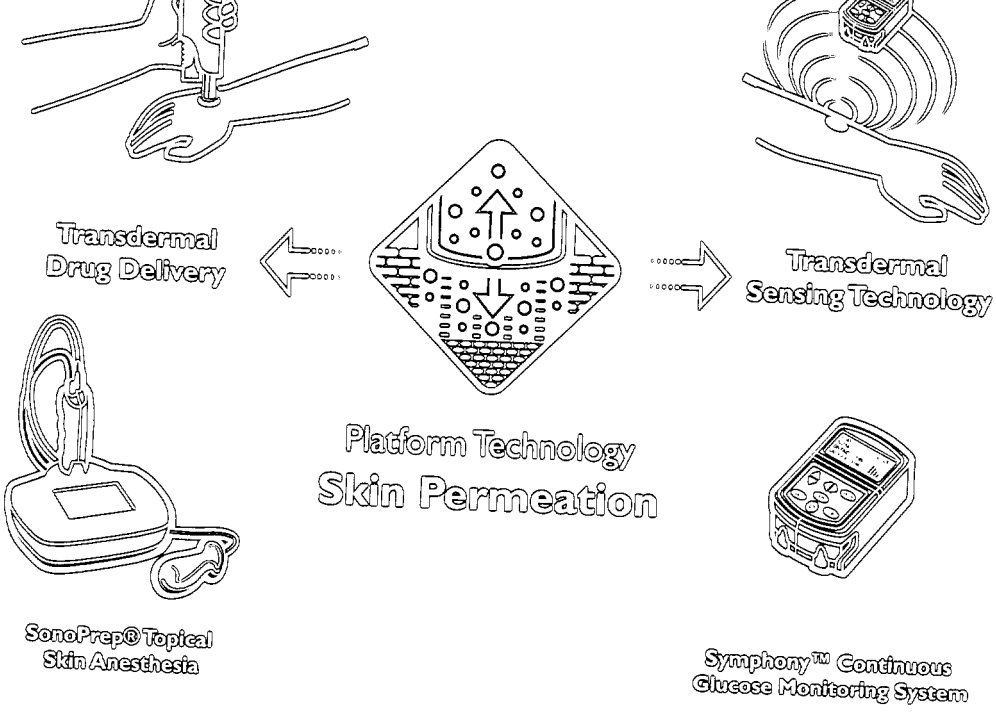
(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ SEAN F. MORAN

Sean F. Moran
Chief Financial Officer

February 16, 2005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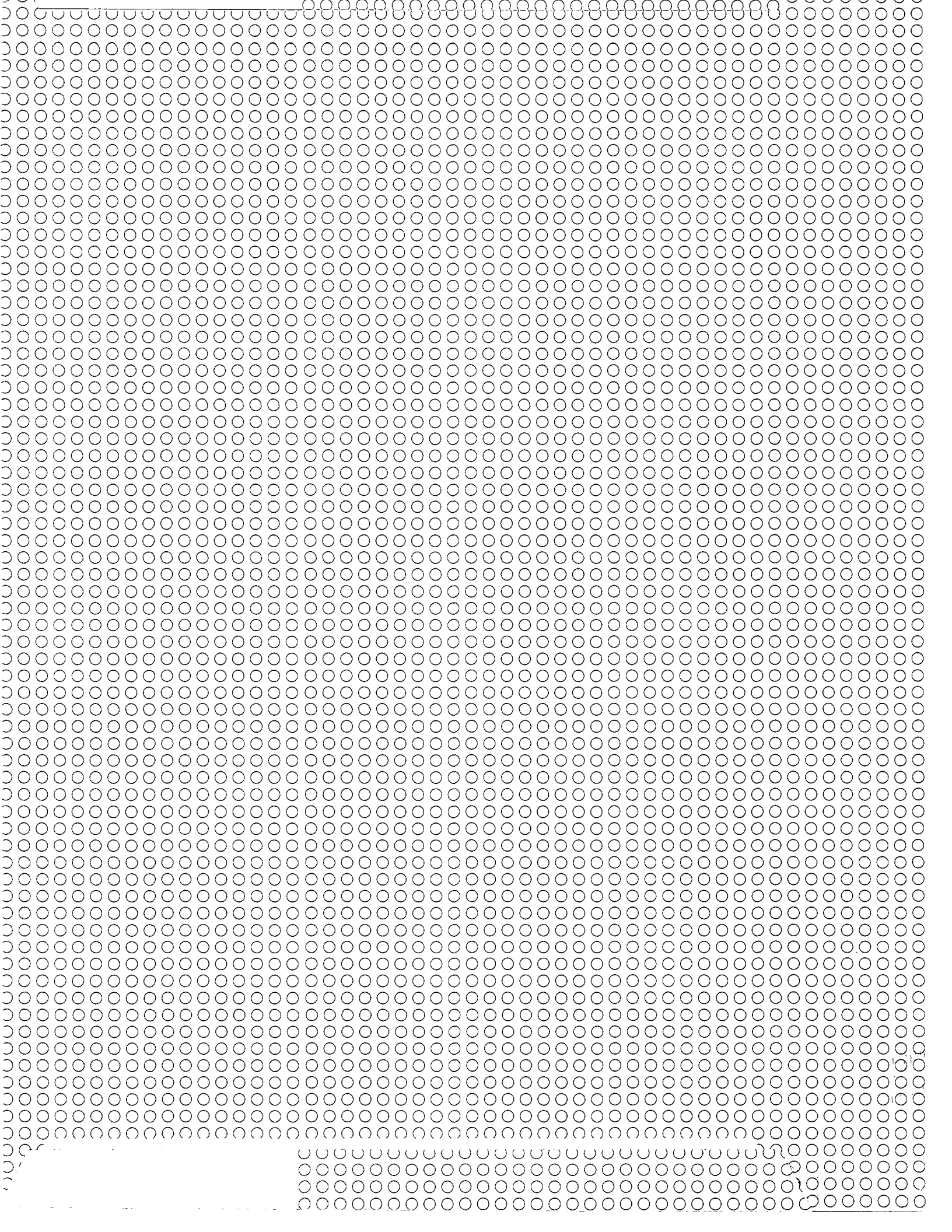
Drug Delivery
Transdermal
Sensing Technology
Platform Technology
Skin Permeation
SonoPrep® Topical
Skin Anesthesia
Symphony™ Continuous
Glucose Monitoring System



MANAGEMENT

Thomas W. Davison, Ph.D.
President & Chief Executive Officer

Sean Moran
Vice President of Finance & Chief Financial Officer

Scott Kellogg
Vice President of Research & Development

Barry Marston
Vice President of Sales & Marketing

Skip Farinha
Vice President of Operations & Regulatory Affairs

Kathy Dickinson
Director of Clinical Research

Nicholas Warner
Director of Product Design & Development

Douglas Kornbluth
Director of Quality Assurance

BOARD OF DIRECTORS

Michael R. Wigley
Chairman of the Board, President & C.E.O., Great Plains Companies, Inc.

Thomas W. Davison, Ph.D.
President & C.E.O., Sontra Medical Corporation

Robert S. Langer, Sc.D.
Professor of Chemical & Biomedical Engineering, Massachusetts Institute of Technology

Gary S. Kohler
Partner & Portfolio Manager, Pyramid Trading, L.P.

Joseph F. Amaral, M.D.
President & C.E.O., Rhode Island Hospital

Brian F. Sullivan
President & C.E.O., SterilMed, Inc.

Gerald E. Puorro
President & C.E.O., Candela Corporation

CORPORATE COUNSEL

Browne Rosedale & Lanouette
31 St. James Avenue, Suite 830
Boston, MA 02116-4101

INDEPENDENT AUDITORS:

Wolf & Company
99 High Street
Boston, MA 02110

TRANSFER AGENT:

Wells Fargo Shareholder Services
161 North Concord Exchange
South Paul, MN 55075-1139
TEL 800-689-8788

STOCK LISTING

The common stock of Sontra Medical Corporation is traded on the Nasdaq Small Cap under the symbol SONT

Sontra
MEDICAL CORPORATION

HEADQUARTERS

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Franklin, MA 02038 USA

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