SONTRA MEDICAL CORP
Form 10QSB
November 12, 2003
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-QSB

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2003

Commission File Number: 000-23017

SONTRA MEDICAL CORPORATION

(Exact name of small business issuer as specified in its charter)

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

(508) 553-8850

(Registrant s telephone number, including area code)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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 x No ¨

As of November 11, 2003, the Registrant had 9,829,761 shares of Common Stock outstanding.

Transitional Small Business Disclosure Format (Check one): Yes ¨ No x

Table of Contents

SONTRA MEDICAL CORPORATION

FORM 10-QSB INDEX

		Page Number
Part I - Financial Information		
Item 1.	Consolidated Financial Statements	
	Consolidated Balance Sheets as of September 30, 2003 (Unaudited) and December 31, 2002	3
	Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2003 and 2002 (Unaudited)	4
	Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2003 and 2002 (Unaudited)	5
	Notes to Consolidated Financial Statements (Unaudited)	6
Item 2.	Management s Discussion and Analysis or Plan of Operation	13
Item 3.	Controls and Procedures	20
Part II - Other Information		
Item 1.	Legal Proceedings	21
Item 2.	Changes in Securities	21
Item 4.	Submission of Matters to a Vote of Security Holders	22
Item 6.	Exhibits and Reports on Form 8-K	23
	Signatures	24

Table of Contents

SONTRA MEDICAL CORPORATION

Consolidated Balance Sheets

	As of	
	September 30, 2003	**December 31, 2002**
	(Unaudited)	
Assets:		
Current Assets:		
Cash and cash equivalents	$ 2,800,435	$ 2,231,104
Accounts receivable	1,500,000	
Prepaid expenses and other current assets	170,017	138,454
Total current assets	4,470,452	2,369,558
Property and Equipment, at cost		
Computer equipment	162,408	154,479
Office and laboratory equipment	403,496	383,807
Furniture and fixtures	14,288	14,071
Leasehold improvements	166,288	287,035
	746,480	839,392
Less: accumulated depreciation and amortization	(460,623)	(644,055)
Net property and equipment	285,857	195,337
Restricted Cash	148,746	100,000
Other Assets	2,000	31,675
Total assets	$ 4,907,055	$ 2,696,570
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 287,828	$ 169,368
Accrued expenses	335,823	554,217
Total current liabilities	623,651	723,585
Commitments		
Stockholders Equity:		
Series A Convertible Preferred Stock $0.01 par value, authorized 7,000,000 shares at September 30, 2003 issued and outstanding 3,674,167 shares at September 30, 2003 (preference in liquidation of $3,683,614 at September 30, 2003)	3,233,405	
Common Stock, $0.01 par value, authorized 40,000,000 shares issued and outstanding 9,425,186 shares at September 30, 2003 and 9,355,880 at December 31, 2002	94,252	93,559
Additional paid-in capital	17,977,397	19,473,410
Deferred stock-based compensation	(322,298)	(2,033,765)

Subscriptions receivable		(17,294)
Accumulated deficit	(16,699,352)	(15,542,925)
Total stockholders equity	4,283,404	1,972,985
Total liabilities and stockholders equity	$ 4,907,055	$ 2,696,570

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

Table of Contents

SONTRA MEDICAL CORPORATION

Consolidated Statements of Operations

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	**2002**	**2003**	**2002**
Licensing Revenue	$ 1,500,000	$	$ 1,500,000	$
Operating Expenses:				
Research and development	509,143	539,461	1,482,991	1,400,085
General and administrative	137,705	544,494	1,187,930	1,370,874
Total operating expenses	646,848	1,083,955	2,670,921	2,770,959
Income (loss) from operations	853,152	(1,083,955)	(1,170,921)	(2,770,959)
Interest income	2,357	20,290	14,494	23,016
Net income (loss)	855,509	(1,063,665)	(1,156,427)	(2,747,943)
Accretion of dividend and beneficial conversion feature on Series A Convertible Preferred Stock	(2,206,371)		(2,206,371)	
Accretion of dividend on Series B Redeemable Convertible Preferred Stock				(148,101)
Net loss applicable to common stockholders	$ (1,350,862)	(1,063,665)	$ (3,362,798)	$ (2,896,044)
Net loss per common share, basic and diluted	$ (0.14)	$ (0.11)	$ (0.36)	$ (0.57)
Basic and diluted shares outstanding	9,411,395	9,265,775	9,383,232	5,099,338

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

Table of Contents

Sontra Medical Corporation

Consolidated Statements of Cash Flows

	Nine Months Ended September 30,	
	2003	**2002**
	(Unaudited)	**(Unaudited)**
Cash Flows From Operating Activities:		
Net loss	$ (1,156,427)	$ (2,747,943)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	117,213	104,086
Gain on sale of property and equipment	(4,239)	
Stock based compensation	30,450	312,533
Stock issued to 401(k) plan	31,097	
Write-off of subscription receivable	17,293	
Changes in operating assets and liabilities:		
Accounts receivable	(1,500,000)	
Prepaid expenses and other current assets	(31,563)	(113,408)
Accounts payable	118,460	80,447
Accrued expenses	(81,955)	(101,719)
Net cash used in operating activities	(2,459,671)	(2,466,004)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(219,794)	(76,782)
Sale of property and equipment	16,300	8,428
(Increase) decrease in restricted cash	(48,746)	10,500
Decrease in other assets	29,675	
Net cash used in investing activities	(222,565)	(57,854)
Cash Flows From Financing Activities		
Cash received and adjustments to net assets related to ChoiceTel merger		4,727,566
Proceeds from the sale of preferred stock and warrants	3,223,958	980,107
Proceeds from stock option exercise	27,609	29,449
Net cash provided by financing activities	3,251,567	5,737,122
Net Increase in Cash and Cash Equivalents	569,331	3,213,264
Cash and Cash Equivalents, beginning of period	2,231,104	381,067
Cash and Cash Equivalents, end of period	$ 2,800,435	$ 3,594,331
Supplemental Disclosure of Non Cash Financing Transactions:		
Accretion of dividend on Series A & B Preferred Stock	$ 9,447	$ 148,101
Accretion of beneficial conversion feature on Series A Convertible Preferred Stock	$ 2,196,924	$

Conversion of Series A and B Preferred Stock into common stock	$	$ 11,548,997
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	$	$

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

Table of Contents

SONTRA MEDICAL CORPORATION

Notes to Consolidated Financial Statements

September 30, 2003

(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

On June 20, 2002, the Company (previously operating under the name ChoiceTel Communications, Inc. (ChoiceTel)) consummated the 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 period from inception for the Company 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 presented above 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. Accordingly, the financial statements may not be indicative of future results of operations or the historical results that would have resulted if the Merger had occurred at the beginning of a historical financial period.

The condensed consolidated financial statements included herein have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). These consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, SMI. All significant inter-company balances and transactions have been eliminated in consolidation. These financial statements should be read in conjunction with the Company s audited financial statements and related footnotes for the fiscal year ended December 31, 2002, which are included in the Company s Annual Report on Form 10-KSB filed with the SEC on March 31, 2003. In the opinion of the Company s management, the unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments (consisting only of normal recurring accruals) necessary to present fairly the Company s financial position as of September 30, 2003 and the results of operations and cash flows for the three and nine months ended September 30, 2003 and 2002. Certain information and footnote disclosures normally included in the financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to the relevant SEC rules and regulations. However, the Company believes that its disclosures are adequate to make the information presented not misleading. The results of operations for the interim periods are not necessarily indicative of the results of operations for the full fiscal year or any other interim period.

The Company is a medical device 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 entered into on July 28, 2003. As a result, the Company is no longer considered a development stage company for financial reporting purposes.

Table of Contents

SONTRA MEDICAL CORPORATION

Notes to Consolidated Financial Statements

September 30, 2003

(Unaudited)

(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 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 reported amounts of expenses 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 recoverability of long-lived assets, value of intellectual property and the realizability of deferred tax assets.

(b) Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of ninety days or less to be cash equivalents. Cash equivalents consist primarily of money market funds as of September 30, 2003 and December 31, 2002.

(c) 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
Leasehold improvements	Life of lease

(d) Revenue Recognition

The Company complies with Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition in Financial Statements and related guidance. SAB No. 101 provides guidance regarding the recognition, presentation and disclosure of revenue in financial statements filed with the SEC.

Revenue is recognized when all of the following criteria have been met: (a) evidence of an agreement exists, (b) delivery to the customer has occurred, (c) the price to the customer is fixed and determinable, and (d) collectibility is reasonably assured.

(e) Merger Ratio

On June 20, 2002, in connection with the Merger Agreement with SMI, SMI s stockholders approved a merger ratio in which 0.1927 shares of the Company s Common Stock were issued for each share of SMI s Common Stock. All Common Stock information presented herein has been retroactively adjusted to reflect the 0.1927 merger ratio (see Note 3).

(f) Stock-Based Compensation

In December 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure, an Amendment of FASB Statement No. 123.* This Statement provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends disclosure requirements to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results.

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 APB

Table of Contents

SONTRA MEDICAL CORPORATION

Notes to Consolidated Financial Statements

September 30, 2003

(Unaudited)

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 Opinion No. 25 no compensation cost is recognized for them.

The Company does not plan to adopt the fair value accounting model for stock-based employee compensation under SFAS No. 123. The Company applies Opinion No. 25 and related interpretations in accounting for stock options issued to employees, consultants and directors. 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:

	Three months ended September 30,		Nine months ended September 30,	
	2003	2002	2003	2002
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Net income (loss), as reported	$ 855,509	$ (1,063,665)	$ (1,156,427)	$ (2,747,943)
Add: stock-based employee compensation expense (benefit) included in reported loss	(21,657)	12,533	30,450	312,533
Deduct: Total stock based employee compensation determined under fair value based methods for all awards	(207,949)	(34,174)	(685,780)	(850,839)
Pro forma net income (loss)	625,903	(1,085,306)	(1,811,757)	(3,286,249)
Less accretion of beneficial conversion feature and dividends on preferred stock	2,206,371		2,206,371	148,101
Pro forma net loss applicable to common stockholders	$ (1,580,468)	$ (1,085,306)	$ (4,018,128)	$ (3,434,350)
Basic and diluted net loss per share, as reported	$ (0.14)	$ (0.11)	$ (0.36)	$ (0.57)
Basic and diluted net loss per share, pro forma	$ (0.17)	$ (0.11)	$ (0.43)	$ (0.67)

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 September 30, 2003, there were options to purchase an aggregate of 1,398,281 shares of Common Stock outstanding under the 1997 Plan, and 23,179 shares available for option grants thereunder.

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 September 30, 2003, there were options to purchase an aggregate of 659,228 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 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 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 September 30, 2003, there were options to purchase an aggregate of 750,000 shares of Common Stock outstanding under the 2003 Plan.

Table of Contents

SONTRA MEDICAL CORPORATION

Notes to Consolidated Financial Statements

September 30, 2003

(Unaudited)

On July 24, 2002 the Company granted 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 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 quarter ended September 30, 2003, the Company decreased additional paid-in capital and deferred compensation by $32,000 and $34,000, respectively, and recorded a non-cash compensation expense of $2,000 in the Statement of Operations.

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 quarter ended September 30, 2003, the Company decreased additional paid-in capital and deferred compensation by $102,000 and $78,000, respectively, and recorded a non-cash compensation benefit of $24,000 in the Statement of Operations. This re-measurement may result in unpredictable charges or credits to the Statement of Operations, which will depend on the fair value of the Company s Common Stock.

During the quarter ended September 30, 2003, the Company granted options to purchase an aggregate of 610,000 shares of the Company s common stock at prices ranging from $1.45 to $2.10 to certain employees. One employee received an option with intrinsic value on the grant date of $12,000. As a result, in the quarter ending September 30, 2003, the Company increased additional paid-in capital and deferred compensation by $12,000 and $11,000, respectively, and recorded a non-cash compensation expense of $1,000 in the Statement of Operations.

(g) Net Loss per Common Share

Basic and diluted net loss per share of the Company s Common Stock are presented in conformity with SFAS No. 128, *Earnings per Share*, for all periods presented. For the periods represented, options, warrants and convertible securities were anti-dilutive and excluded from diluted net income (loss) per share calculation. Accordingly, for these periods, 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.

(h) 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, information technology and facilities costs.

(i) 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. Valuation allowances are provided as needed to reduce deferred tax assets to the amount expected to be realized. 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. No provision or benefit for federal or state income taxes has been recorded.

(j) Recently Issued Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. This statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability. Many of those instruments were previously classified as equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of this statement did not have any impact on the Company s financial position or results of operations.

Table of Contents

SONTRA MEDICAL CORPORATION

Notes to Consolidated Financial Statements

September 30, 2003

(Unaudited)

(3) MERGER AGREEMENT WITH SONTRA MEDICAL, INC.

On June 20, 2002, the Company consummated the Merger with SMI, pursuant to which SMI merged with and into a wholly owned subsidiary of the Company. 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. 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.

Pursuant to the recapitalization and in consideration for the $4,612,480 of net assets that SMI received from ChoiceTel on June 20, 2002, the shareholders of ChoiceTel were deemed, for accounting purposes, to have received 3,035,795 shares of SMI 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 0.1927 for 6,210,289 shares of the Company s Common Stock. In addition, all outstanding options of SMI were assumed by the Company in connection with the Merger 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. The share data for all periods presented have been retroactively adjusted by the 0.1927 exchange ratio to reflect the recapitalization. Since the Merger date, certain adjustments including an additional litigation liability were made to the net assets of ChoiceTel. These adjustments, which reduced net assets acquired by $60,848 since the Merger date, were recorded as a reduction in additional paid in capital.

(4) 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. The defendants have filed a motion to dismiss the case. The Company had reached an agreement with plaintiffs counsel in the case that limits the Company s legal costs to $150,000 for this case in exchange for sharing a portion of any proceeds the Company may receive with plaintiffs counsel. Under the agreement with plaintiffs counsel (as amended on each of April 4, 2003, May 7, 2003 and July 11, 2003), the Company had deposited 33,529 shares of its Common Stock with an initial value of $150,000 in an escrow account. In September 2003, plaintiffs counsel notified the Company that it was withdrawing from the suit. Plaintiffs counsel returned the 33,529 shares of Common Stock to the Company and the Company has no further obligations to make payments to Plaintiffs counsel. In the quarter ended September 30, 2003, the Company recorded a benefit of $150,000 in the Statement of Operations to reflect the return of the 33,529 shares of Common Stock and the release from obligation. The Company has decided to withdraw from the suit and expects to file a notice of voluntary dismissal without prejudice with the Court.

10

Table of Contents

SONTRA MEDICAL CORPORATION

Notes to Consolidated Financial Statements

September 30, 2003

(Unaudited)

(5) COMMITMENTS

On January 24, 2003, the Company entered into a five-year lease agreement for 12,999 square feet of office, laboratory and manufacturing space in a single facility located at 10 Forge Parkway, Franklin, Massachusetts. Future minimum rental payments under this lease are approximately as follows:

	Amount
For the years ended December 31,	
2003	$ 142,000
2004	142,000
2005	163,000
2006	164,000
2007	172,000
Thereafter	33,000
Total	$ 816,000

(6) SERIES A CONVERTIBLE PREFERRED STOCK FINANCING

The Company has completed a 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). On September 15, 2003, the Company completed the initial closing of the Private Placement, providing the Company with proceeds of approximately $2.9 million, net of the placement agent fee. Individual investors, institutions and certain members of the Board of Directors purchased 3,139,167 shares of the Company s Series A Convertible Preferred Stock, at a per share purchase price of $1.00. The investors also received warrants to purchase up to 3,139,167 shares of Common Stock.

On September 30, 2003, the Company completed the second closing of the Private Placement, providing the Company with approximately $500,000 in additional proceeds, net of the placement agent fee. Investors purchased 535,000 shares of Series A Preferred Stock, at a per share purchase price of $1.00. The investors also received warrants to purchase up to 535,000 shares of Common Stock.

Each share of Series A Preferred Stock is initially convertible into one share of Common Stock, subject to adjustment in certain events. The holders of shares of Series A 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 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 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 gross proceeds received through September 30, 2003 to the Series A Preferred Stock and the warrants, including the placement agent warrants, based on the relative fair values as follows:

Series A Preferred Stock	$ 2,196,924
Warrants	1,477,243
Gross proceeds	$ 3,674,167

Table of Contents

SONTRA MEDICAL CORPORATION

Notes to Consolidated Financial Statements

September 30, 2003

(Unaudited)

Based on the effective conversion price after the allocation of the gross proceeds, the Company recorded a beneficial conversion discount of $2,196,924. As the Series A 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 Operations for the quarter ended September 30, 2003 for purposes of calculating net income (loss) applicable to common stockholders.

In conjunction with the 8% dividend on the Series A Preferred Stock, the Company accreted dividends of $9,447 in the quarter ended September 30, 2003.

Subsequent to September 30, 2003, the Company completed the third and final closing of the Private Placement, providing the Company with approximately $3.1 million in additional proceeds, net of the placement agent fee. Investors purchased the remaining 3,325,833 shares of Series A Preferred Stock, at a per share purchase price of $1.00. The investors also received warrants to purchase up to 3,325,833 shares of Common Stock. In the Private Placement, the Company issued to investors an aggregate of 7,000,000 shares of Series A Preferred Stock and warrants to purchase 7,000,000 shares of Common Stock.

(7) 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 Symphony Diabetes Management System. In consideration of the license and the Company s delivery of all information, materials and know-how related to the licensed technology, Bayer agreed to pay to the Company, no later than January 15, 2004, a one-time, non-refundable license fee of $1.5 million, subject to (i) receipt from the Nasdaq Listing Qualifications Panel of an exception from the Nasdaq SmallCap Market s minimum $2.5 million stockholders equity continued listing requirement, (ii) receipt of a minimum of $1.5 million in financing from third parties prior to such date, and (iii) having stockholders equity on September 30, 2003 of at least $2.5 million.

On August 27, 2003, the Nasdaq Listing Qualifications Panel granted the Company a conditional exception from Nasdaq s minimum $2.5 million stockholders equity requirement for continued listing on the Nasdaq SmallCap Market. On September 15, 2003 and September 30, 2003, the Company completed two closings of its Series A Preferred Stock financing, yielding aggregate proceeds of approximately $3.4 million (see Note 6). On September 30, 2003, the Company had total stockholders equity of $4,283,000. As of September 30, 2003, the Company had met all of the conditions required under the Bayer license agreement obligating Bayer to pay the Company $1.5 million as a licensing payment, such payment to be made prior to January 15, 2004. The Company recorded the $1.5 million license payment as accounts receivable and licensing revenue for the quarter ended September 30, 2003.

The Company and Bayer are also expected to enter into one or more additional agreements to continue the joint development of the Symphony Diabetes Management 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.

Table of Contents

Item 2. Management s Discussion and Analysis or Plan of Operation

Forward-Looking Statements

The following discussion of the consolidated financial condition and results of operations of the Company should be read in conjunction with the unaudited consolidated financial statements and the related notes thereto included elsewhere in this Form 10-QSB. Except for the historical information contained herein, the following discussion, as well as other information in this report, contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. Some of the forward-looking statements can be identified by the use of forward-looking terms such as believes, expects, may, will, should, could, seek, intends, plans, estimates, anticipates or other comparable t Forward-looking statements involve inherent risks and uncertainties. A number of important factors could cause actual results to differ materially from those in the forward-looking statements. We urge you to consider the risks and uncertainties described in Factors That May Affect Future Results in this report. We undertake no obligation to update our forward-looking statements to reflect events or circumstances after the date of this report. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made.

Overview

On June 20, 2002, we consummated the Merger with SMI, pursuant to which SMI merged with and into a wholly-owned subsidiary of the Company. Subsequent to the consummation of the Merger, we changed our 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. 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 results of the Company discussed herein reflect the historical results of only SMI prior to the Merger, and the combined company following the Merger on June 20, 2002, they do not include the historical financial results of ChoiceTel prior to the consummation of the Merger. Accordingly, the financial results may not be indicative of future results or the historical results that would have resulted if the Merger had occurred at the beginning of a historical financial period.

We are a medical device company focused on developing non-invasive, transdermal, diagnostic and drug delivery products based on our SonoPrep® ultrasound-mediated skin permeation technology. Our lead product in development is our Symphony Diabetes Management System for the continuous non-invasive monitoring of glucose levels in diabetic patients. Other products in development that are based upon the our SonoPrep® skin permeation technology include skin preparation to improve electrophysiology tests, the enhanced transdermal delivery of topically applied drugs, and the transdermal drug delivery of large molecule injectable biopharmaceuticals.

On an historical basis, we have incurred net losses since the inception of SMI in 1996. As of September 30, 2003, we had an historical accumulated deficit of $16,699,000. Our losses have resulted principally from costs incurred in conjunction with our research and development initiatives. We expect additional losses in the foreseeable future primarily as a result of our research and development activities and other administrative-related expenses.

Critical Accounting Policies

Financial Reporting Release No. 60, which was recently issued by the Securities and Exchange Commission, requires all registrants to discuss critical accounting policies or methods used in the preparation of the financial statements. Management has determined that its critical accounting policies relate to revenue recognition and the accounting for equity instruments.

As described in more detail in the notes to the consolidated financial statements, we apply SAB No. 101, Revenue Recognition in Financial Statements and related guidance. Accordingly, we recognize revenue when all of the following criteria have been met: (a) evidence of an agreement exists, (b) delivery to the customer has occurred, (c) the price to the customer is fixed and determinable, and (d) collectibility is reasonably assured. The Company is required to use judgment in determining when all of the above criteria have been met.

The Company has elected to continue to apply the provisions of APB No. 25 rather than adopt SFAS No. 123. This means that for options granted to employees and board members with an exercise price equal to the fair value on the grant date, the Company does not record any compensation expense in its consolidated financial statements. For options granted to non-employees, the Company is required to make a number of estimates in order to determine the fair value of the options. These estimates include a risk-free interest rate, the volatility of the Company s stock and, in certain cases, expectations about the number of shares that will eventually vest.

Table of Contents

Further, we have made a number of estimates and assumptions that affect reported amounts of assets, liabilities and expenses, and actual results may differ from those estimates. As we are a company that has not yet generated recurring revenues, the areas that require the greatest degree of management judgment are the assessment of the recoverability of long-lived assets, value of intellectual property, and the realization, if any, of our net deferred tax assets.

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

Results of Operations

Comparison of the quarter and nine months ended September 30, 2003 versus 2002

Licensing Revenue. Licensing revenue of $1,500,000 in the quarter ending September 30, 2003 represents the license payment due from Bayer under the license agreement signed on July 28, 2003.

Research and Development Expenses. Research and development expenses decreased by $30,000 to $509,000 for the quarter ended September 30, 2003 from $539,000 for the quarter ended September 30, 2002. This decrease was primarily due to a reduction in consulting costs, partially offset by an increase in clinical trial expenses.

Research and development expenses increased by $83,000 to $1,483,000 for the nine months ended September 30, 2003 from $1,400,000 for the nine months ended September 30, 2002. This increase was primarily due to an increase in clinical trial expenses, partially offset by a reduction in consulting costs.

General and Administrative Expenses. General and administrative expenses decreased by $407,000 to $138,000 for the quarter ended September 30, 2003 from $545,000 for the quarter ended September 30, 2002. The decrease was primarily attributable to a $150,000 reversal of an accrual for legal expenses, reduction in head-count, travel and outside consulting and investor relations costs.

General and administrative expenses decreased by $183,000 to $1,188,000 for the nine months ended September 30, 2003 from $1,371,000 for the nine months ended September 30, 2002. The decrease is attributable to a reduction in stock compensation expense of $283,000, the $150,000 reversal of an accrual for legal expenses and reductions in investor relations and outside consulting costs, partially offset by having three quarters of expenses in 2003 for the senior management team and public company expenses versus only one quarter of these costs in 2002.

Interest Income. Interest income was $2,000 for the quarter ended September 30, 2003 compared to interest income of $20,000 for the quarter ended September 30, 2002. This decrease in interest income is attributable to the Company having a lower average cash balance in 2003 compared to 2002 and also to lower interest rates.

Interest income was $15,000 for the nine months ended September 30, 2003 compared to interest income of $23,000 for the six months ended September 30, 2002. This decrease in interest income is attributable to the Company having a lower average cash balance in 2003 compared to 2002 and also to lower interest rates.

Liquidity and Capital Resources

The Company is a medical device company that has not yet generated recurring product revenue and, on an historical basis, has financed its operations, since the inception of SMI, primarily through private sales of preferred stock, the issuance of convertible promissory notes, and the cash received in connection with the Merger.

Net cash used in operating activities was $2,460,000 for the nine months ended September 30, 2003. The net loss for the nine months ended September 30, 2003 was $1,156,000 and included in this loss were non-cash expenses of $117,000 for depreciation and amortization, $30,000 non-cash stock compensation expense and $31,000 of non-cash expense related to stock contributed to the Company s 401(k) plan**.** Although the Company recognized $1,500,000 of licensing revenue in the nine months ended September 30, 2003, all of this was receivable at September 30, 2003 and is not expected to be collected until January 2004.

Net cash used in investing activities was $223,000 for the nine months ended September 30, 2003. Purchases of property and equipment, primarily related to the build-out of the Company s new office space, used $220,000 of cash. There was a $49,000 increase in restricted cash due to cash collateralizing a letter of credit related to the new office space partially offset by a decrease in long term assets of $30,000 representing the deposit on the Company s former office space.

Net cash from financing activities provided $3,252,000 of cash for the nine months ended September 30, 2003. The first two closings from the Series A Preferred Stock financing raised $3,224,000 and option exercises generated cash of $28,000**.** Subsequent to September 30, 2003, the Company raised an additional $3,100,000 from the third and final closing of the Series A Preferred Financing.

Table of Contents

As discussed above, as of September 30, 2003 we had an accumulated deficit of $16,699,000 from an historical accounting perspective and expect to continue to generate operating losses for the foreseeable future. The Company had $2.8 million of cash at September 30, 2003 and together with the additional $3.1 million raised in October 2003 and the $1.5 million that Bayer is obligated to pay no later than January 2004, the Company expects that these funds will be sufficient to meet its operating requirements for the foreseeable future. The Company will be required to raise a substantial amount of capital in order to reach and sustain profitability and to complete the commercialization of our products. Our ability to fund these future capital requirements will depend on many factors, including the following:

- our ability to obtain funding from third parties, including any future collaborative partners;
- our 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 our 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 our products, if successfully developed and approved.

Factors That May Affect Future Results

The Company operates in a rapidly changing environment that involves a number of risks, some of which are beyond our control. The following discussion highlights some of these risks, which may adversely affect our future operating results.

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 $16,699,000 as of September 30, 2003. It is possible that the Company will never generate any additional revenue or 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 its obligations in strategic collaborations.

Our independent accountants have noted concerns about our ability to continue as a going concern in their report on our audited financial statements for the year ended December 31, 2002, which may have an adverse impact on our ability to raise necessary additional capital and on our stock price.

The Company has generated limited revenue since inception (from an historical accounting perspective), and does not expect to generate revenues 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 its SonoPrep® technology and to meet other cash requirements in the future. However, 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. If the Company is unable to raise sufficient additional financing we will not be able to continue our operations.

Given these future capital requirements, our auditors have added a going concern paragraph to their audit report for our financial statements for the fiscal year ended December 31, 2002. A going concern paragraph with an audit opinion means that the auditor has identified certain conditions or events that indicate there could be substantial doubt about our ability to continue as a going entity for a period of at least one year from the date of the financial statements. The inclusion of this explanatory paragraph in the report of our auditors on our 2002 financial statements may have an adverse impact on our ability to raise necessary additional capital and on our stock price. We cannot assure you that we will be able to continue as a going concern. Even if we successfully raise adequate financing to continue as a going concern beyond December 31, 2003, we will need substantial additional capital to reach product commercialization and reach and sustain profitability. 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.

We have received a delisting notice from Nasdaq because of our failure to meet the stockholders equity continued listing requirement.

Table of Contents

Our Common Stock is currently listed for trading on the Nasdaq SmallCap Market. On June 18, 2003 we received a letter from Nasdaq stating that Sontra had failed to comply with the minimum $2.5 million stockholders equity requirement for continued listing set forth in Marketplace Rule 4310(c)(2)(B) and that as a result, our Common Stock is subject to delisting from the Nasdaq SmallCap Market. On July 31, 2003 we had a hearing with the Nasdaq Listing Qualifications Panel and on August 25, 2003, the Nasdaq Listings Qualifications Panel granted Sontra a conditional exception from Nasdaq s minimum $2.5 million stockholders equity requirement for continued listing set forth in Marketplace Rule 4310(c)(2)(B). The exception received from Nasdaq is subject to certain conditions. As required by Nasdaq, we filed with the Securities and Exchange Commission on October 14, 2003, a balance sheet evidencing stockholders equity of at least $2.5 million. In addition, Nasdaq has required that we timely file our Form 10-QSB for the third quarter of 2003 showing stockholders equity of at least $2.5 million as of September 30, 2003. We will also be required to submit to Nasdaq, on or before January 30, 2004, an unaudited balance sheet and income statement for the fiscal year ending December 31, 2003 evidencing stockholders equity of at least $2.5 million. Finally, we will be required to timely file our Form 10-KSB for fiscal 2003 showing stockholders equity of at least $2.5 million as of December 31, 2003. Provided that Sontra is deemed to meet each of the conditions on a timely basis, our Common Stock will remain listed on The Nasdaq SmallCap Market. In the event that Sontra fails to meet any of the conditions, our Common Stock will be delisted from Nasdaq. If the Company s Common Stock is removed from the Nasdaq SmallCap Market, stockholders ability to sell, or obtain quotations of the market value of, shares of Sontra s Common Stock would be severely limited. 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.

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 Symphony Diabetes Management System, will require the formation 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 the Symphony Diabetes Management System. Sontra and Bayer are also expected to enter into one or more additional agreements to continue the joint development of the Symphony Diabetes Management System. We may not be able to enter into any additional collaborative arrangements 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 operation 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 operation 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, some of which may be outside of our control;

Table of Contents

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.

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

Our products under development have a high risk of failure because they are in the early stages of development. To date, we have only tested the feasibility of our SonoPrep® technology for various applications, including glucose monitoring, transdermal drug delivery and certain aesthetic applications. Although the Company has filed a 510(k) application seeking marketing clearance from the FDA for our SonoPrep® device for use in electrophysiology applications, none of the products currently being developed by the Company have received regulatory approval or clearance for commercial sale. Substantial expenditures for additional research and development, 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 before commercial production of any 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 Symphony Diabetes Management 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 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 clearance 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, from the United States Food and Drug Administration (FDA). In November 2002, we filed a 510(k) application seeking marketing clearance from the FDA for our SonoPrep® device for use in electrophysiology applications. In order to obtain marketing clearance for our Symphony Diabetes Management System, we will be required to file a PMA application that demonstrates the safety and effectiveness of the product. The PMA process is more rigorous and lengthier 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 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. 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.

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

We have an exclusive world-wide license to use and sell certain technology owned by the Massachusetts Institute of Technology (MIT) related to our ultrasound-mediated skin permeation technology. This license, which includes eight issued patents in the United States, three issued foreign patents, one pending U.S. patent and three pending foreign patent applications, comprises a substantial portion of our patent portfolio relating to our technology.

Table of Contents

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 or the strategy for determining when such licensed patents should be enforced. Instead, the Company relies upon MIT to determine the appropriate strategy for prosecuting and enforcing these patents. If MIT does not adequately protect or enforce 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 obtain and 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, one pending U.S. patent and three pending foreign patent applications, and as of November 10, 2003, we owned three issued patents and seven pending patent applications in the United States and sixteen PCT 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® device and Symphony Diabetes Management System, 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.

Table of Contents

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 Symphony Diabetes Management 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, Cygnus, Inc., SpectRx and TheraSense, Inc. The Company s SonoPrep® device will also compete with numerous companies developing drug delivery products such as Nektar Therapeutic Systems, Inc., 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 and 3M Company.

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 our competitors have products in various stages of development and commercialization similar to our SonoPrep® device and Symphony Diabetes Management 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 and upon successful development and commercialization of our products, we intend to obtain product liability insurance in the amount of $5,000,000. 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.

Our management has significant influence over the control of Sontra.

Our officers and directors beneficially own a significant percentage of the outstanding shares of our Common Stock. Accordingly, our officers and directors currently have significant influence over the outcome of any corporate transaction or other matters submitted to the shareholders for approval, including mergers, consolidations and the sale of all or substantially all of the Company s assets, and also could prevent or cause a change in control. Third parties may be discouraged from making a tender offer or bid to acquire the Company because of this concentration of ownership. Our officers and directors percentage ownership of shares of our Common Stock will decrease when and if our outstanding shares of Series A Preferred Stock and warrants to purchase common stock are exercised or converted, as the case may be.

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 is understaffed and has very 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 if the business begins to grow. Failure to attract and retain personnel, particularly management and technical personnel would materially harm our business, financial condition and results of operations.

Table of Contents

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;
- 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 your ownership 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 stockholders 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.

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, including shares issued subsequent to September 30, 2003, of Series A Preferred Stock are currently issued and outstanding. 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 our Common Stock or limit the price that investors might be willing to pay for shares of our Common Stock.

Item 3. Controls and Procedures

Disclosure Controls and Procedures. The Company s management, with the participation of the Company s Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company s disclosure controls and procedures (as such term is defined in Rules 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of the end of the period covered by this report. Based on such evaluation, the Company s Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company s disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act.

Internal Control Over Financial Reporting. There have not been any changes in the Company s internal control over financial reporting (as such term is defined in Rules 13a-15(f) under the Exchange Act) during the fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Table of Contents

Part II Other Information

Item 1. Legal Proceedings

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. The defendants have filed a motion to dismiss the case. The Company had reached an agreement with plaintiffs counsel in the case that limits the Company s legal costs to $150,000 for this case in exchange for sharing a portion of any proceeds the Company may receive with plaintiffs counsel. Under the agreement with plaintiffs counsel (as amended on each of April 4, 2003, May 7, 2003 and July 11, 2003), the Company had deposited 33,529 shares of its Common Stock with an initial value of $150,000 in an escrow account. In September 2003, plaintiffs counsel notified the Company that it was withdrawing from the suit. Plaintiffs counsel returned the 33,529 shares of Common Stock to the Company and the Company has no further obligations to make payments to Plaintiffs counsel. The Company has decided to withdraw from the suit and expects to file a notice of voluntary dismissal without prejudice with the Court.

Item 2. Changes in Securities

Statement of the Powers, Designations, Preferences and Rights of the Series A Convertible Preferred Stock

On September 15, 2003, in connection with the Private Placement described below, the Company 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 terms of the Series A Preferred Stock are as follows:

Rank; Liquidation Preference. The Series A Preferred shall rank prior to the holders of Common Stock and prior to all other classes of capital stock currently outstanding, or hereafter established, unless otherwise provided in the terms of such class, with respect to the distribution of the Company s assets upon a change of control, bankruptcy, liquidation or other similar event. The liquidation preference for the Series A Preferred is an amount equal to the purchase price of the Series A Preferred plus any accrued and unpaid dividends.

Dividends and Voting Rights. The Series A Preferred bears 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 Common Stock at the Company s discretion. The Series A Preferred has no voting power, except as otherwise required under the Minnesota Business Corporations Act.

Conversion. The Series A Preferred is convertible, at the option of the holder, into shares of Common Stock at an initial conversion price equal to the per unit price in the Private Placement. Therefore, initially each share of Series A Preferred is convertible into one share of Common Stock.

Forced Conversion. If, on any date after the effectiveness of the Registration Statement filed in connection with the Private Placement, the closing price of the Common Stock for twenty (20) consecutive trading days equals at least $3.00, the Company shall have the right, at its option, to convert all, but not less than all, of the outstanding shares of Series A Preferred into shares of Common Stock at an initial conversion price equal to the per unit price in the Private Placement.

Adjustments to Conversion Price. During the period of time ending on the later to occur of (1) the first anniversary of the initial closing of the Private Placement, (2) the date that is 90 days after the effectiveness of the Registration Statement filed in connection with the Private Placement and (3) the date that is the 30th consecutive trading day where the closing price of the Common Stock equals at least $1.00 per share, the Series A Preferred shall have full ratchet anti-dilution rights with respect to certain future issuances of the Company s equity securities. The Series A Preferred also contains adjustment provisions upon the occurrence of stock splits, stock dividends, combinations, distributions, reclassifications or similar events affecting the Common Stock.

Redemption. At any time after the fifth anniversary of the initial closing of the Private Placement, the Company shall have the right to redeem the shares of Series A Preferred at a price equal to the purchase price of the Series A Preferred plus any accrued and unpaid dividends, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting the number of issued and outstanding shares of Series A Preferred.

The foregoing description of the Certificate of Designations does not purport to be complete and is qualified in its entirety by reference to the full text of the Certificate of Designations which is filed as an exhibit to this Form 10-QSB and is incorporated by reference herein.

Table of Contents

Series A Preferred Stock Financing

We have completed a private placement to selected qualified purchasers of units consisting of shares of our Series A Convertible Preferred Stock and Warrants to purchase shares of our Common Stock (the Private Placement). On September 15, 2003, we completed the initial closing of the Private Placement, providing Sontra with proceeds of approximately $2.9 million net of a placement agent fee. Individual investors, institutions and certain members of the Board of Directors purchased 3,139,167 shares of the Company s Series A Convertible Preferred Stock, at a per share purchase price of $1.00. The investors also received warrants to purchase up to 3,139,167 shares of Common Stock. On September 30, 2003, we completed the second closing of the Private Placement, providing Sontra with approximately $500,000 in additional proceeds, net of a placement agent fee. Investors purchased 535,000 shares of Series A Preferred Stock, at a per share purchase price of $1.00. The investors also received warrants to purchase up to 535,000 shares of Common Stock. On October 14, 2003, we completed the final closing of the Private Placement, providing Sontra with approximately $3.1 million in additional proceeds, net of a placement agent fee. Investors purchased the remaining 3,325,833 shares of Series A Preferred Stock, at a per share purchase price of $1.00. The investors also received warrants to purchase up to 3,325,833 shares of Common Stock.

Each share of Series A Preferred Stock is initially convertible into one share of Common Stock, subject to adjustment in certain events. The holders of shares of Series A 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 Preferred Stock in the event that the closing price of our Common Stock for twenty consecutive trading days is equal to or greater than $3.00 per share. 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, we have the right to terminate the warrants, upon thirty days notice, in the event that the closing price of our 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, we have the right to terminate the placement agent warrants, upon thirty days notice, in the event that the closing price of our 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 also paid to the placement agent for its services in connection with the Private Placement a cash fee of seven percent of the proceeds raised in the Private Placement from institutional investors other than members of the Board of Directors of the Company and/or their respective affiliates (three percent in the event such institutional investors were referred by other brokers), a cash fee of ten percent of the proceeds raised in the Private Placement from other investors other than members of the Board of Directors of the Company and/or their respective affiliates, and a cash fee equal to three percent of the proceeds of the Private Placement raised from members of the Board of Directors of the Company and/or their respective affiliates. The Company agreed to pay the reasonable expenses incurred by the placement agent in connection with the Private Placement, subject to an aggregate limitation of $40,000. The placement agent also received a success fee in the form of a one-year consulting agreement with the Company paying an aggregate of $60,000.

The shares of Series A Preferred 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 Private Placement.

Issuance to CEOcast, Inc.

On October 24, 2003, the Company entered into a Consulting Agreement with CEOcast, Inc. whereby the Company will receive certain investor relations-related services from CEOcast, Inc. As partial payment under the Consulting Agreement, on October 24, 2003, the Company issued 10,000 shares of Common Stock to CEOcast, Inc. The offer and sale of these securities was effected without registration in reliance on the exemption afforded by Section 4(2) of the Securities Act of 1933, as amended, as a sale by the Company not involving a public offering. No underwriters were involved in the issuance and sale of these securities

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

At the Special Meeting of Shareholders of the Company (the Special Meeting) held on September 30, 2003, the Company s shareholders voted upon a proposal to approve the issuance of shares of the Company s Common Stock representing more than 19.99% of the outstanding shares of Common Stock upon conversion of shares of the Company s Series A Preferred Stock and the exercise of the Company s Common Stock Purchase Warrants. The number of shares of Common Stock issued, outstanding and eligible to vote as of the record date of August 26, 2003 was 9,458,714. The results of the voting on the matter presented to shareholders at the Special Meeting are set forth below:

Table of Contents

	Votes For	Votes Withheld	Votes Against	Abstentions	Broker Non-Votes
Approval of the issuance of shares of the Company s Common Stock representing more than 19.99% of the outstanding shares of Common Stock upon conversion of shares of the Company s Series A Preferred Stock and the exercise of the Company s Common Stock Purchase Warrants	2,735,367	0	8,150	77,100	0

Item 6. Exhibits and Reports on Form 8-K

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

(b) Reports on Form 8-K

Date Filed or Furnished	Item No.	Description
July 30, 2003	Items 5, 7	On July 30, 2003, Sontra filed a Current Report on Form 8-K dated July 28, 2003 to report that it entered into a definitive license agreement with the Bayer Diagnostics Division of Bayer Healthcare LLC. No financial statements were filed with such report.
August 27, 2003	Items 5, 7	On August 27, 2003, Sontra filed a Current Report on Form 8-K dated August 27, 2003 to report that its Common Stock will continue to be listed on The Nasdaq SmallCap Market pursuant to a conditional exception from Nasdaq s minimum $2.5 million stockholders equity requirement for continued listing set forth in Marketplace Rule 4310(c)(2)(B). No financial statements were filed with such report.
September 16, 2003	Item 5	On September 16, 2003, Sontra filed a Current Report on Form 8-K dated September 15, 2003 to report that it completed the first closing of its Preferred Stock financing. No financial statements were filed with such report.
October 1, 2003	Items 5, 7	On October 1, 2003, Sontra filed a Current Report on Form 8-K dated September 30, 2003 to report that it completed the second closing of its Preferred Stock financing, and that on September 30, 2003, at a special meeting of shareholders, Sontra s shareholders voted upon and approved of the issuance of shares of Sontra s Common Stock representing more than 19.99% of the outstanding shares of Common Stock upon conversion of the Series A Preferred Stock and the exercise of the warrants issued in connection therewith. No financial statements were filed with such report.
October 14, 2003	Items 5, 7	On October 14, 2003, Sontra filed a Current Report on Form 8-K dated October 14, 2003 to file as an exhibit the Company s unaudited consolidated balance sheet as of September 30, 2003 evidencing stockholders equity of at least $2.5 million.
October 16, 2003	Items 5, 7	On October 16, 2003, Sontra filed a Current Report on Form 8-K dated October 14, 2003 to report that it completed the third and final closing of its Preferred Stock financing. No financial statements were filed with such report.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SONTRA MEDICAL CORPORATION

Date: November 12, 2003

By: /s/ THOMAS W. DAVISON

Thomas W. Davison

President and Chief Executive Officer

Date: November 12, 2003

By: /s/ SEAN F. MORAN

Sean F. Moran

Chief Financial Officer

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	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).
10.1	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).
10.2	Form of Voting Agreement (executed by each of Messrs. Kohler, Wigley, McNab, Kost and Langer) is incorporated herein by reference to Appendix A to the Registrant s Definitive Schedule 14A filed September 8, 2003 (File No. 000-23017).
10.3	Form of Voting Agreement (executed by each of Essex Woodlands Health Ventures Fund IV, L.P., Vanguard VI, L.P., Vanguard VI Affiliates Fund, L.P., H&Q Healthcare Investors and H&Q Life Sciences Investors) is incorporated herein by reference to Appendix B to the Registrant s Definitive Schedule 14A filed September 8, 2003 (File No. 000-23017).
10.4	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).
10.5	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).
10.6	Pre-emptive Rights Letter Agreement, dated as of September 9, 2003, by and among the Registrant and Xmark Fund, L.P., Xmark Fund, Ltd., SDS Merchant Fund, LP and OTAPE Investments LLC is incorporated herein by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated October 14, 2003 (File No. 000-23017).
10.7	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).
10.8	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).
10.9	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).
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.