# FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

Filing Date: **2001-08-03** | Period of Report: **2001-06-30**
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## FILER

**SYMPHONIX DEVICES INC**

CIK:**930481**| IRS No.: **770376250** | State of Incorp.:**DE** | Fiscal Year End: **1231**
Type: **10-Q** | Act: **34** | File No.: **000-23767** | Film No.: **1697283**
SIC: **3842** Orthopedic, prosthetic & surgical appliances & supplies

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2001.

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____TO _____.

COMMISSION FILE NO. 000-23767

SYMPHONIX DEVICES, INC.
(Exact name of registrant as specified in its charter)

| DELAWARE | 77-0376250 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

2331 Zanker Road
SAN JOSE, CALIFORNIA 95131-1107
(Address of principal executive offices, including zip code)

(408) 232-0710
(Registrant's telephone number, including area code)

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

As of June 30, 2001; 21,139,000 shares of the Registrant's Common Stock were outstanding.

SYMPHONIX DEVICES, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

SYMPHONIX DEVICES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

<TABLE>
<CAPTION>

| | June 30, 2001 | December 31, 2000 |
|---|---|---|
| <S> | <C> | <C> |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 3,410 | $ 29,535 |
| Short-term investments | 14,898 | -- |
| Accounts receivable, net | 412 | 356 |
| Inventories | 1,694 | 2,034 |
| Prepaid expenses and other current assets | 711 | 634 |
| Total current assets | 21,125 | 32,559 |
| Property and equipment, net | 1,534 | 1,396 |
| Restricted cash | 222 | -- |
| Other assets | 73 | 75 |
| Total assets | $ 22,954 | $ 34,030 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 670 | $ 834 |
| Accrued compensation | 933 | 1,304 |
| Other accrued liabilities | 3,160 | 3,772 |
| Current portion of bank borrowings | 500 | 500 |
| Total current liabilities | 5,263 | 6,410 |
| Deferred revenue | 912 | 1,101 |
| Bank borrowings, less current portion | 750 | 1,000 |
| Total liabilities | 6,925 | 8,511 |
| Stockholders' equity: | | |
| Common stock | 21 | 21 |
| Notes receivable from stockholders | (400) | (421) |
| Deferred compensation | -- | (34) |
| Additional paid-in capital | 92,147 | 91,885 |
| Accumulated other comprehensive income | 167 | 54 |

| | | |
|---|---|---|
| Accumulated deficit | (75,906) | (65,986) |
| Total stockholders' equity | 16,029 | 25,519 |
| Total liabilities and stockholders' equity | $ 22,954 | $ 34,030 |

</TABLE>

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



SYMPHONIX DEVICES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

<TABLE>
<CAPTION>

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| <S> | <C> | <C> | <C> | <C> |
| Revenue | $ 435 | $ 195 | $ 1,011 | $ 413 |
| Costs and expenses: | | | | |
| Cost of goods sold | 1,135 | 735 | 2,323 | 1,758 |
| Research and development | 1,870 | 1,813 | 3,521 | 3,750 |
| Selling, general and administrative | 2,658 | 1,833 | 5,501 | 3,468 |
| Total costs and expenses | 5,663 | 4,381 | 11,345 | 8,976 |
| Operating loss | (5,228) | (4,186) | (10,334) | (8,563) |
| Interest income | 190 | 124 | 476 | 255 |
| Interest expense | (29) | (49) | (62) | (100) |
| Net loss | $ (5,067) | $ (4,111) | $ (9,920) | $ (8,408) |
| Basic and diluted net loss per common share | $ (0.24) | $ (0.31) | $ (0.47) | $ (0.63) |
| Shares used in computing basic and diluted net loss per common share | 21,061 | 13,406 | 21,018 | 13,382 |

</TABLE>

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



SYMPHONIX DEVICES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)
(unaudited)

<TABLE>
<CAPTION>

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| <S> | <C> | <C> | <C> | <C> |
| Net loss | $(5,067) | $(4,111) | $(9,920) | $(8,408) |

| | | | | |
|---|---|---|---|---|
| Change in unrealized gain on short-term investments | 42 | (7) | 105 | 40 |
| Translation adjustments | 1 | (15) | 8 | (13) |
| Comprehensive loss | $(5,024) | $(4,133) | $(9,807) | $(8,381) |

</TABLE>

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



SYMPHONIX DEVICES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

<TABLE>
<CAPTION>

| | Six months ended June 30, | |
|---|---|---|
| | 2001 | 2000 |
| <S> | <C> | <C> |
| Cash flows from operating activities: | | |
| Net loss | $ (9,920) | $ (8,408) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Amortization of deferred compensation | 34 | 155 |
| Stock based compensation | -- | 16 |
| Depreciation and amortization | 398 | 395 |
| Amortization of premium on short-term investments | 76 | -- |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (56) | (27) |
| Inventories | 340 | (116) |
| Prepaid expenses and other current assets | (77) | 318 |
| Accounts payable | (164) | (21) |
| Accrued compensation | (371) | (230) |
| Deferred revenue | (189) | (181) |
| Other accrued liabilities | (535) | 360 |
| Net cash used in operating activities | (10,464) | (7,739) |
| Cash flows from investing activities | | |
| Purchases of short-term investments | (26,879) | (3,656) |
| Maturities of short-term & long-term investments | 12,010 | 9,085 |
| Purchases of property and equipment | (613) | (234) |
| Increase in restricted cash | (222) | -- |
| Change in other assets | 2 | 4 |
| Net cash provided by (used in) investing activities | (15,702) | 5,199 |
| Cash flows from financing activities | | |
| Payments on capital lease obligations | -- | (60) |
| Payments on bank borrowings | (250) | (250) |
| Proceeds from issuance of common stock | 262 | 190 |
| Payments on stockholders notes receivable | 21 | 182 |
| Issuance of notes receivable to stockholder | -- | (120) |
| Net cash provided by (used in) financing activities | 33 | (58) |
| Net decrease in cash and cash equivalents | (26,133) | (2,598) |
| Effect of exchange rates on cash and cash equivalents | 8 | (13) |
| Cash and cash equivalents, beginning of period | 29,535 | 7,998 |
| Cash and cash equivalents, end of period | $ 3,410 | $ 5,387 |
| Supplemental disclosure of non-cash financing activities | | |

| | | |
|---|---|---|
| Reversal of unrealized deferred compensation | $ -- | $ 245 |
| Cancellation of note receivable to stockholder for unvested restricted stock | $ -- | $ 107 |

</TABLE>

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



SYMPHONIX DEVICES, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Basis of Presentation:

The accompanying unaudited condensed consolidated financial statements as of June 30, 2001 of Symphonix Devices, Inc. (the "Company") have been prepared in accordance with generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation. Operating results for the six month period ended June 30, 2001 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2001, or any future interim period.

These financial statements and notes should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2000 and footnotes thereto, included in the Company's Annual Report on Form 10-K.

2. Computation of Basic and Diluted Net Loss per Common Share:

Basic earnings per share ("EPS") is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur from common shares issuable through stock options, warrants and other convertible securities, if dilutive. The following table is a reconciliation of the numerator (net loss) and the denominator (number of shares) used in the basic and diluted EPS calculations and sets forth potential shares of common stock that are not included in the diluted net loss per share calculation as their effect is antidilutive (in thousands except per share data):

<TABLE>
<CAPTION>

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| <S> | <C> | <C> | <C> | <C> |
| Numerator - Basic and Diluted | | | | |
| Net loss | $ (5,067) | $ (4,111) | $ (9,920) | $ (8,408) |
| Denominator - Basic and Diluted | | | | |
| Weighted average common shares outstanding | 21,119 | 13,489 | 21,079 | 13,468 |
| Weighted average unvested common shares subject to repurchase | (58) | (83) | (61) | (86) |
| Total | 21,061 | 13,406 | 21,018 | 13,382 |
| Basic and diluted net loss per common share | $ (0.24) | $ (0.31) | $ (0.47) | $ (0.63) |
| Antidilutive Securities: | | | | |
| Options to purchase common stock | 2,450 | 2,001 | 2,450 | 2,001 |
| Common stock subject to repurchase | 54 | 79 | 54 | 79 |

| | | | | |
|---|---|---|---|---|
| Warrants | 7 | 7 | 7 | 7 |
| | 2,511 | 2,087 | 2,511 | 2,087 |

</TABLE>



3. Inventories:

Inventories comprise (in thousands):

| | June 30, 2001 | December 31, 2000 |
|---|---|---|
| Raw materials | $ 304 | $ 253 |
| Work in Progress | 818 | 1,097 |
| Finished goods | 572 | 684 |
| | $ 1,694 | $ 2,034 |

4. Nonrecurring Charges

In November 2000, the Company approved plans to restructure its operations in order to accelerate the Marketing and Distribution Agreement signed with Siemens in December 1999. In the fourth quarter of 2000, the Company recorded a charge of $509,000 in connection with the restructuring. The following table sets forth certain details associated with the net reorganization charges as of June 30, 2001 (in thousands of dollars):

<TABLE>
<CAPTION>

| | Accrual at December 31, 2000 | Cash Payments | Adjustments | Accrual at June 30, 2001 |
|---|---|---|---|---|
| <S> | <C> | <C> | <C> | <C> |
| Severance & benefits | $ 262 | $(165) | $ (50) | $ 47 |
| Facility charges | 111 | (45) | (32) | 34 |
| Other | 136 | (127) | -- | 9 |
| | $ 509 | $(337) | $ (82) | $ 90 |

</TABLE>

Severance and benefits represent the reduction of 10 sales and marketing employees in Europe. Facility charges include early termination costs associated with the closing of the international sales office and write-off of certain assets. In the first quarter of 2001, the Company reversed $82,000 of excess reorganization charges related to severance and facilities charges which is included in selling, general and administrative expenses in the statement of operations.

5. Reclassification:

Certain prior year financial statement items have been reclassified to conform to the current year's presentation.

6. Recent Accounting Pronouncements

In July 2001, the Financial Accounting and Standards Board ("FASB") issued Statements of Financial Accounting Standards No. 141 ("SFAS 141"), "Business Combinations," and No. 142 ("SFAS 142"), "Goodwill and Other Intangible Assets." SFAS 141 requires that all business combinations initiated after June 30, 2001 be accounted for under a single method - the purchase method. Use of the pooling-of-interests method is no longer permitted. SFAS 142 requires that

goodwill no longer be amortized to earnings, but instead be reviewed for impairment upon initial adoption of the Statement and on an annual basis going forward. The amortization of goodwill will cease upon adoption of SFAS 142. The provisions of SFAS 142 will be effective for fiscal years beginning after December 15, 2001. The Company believes that SFAS 142 will not have a material effect on the financial position or results of operations of the Company.

7. Subsequent Event

On July 2, 2001, certain stockholders who entered into the Common Stock Purchase Agreement (the "Agreement") dated September 18, 2000 have exercised their right to a one-time adjustment to the original purchase price of the common stock in accordance with the Agreement. The one-time purchase price adjustment resulted in the issuance of an additional 14,336,000 shares of common stock to the investors at no additional cost.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with the condensed consolidated financial statements and footnotes thereto, and with the Company's audited financial statements for the year ended December 31, 2000 and the footnotes thereto.

Overview

Statements in this Management's Discussion and Analysis of Financial Condition and Results of Operations which express that the company "believes", "anticipates" or "plans to....." as well as other statements which are not historical fact, are forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially as a result of the risks and uncertainties described herein and elsewhere including, in particular, those factors described under "Factors That Might Affect Future Results."

Symphonix has developed a family of proprietary implantable Soundbridges for the management of mild to severe hearing impairment. The Company's family of Vibrant Soundbridges is based on its patented core FMT technology. Late in 2000, the Company received approval from the Food and Drug Administration to commercially market the product in the United States. Subsequent to FDA approval, the product was successfully launched to the otology community. Otologists are ear surgeons within the ear, nose and throat, or ENT, group of doctors. The Company is working with more than 60 otologists to establish implanting centers across the United States.

The Company has established a United States sales and marketing organization which, as of June 30, 2001, is comprised of seventeen sales, marketing and clinical support personnel. Going forward, while the Company expects to continue to increase the number of otologists it works with, the Company plans to initiate marketing efforts focused on audiologists--the health professionals who assess hearing problems and recommend hearing devices--and directly to those suffering hearing loss.



The Company received the authorization to affix the CE Mark to the first generation Vibrant Soundbridge and the second generation Vibrant P Soundbridge in March 1998. Authorization to affix the CE Mark to the Vibrant HF Soundbridge and the Vibrant D Soundbridge was received in July 1998 and in May 1999, respectively. The Company began selling activities for the Vibrant P Soundbridge and for the Vibrant D Soundbridge in the European Union in March 1998 and in June 1999, respectively. In August 2000, the Company received FDA approval for its premarket approval application, or PMA, for the Vibrant P and Vibrant D Soundbridges. In October 2000, Symphonix received its device license for the Vibrant Soundbridge from Health Canada.

In December 1999, the Company established a distribution partnership with Siemens Audiologische Technik GmbH covering most of the markets in Europe. As of January 1, 2001, Siemens was granted full distributorship of the European market. The Company believes this partnership will significantly enhance its presence in Europe, especially within the audiology community.

The Company's initial selling efforts in Europe have been targeted

primarily at those ENT surgeons specializing in otology. The Company intends to continue to market its products to these specialists; however, with the Siemens agreement, it also plans to focus on referring physicians, audiologists, the general population of ENT physicians and potential patients in an attempt to increase the patient flow to the otology centers. There can be no assurance that the Company will be successful in its efforts to increase the number of patients who become candidates for the Company's Soundbridge or in obtaining reimbursement for its products.

Symphonix has a limited operating history. Through June 30, 2001 the Company had not generated significant revenue from product sales. The Company expects to incur substantial losses through at least 2001. To date, the Company's principal sources of funding have been net proceeds from its initial public offering completed in February 1998, private equity financings, an equipment lease financing and bank borrowings.

Results of Operations

Revenue. Revenue was $0.4 million in the three months ended June 30, 2001 compared to $0.2 million in the three months ended June 30, 2000. Revenue was $1.0 million in the six months ended June 30, 2001 compared to $0.4 million in the six months ended June 30, 2000. Revenue in these periods was the result of selling activities to distributors and direct sales in Europe and direct sales in the United States. The increase in revenue is primarily due to increased investments in sales and marketing activities and due to the Company receiving FDA approval to commercially market its products in the United States. Revenue in the six months ended June 30, 2001 and 2000 included $189,000 and $182,000, respectively, representing the amortization of the difference between the purchase price and fair value of the Company's common stock purchased by Siemens in connection with a Marketing and Distribution Agreement. The remaining deferred income will be amortized over the life of the agreement.

Cost of Goods Sold. Cost of goods sold increased to $1.1 million for the three months ended June 30, 2001 from $0.7 million for the three months ended June 30, 2000 and increased to $2.3 million for the six months ended June 30, 2001 from $1.8 million for the six months ended June 30,



2000. The increases in cost of goods sold are primarily due to increased product sales. Cost of goods sold represents the direct cost of the products sold as well as manufacturing variances and provisions for warranty.

Research and Development Expenses. Research and development expenses were $1.9 million in the three months ended June 30, 2001 compared to $1.8 million in the three months ended June 30, 2000. Research and development expenses were $3.5 million for the six months ended June 30, 2001 compared to $3.8 million for the six months ended June 30, 2000. Spending for the six months ended June 30, 2001 decreased by $0.3 million compared to the same period ended June 30, 2000 due to lower clinical trial activity for the Company's Vibrant Soundbridge. Research and development expenses consist primarily of personnel costs, professional services, materials, supplies and equipment in support of product development, clinical trials, regulatory submissions, and the preparation and filing of patent applications. The Company expects to continue to invest in research and development in the remainder of 2001 primarily in the development of the totally implantable version of the Soundbridge.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $2.7 million in the three months ended June 30, 2001 compared to $1.8 million in the three months ended June 30, 2000 and were $5.5 million for the six months ended June 30, 2001 compared to $3.5 million for the six months ended June 30, 2000. The $0.9 million increase for the three months ended June 30, 2001 and $2.0 million increase for the six months ended June 30, 2001 were primarily due to the presence of a sales force in the U.S. in 2001 and not in 2000. Selling, general and administrative expenses consist primarily of personnel costs, promotional costs, legal and consulting costs. The Company expects to continue investing in these areas in developing a U.S. sales and marketing organization and associated programs for the remainder of 2001.

Deferred compensation of $2.3 million was recorded in 1997, representing the difference between the exercise prices of certain options granted and the deemed fair value of the Company's common stock on the options' grant dates. Deferred compensation expense, net of terminated employees, attributed to such options was $34,000 during the six months ended June 30, 2001 compared to $155,000 during the six months ended June 30, 2000.

Interest Income (Expense). Interest income, net of expense, increased to $0.2 million in the three months ended June 30, 2001 from $0.1 million in the three months ended June 30, 2000 and increased to $0.4 million for the six months ended June 30, 2001 compared to $0.2 million in the six months ended June 30, 2000. The increase in net interest income was due to the increase in the Company's cash and short-term investment balances resulting from the Company's private equity financings in September and November 2000 of $30.9 million. Interest earned in the future will depend on the Company's funding cycles and prevailing interest rates.

Income Taxes. To date, the Company has not incurred any U.S. income tax obligations. At December 31, 2000, the Company had net operating loss carryforwards of approximately $58.0 million for federal and $28.4 million for state income tax purposes, which will expire at various dates through 2020 and 2010, respectively, if not utilized. The principal differences between losses for financial and tax reporting purposes are the result of the capitalization of research and development and start-up expenses for tax purposes. Federal and state tax laws contain provisions



that may limit the net operating loss carryforwards that can be used in any given year, should certain changes in the beneficial ownership of the Company's outstanding common stock occur. Such events could limit the future of the Company's net operating loss carryforwards.

Liquidity and Capital Resources

Since inception, the Company has funded its operations and its capital investments from proceeds from its initial public offering completed in February 1998 totaling $28.4 million, from the private sale of equity securities totaling approximately $62.5 million, from equipment lease financing totaling $1.3 million and from bank borrowings totaling $2.0 million. At June 30, 2001, the Company had $15.9 million in working capital, and its primary source of liquidity was $18.3 million in cash and cash equivalents and short-term investments. Additionally, the Company had $222,000 of restricted cash held in certificates of deposit as collateral for letters of credit.

Symphonix used $10.5 million in cash for operations in the six months ended June 30, 2001, compared to $7.7 million in the six months ended June 30, 2000 primarily in funding its operating losses.

Capital expenditures, primarily related to the Company's research and development and manufacturing activities, were $613,000 and $234,000 in the six months ended June 30, 2001 and 2000, respectively. At June 30, 2001, the Company did not have any material commitments for capital expenditures.

The Company has a loan agreement with a bank that provides for borrowings of up to $2.0 million and for the issuance of letters of credit up to $250,000. At June 30, 2001, the Company had borrowings of $1.3 million and an outstanding letter of credit in the amount of $97,000 under the loan agreement. Borrowings under the loan agreement are repayable over four years commencing in January 2000.

The Company intends to expend substantial funds in the future for research and development, preclinical and clinical testing, capital expenditures and the manufacturing, marketing and sale of its products. The timing and amount of spending of such capital resources cannot be accurately predicted and will depend on several factors, including the progress of its research and development efforts and preclinical and clinical activities, the time and costs of obtaining regulatory approvals, the progress and cost of commercialization of products currently under development, market acceptance and demand for the Company's products and other factors not within the Company's control. While the Company believes that its existing capital will be sufficient to fund its operations and its capital investments through July 2002, the Company may require additional financing beyond that time. Such additional financing may not be available on a timely basis on terms acceptable to the Company, or at all. Or, if available, such financing may be dilutive to stockholders. If adequate funds are not available, the Company could be required to delay development or commercialization of certain of its products, license to third parties the rights to commercialize certain products or technologies that the Company would otherwise seek to commercialize for itself, or reduce the marketing, customer support or other resources devoted to certain of its products, any of which could

have a material adverse effect on the Company's business, financial condition and results of operations.

Recent Accounting Pronouncements

In July 2001, the Financial Accounting and Standards Board ("FASB") issued Statements of Financial Accounting Standards No. 141 ("SFAS 141"), "Business Combinations," and No. 142 ("SFAS 142"), "Goodwill and Other Intangible Assets." SFAS 141 requires that all business combinations initiated after June 30, 2001 be accounted for under a single method - the purchase method. Use of the pooling-of-interests method is no longer permitted. SFAS 142 requires that goodwill no longer be amortized to earnings, but instead be reviewed for impairment upon initial adoption of the Statement and on an annual basis going forward. The amortization of goodwill will cease upon adoption of SFAS 142. The provisions of SFAS 142 will be effective for fiscal years beginning after December 15, 2001. The Company believes that SFAS 142 will not have a material effect on the financial position or results of operations of the Company.

Factors That May Affect Future Results

We have a history of losses and negative cash flows, and we may never be profitable.

We have incurred losses every year since we began operations in 1994. At June 30, 2001, we had an accumulated deficit of $75.9 million. This deficit resulted primarily from expenses we incurred from dedicating substantially all of our resources to research and development, clinical trials, establishment of European and United States sales and marketing organizations and the initiation of sales and marketing activities in Europe and the United States. Even though Vibrant P and Vibrant D Soundbridges became available for sale in the European Union in 1998 and in the United States and Canada in 2000, we have not generated significant revenues from product sales to date. We may never realize significant product revenues.

Even if we do achieve significant product revenues, we may never be profitable. We expect our operating losses to continue at least through the year 2001 as we continue to, among other things:

. attempt to establish sales and marketing capabilities;

. expand research and development activities;

. conduct clinical trials in support of regulatory approvals; and

. establish commercial-scale manufacturing capabilities.



If our Soundbridge products do not achieve market acceptance, our business may fail.

We have sold the semi-implantable Vibrant Soundbridge in Europe since 1998 and in the United States since late 2000. This product has not yet achieved market acceptance and may never achieve market acceptance. Market acceptance of our current and future Soundbridge products will depend upon their acceptance by the medical community and patients as safe, effective, and cost-effective compared to other devices. Our Soundbridge products may not be preferable alternatives to existing or future products, some of which, such as the acoustic hearing aid, do not require surgery. Patient acceptance of our Soundbridge products will depend in part upon physician, audiologist and surgeon recommendations as well as other factors, including the effectiveness, safety, reliability and invasiveness of the procedure as compared to established approaches. Prior to undergoing surgery for the implantation of our Soundbridge, a patient may speak with a number of medical professionals, including the patient's primary care physician, an audiologist, an ear, nose and throat specialist, as well as surgeons who specialize in ear surgery. The failure by any of these medical professionals to favorably recommend our products and the surgery required to implant the Soundbridge could limit the number of potential patients who are introduced to an ear surgeon as candidates for our Soundbridge

products. If our Soundbridge products do not achieve market acceptance, our business may fail.

Symphonix may be delisted on the Nasdaq National Market

The minimum per share bid price required under marketplace Rule 44 5c(a)(5) to maintain a listing on the Nasdaq National Market is $1.00. If our common stock trades below $1.00, we could lose our listing on the Nasdaq National Market. A delisting would severely impair our ability to raise additional working capital. A delisting would also impair the liquidity of our common stock.

If we fail to successfully develop and commercialize our next generation of Vibrant Soundbridge products, we may not achieve profitability.

Although we have offered the semi-implantable Vibrant Soundbridge for sale in Europe since 1998 and in the United States since late 2000, we have not realized significant sales revenues to date. Our success depends on our ability to successfully commercialize an improved semi-implantable Soundbridge as well as a totally implantable Soundbridge. Our Vibrant HF and totally-implantable Soundbridge, currently under development, will require additional development, clinical trials and regulatory approval prior to commercialization. Successful completion of clinical trials for the Vibrant HF and totally-implantable Soundbridge products may never occur. Completion of clinical trials my be delayed by many factors, including research and development difficulties, slower than anticipated patient enrollment or adverse events occurring during clinical trials. Any delays in our clinical trials or any failure to obtain regulatory approval for these next generation Soundbridge products would impair our ability to achieve profitability. We may not be able to secure additional funding to support our substantial future capital requirements.

We will expend substantial funds in the future for research and development, preclinical and clinical testing, capital expenditures and the manufacturing, marketing and sale of our products. The timing and amount of spending of such capital resources cannot be accurately predicted and will depend upon several factors not within our control, including:



. market acceptance and demand for our products in the United States and internationally;

. the progress of our research and development efforts and preclinical and clinical activities;

. competing technological and market developments;

. the time and costs involved in obtaining regulatory approvals;

. the time and costs involved in filing, prosecuting and enforcing patent claims; and

. the progress and cost of commercialization of products currently under development.

We believe that the net proceeds of approximately $31.0 million from the recent private placements of securities to Siemens Audiologische Technik GmbH and other investors, together with our previously existing capital resources and projected interest income, will be sufficient to fund our operations and capital investments through 2001. However, we may require additional financing after that time. Such additional financing, if required, may not be available on a timely basis on terms acceptable to us, or at all. If adequate funds are not available, we could be required to delay development or commercialization of some of our products, to license to third parties the rights to commercialize some products or technologies that we would otherwise seek to commercialize for ourselves, or to reduce the marketing, customer support or other resources devoted to some of our products, any of which could have a material adverse effect on our business, financial condition and results of operations.

If we do not receive and maintain regulatory approvals for new products, we will not be able to manufacture or market new products.

Approval from the FDA is necessary to manufacture and market medical devices in the United States. Other countries have similar requirements. Since we have not realized significant revenues from sales of our current products, we

must receive and maintain regulatory approval for new products in order to grow our business significantly.

The process that medical devices must undergo to receive necessary approval is extensive, time-consuming and costly, and there is no guarantee that regulatory authorities will approve any of our product candidates. FDA approval can be delayed, limited or not granted for many reasons, including:

. a product candidate may not be safe or effective;

. even if we believe data from preclinical testing and clinical trials should justify approval, FDA officials may disagree;

. the FDA might not approve our manufacturing processes or facilities or the processes or facilities of our contract manufacturers or raw material suppliers;



. the FDA may change its approval policies or adopt new regulation; and

. the FDA may approve a product candidate for indications that are narrow, which may limit our sales and marketing activities.

The process of obtaining approvals in foreign countries is subject to delay and failure for the same reasons.

We face intense competition in our current and potential markets and if we cannot demonstrate the superiority of our products, we may fail to achieve profitability.

The medical device industry and the acoustic hearing aid market are subject to intense competition in the United States and abroad. We believe our products will compete primarily with hearing aids. Principal manufacturers of acoustic hearing aids include Siemens Hearing Instruments, Inc., Starkey Laboratories, Inc., Dahlberg, Inc., GN ReSound, Inc., Oticon, Inc., Widex Hearing Aid Co., Inc., Sonic Innovations, Inc. and Phonak, Inc. Our products may not be as reliable or effective as established hearing aid products. If our products are not perceived as high quality, reliable and effective alternatives to conventional hearing aids, we may not successfully compete with established hearing aid products. Our competitors may also develop technologies and products in the future that are more reliable and effective and less expensive than those being developed by us or that do not require surgery.

Several university research groups and development-stage companies have active research or development programs related to direct drive devices for sensorineural hearing loss. One such company, IMPLEX AG Hearing Technology, was authorized by its European reviewing body on November 15, 1999 to affix the CE Mark on its totally integrated cochlear amplifier. IMPLEX has reported its intent to pursue a clinical investigation in the United States to support FDA regulatory requirements. Otologics, LLC has developed a semi-implantable direct drive device for sensorineural hearing loss called the middle ear transducer. This device has begun the FDA regulatory process and the European regulatory process and initiated multicenter clinical trials. The Company believes St. Croix Medical, Inc. has begun clinical trials in Europe and has recently received an IDE approval to begin clinical studies on its fully implantable pizo electric device for sensorineural hearing loss. Soundtec, Inc. has completed clinical trials in the United States on a hybrid implantable/ear canal based hearing aid and expects to receive a determination by the FDA later this year on marketing their product in the U.S. In addition, some large medical device companies, some of which are currently marketing implantable medical devices, may develop programs in hearing management. Many of these companies have substantially greater financial, technical, manufacturing, marketing and other resources than we have. If we fail to compete effectively with any or all of these companies and products, we will not achieve profitability.

Our lack of sales, marketing and distribution experience could delay and increase the costs of introducing our Soundbridge products into those markets where we have received regulatory approvals.

In the United States, a direct sales force is concentrating our product marketing efforts on approximately 400 specialists in ear surgery and a targeted group of professional audiologists. In

Europe, our sales and marketing effort is conducted through a distribution partnership with Siemens. In other international markets, including Japan, we intend to establish either a network of distributors or a strategic partner.

We may fail to build a direct sales force or marketing organization that is cost effective or successful in one or more countries. In addition, we have entered into distribution agreements with only a limited number of international distributors. There can be no assurance that we will be able to enter into similar agreements with other qualified distributors on a timely basis on terms acceptable to us, or at all, or that such distributors will develop adequate resources to selling our products. If we fail to establish an adequate direct sales force domestically and in select international markets, and to enter into successful distribution relationships, we will have difficulty selling our products and our business may fail.

Since third-party reimbursement is not currently available for procedures using our Soundbridge products, our products may not achieve market acceptance.

In the United States and abroad, patients generally rely on third-party payors, principally Medicare, Medicaid, private health insurance plans, health maintenance organizations and other sources of reimbursement, to pay health care expenses, including reimbursement of all or part of the cost of the procedure in which our medical device is being used. These third-party payors are increasingly attempting to limit both the coverage and the level of reimbursement of procedures involving new devices. Currently, no third-party payors will pay for procedures using our products, and patients must bear the total cost of the procedures themselves. If third-party payors do not establish adequate levels of reimbursement for procedures using our products, we may not achieve market acceptance.

We have limited manufacturing experience, and may be unable to expand our manufacturing capabilities sufficiently, which could limit our ability to develop and deliver sufficient quantities of products in a timely manner.

We currently manufacture our products in small quantities for laboratory testing, for clinical trials and for limited commercial sales. The manufacture of our Soundbridge products is a complex operation involving a number of separate processes, components and assemblies. We have no experience manufacturing our products in the volumes or with the yields that will be necessary for us to achieve significant commercial sales, and there can be no assurance that we can establish high volume manufacturing capacity or, if established, that we will be able to manufacture our products in high volumes with commercially acceptable yields. We will need to expend significant capital resources and develop manufacturing expertise to establish commercial-scale manufacturing capabilities. Our inability to successfully manufacture or commercialize our Soundbridge products in a timely manner may harm our competitive position and market success.

If Siemens does not perform its duties under our agreements, our ability to commercialize our products may be impaired.

We have entered into a collaboration with Siemens Audiologische Technik GmbH. As a result of our agreements, we depend on Siemens to market and distribute our products in Europe. We



also depend on Siemens to provide integrated circuits and software for use in our Soundbridge products. Any breach or termination by Siemens of our agreements could delay or stop the international commercialization of our products.

We rely on several sole source or limited source suppliers, and our production will be seriously harmed if these suppliers are not able to meet our demand and alternative sources are not available.

A number of components and sub-assemblies, such as silicone, signal processing electronics implant packaging, as well as sterilization services are provided by single source suppliers. Furthermore, the key analog and digital signal processing microcircuits of the Vibrant P, Vibrant D and Vibrant HF Soundbridges are provided by sole source suppliers. None of our suppliers are contractually obligated to continue to supply us nor are we contractually

obligated to buy from a particular supplier. For some of these components and sub-assemblies, there are relatively few alternative sources of supply, and we cannot quickly establish additional or replacement suppliers for such components and sub-assemblies. In addition, additional approvals will be required from the FDA before we can significantly modify our manufacturing processes or change the supplier of a critical component. Because of the long lead time for some components and subassemblies that are currently available from a single source, a supplier's inability or failure to supply such components or subassemblies in a timely manner or our decision to change suppliers could have a material adverse effect on our business, financial condition and results of operation.

If we are unable to protect our intellectual property, our competitors could develop and market products with similar features that may reduce demand for our products.

Our success depends in part on our ability to protect our issued and pending patents, trade secrets and other intellectual property. The strength of this protection is uncertain. Our competitors could challenge, invalidate or circumvent our issued patents as well as any future patents. Even if upheld, our issued patents may not exclude competitors or otherwise provide competitive advantages to us.

In addition, a competitor may obtain patents that will interfere with our ability to make, use or sell our products either in the United States or in international markets. There may be pending applications, which if issued, might provide proprietary rights to third parties relating to products or processes used or proposed to be used by us. We may be required to obtain licenses to patents or proprietary rights of others. Further, the laws of some foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States. Litigation or regulatory proceedings, which could result in substantial cost and uncertainty to us, may also be necessary to enforce our patent or other intellectual property rights or to determine the scope and validity of other parties' proprietary rights. We may not have the financial resources to defend our patents from infringement or claims of invalidity.

We also rely upon trade secrets and other unpatented proprietary technology. Our competitors may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to or disclose our proprietary technology. Our policy is to require each of our employees, consultants, investigators and advisors to execute a confidentiality agreement upon commencement of an employment or consulting relationship with us. However,



these agreements may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure of such information.

Title 35, Section 287 of the United States Code limits the enforcement of patents relating to the performance of surgical or medical procedures on a body. This law precludes medical practitioners and health care entities, which practice these procedures, from being sued for patent infringement. Therefore, depending upon how these limitations are interpreted by the courts, they could have a material adverse effect on our ability to enforce any of our proprietary methods or procedures deemed to be surgical or medical procedures on a body. In some countries other than the United States, patent coverage relating to the performance of surgical or medical procedures is not available. Therefore, patent coverage in such countries will be limited to the Floating Mass Transducer, the patented core direct drive technology upon which all of our Soundbridge products are based, or to narrower aspects of the Floating Mass Transducer.

The medical device industry in general has been characterized by substantial litigation. Litigation regarding patent and other intellectual property rights, whether with our without merit, could be time-consuming and expensive to respond to and could distract our technical and management personnel. We may become involved in litigation to defend against claims of infringement, to enforce patents issued to us or to protect our trade secrets. If any relevant claims of third-party patents are held as infringed and not invalid in any litigation or administrative proceeding, we could be prevented from practicing the subject matter claimed in such patents, or would be required to obtain licenses from the patent owners of each such patent, or to redesign our products or processes to avoid infringement. In addition, in the event of any possible infringement, there can be no assurance that we would be successful in any attempt to redesign our products or processes to avoid such infringement

or in obtaining licenses on terms acceptable to us, if at all. Accordingly, an adverse determination in a judicial or administrative proceeding or failure by us to redesign our products or processes or to obtain necessary licenses could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, financial condition and results of operations. Although we have not been involved in any litigation to date, in the future, costly and time-consuming litigation brought by us may be necessary to enforce patents issued to us, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others.

If we cannot retain or hire key personnel, our business will suffer.

Our future success depends in significant part upon the continued service of key scientific, technical, sales and marketing, and management personnel. Competition for such personnel is intense. There can be no assurance that we can retain our key scientific, technical, sales and marketing and managerial personnel or that we can attract, assimilate or retain other highly qualified scientific, technical, sales and marketing, and managerial personnel in the future. The loss of key personnel, especially if without advance notice, or the inability to hire or retain qualified personnel could impair our ability to commercialize our Vibrant Soundbridge products and develop future products.



Complications may result from the use of our Soundbridge products, and insurance may be insufficient or unavailable to cover potentially significant product liability expenses if we are sued.

Our business involves the inherent risk of product liability claims. We maintain limited product liability insurance at coverage levels which we believe to be commercially reasonable and adequate given our current operations. However, this insurance may not be available in the future on commercially reasonable terms, or at all. Even if it is available, it may not be adequate to cover liabilities that may arise. If we are sued for an injury caused by our products, the resulting liability could result in significant expense, which could harm our business and financial condition.

Our international sales and operations expose us to foreign currency and political risks.

We desire to continue to expand our operations outside of the United States and to enter additional international markets, which will require significant management attention and financial resources and subject us further to the risks of operating internationally. These risks include:

. unexpected changes in regulatory requirements;

. delays resulting from difficulty in obtaining export licenses for certain technology;

. tariffs and other barriers and restrictions;

. the burdens of complying with a variety of foreign laws and regulations; and

. difficulty in staffing and managing international operations.

We are also subject to general political and economic risks in connection with our international operations, such as political instability, changes in diplomatic and trade relationships and general economic fluctuations in specific countries or markets.

We cannot predict whether quotas, duties, taxes, or other charges or restrictions will be imposed by the United States, the European Union, Japan, or other countries upon the import or export of our products in the future, or what effect any such actions would have on our business, financial condition or results of operations. There can be no assurance that regulatory, geopolitical and other factors will not adversely affect our business in the future or require us to modify our current business practices.

In addition, because most of our international sales are denominated in foreign currencies, gains and losses on the conversion to U.S. dollars of accounts receivable arising from international operations may contribute to fluctuations in our operating results. Further, fluctuations in currency exchange rates may negatively impact our ability to compete in terms of price

against products denominated in local currencies. To date, we have not found it appropriate to hedge the risks associated with fluctuations in exchange rates. However, even if we undertake such transactions in the future, they may fail.



Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company considered the provisions of Financial Reporting Release No. 48 "Disclosure of Accounting Policies for Derivative Financial Instruments and Derivative Commodity Instruments, and Disclosure of Quantitative and Qualitative Information about Market Risk Inherent in Derivative Financial Instruments, Other Financial Instruments and Derivative Commodity Instruments". The Company had no holdings of derivative financial or commodity instruments at June 30, 2001. The Company is exposed to financial market risks, including changes in interest rates and foreign currency exchange rates. The fair value of the Company's investment portfolio or related income would not be significantly impacted by either a 100 basis point increase or decrease in interest rates due mainly to the short-term nature of the Company's investment portfolio. The Company's fixed rate debt obligations are subject to interest rate risk with minimal impact. An increase in interest rates would not significantly affect the Company's net loss. Much of the Company's revenue and all of its capital spending is transacted in U.S. dollars. However, the Company does enter into transactions in other currencies, primarily certain European currencies. At June 30, 2001, the Company performed sensitivity analyses to assess the potential effect of this risk and concluded that near-term changes in interest rates and foreign currency exchange rates should not materially adversely affect the Company's financial position, results of operations or cash flows.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

None

Item 2. Changes in Securities and Use of Proceeds.

None

Item 3. Defaults upon Senior Securities.

None

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

None

Item 5. Other Information.

None



Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

None

(b) On July 2, 2001, Symphonix Devices, Inc. filed a report on Form 8-K announcing that stockholders who entered into the Common Stock Purchase Agreement dated September 18, 2000 with Symphonix have exercised their right to a one-time adjustment to the purchase price under the agreement. The effect of the price adjustment is to increase the number of shares of common stock issued to the investors under the agreement from 6.4 million to 20.7 million, at no additional cost to the investors. As a result, the shares of common stock outstanding will increase from approximately 21.0 million shares to approximately 35.4 million shares, and the investors will own approximately 58% of the outstanding shares of Symphonix common stock.

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this 10-Q report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: Aug 3, 2001 SYMPHONIX DEVICES, INC.

/s/ Kirk B. Davis
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Kirk B. Davis
Chairman of the Board, President and Chief Executive Officer

/s/ Terence J. Griffin
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Terence J. Griffin
Vice President Finance and Chief Financial Officer (Principal Financial and Accounting Officer