CONCEPTUS INC
Form 10-Q
May 13, 2002
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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 Fiscal Quarter Ended March 31, 2002

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

For the transition period from _____ to _____.

Commission file number: 0-27596

CONCEPTUS, INC.

(Exact name of registrant as specified in its charter)

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

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

Registrant s telephone number, including area code: (650) 802-7240

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 at least the past 90 days. Yes x No ¨

As of April 30, 2002, 16,557,003 shares of the registrant s Common Stock were outstanding.

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PART I: FINANCIAL INFORMATION

Item 1. ***Financial Statements***

CONCEPTUS, INC.

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

	March 31, 2002	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,483	$ 33,734
Short-term investments	5,944	
Restricted cash	69	69
Accounts receivable, net	304	247
Inventories, net	1,442	1,134
Other current assets	801	556
Total current assets	29,043	35,740
Property and equipment, net	1,748	1,658
Other assets	356	380
Total assets	$ 31,147	$ 37,778
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,528	$ 1,809
Clinical trial accruals	312	422
Accrued compensation	801	1,025
Other accrued liabilities	342	861
Total current liabilities	2,983	4,117
Long-term clinical liabilities	389	486
Total liabilities	3,372	4,603
Stockholders equity:		
Common stock	50	49
Additional paid-in capital	118,806	118,348
Other comprehensive loss	(4)	
Accumulated deficit	(91,077)	(85,222)
Total stockholders equity	27,775	33,175
Total liabilities and stockholders equity	$ 31,147	$ 37,778

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

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CONCEPTUS, INC.

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

	Three Months Ended March 31,	
	2002	2001
Net sales	$ 276	$
Operating costs and expenses:		
Cost of sales and start-up manufacturing costs	746	
Research and development	1,982	2,189
Selling, general and administrative	3,214	2,054
Total operating costs and expenses	5,942	4,243
Operating loss	(5,666)	(4,243)
Other expenses	(314)	
Interest and other income	125	187
Net loss	$ (5,855)	$ (4,056)
Basic and diluted net loss per share	$ (0.36)	$ (0.35)
Shares used in computing basic and diluted net loss per share	16,471	11,723

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

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CONCEPTUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2002	**2001**
Cash flows from operating activities		
Net loss	$ (5,855)	$ (4,056)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	315	162
Stock compensation expense	120	
Provision for inventories	71	
Changes in operating assets and liabilities:		
Accounts receivable	(57)	
Inventories	(379)	(377)
Other current assets	(240)	(240)
Other assets	24	(75)
Accounts payable	(283)	49
Accrued liabilities	(985)	(988)
Net cash used in operating activities	(7,269)	(5,525)
Cash flows from investing activities		
Purchase of investments	(5,944)	
Maturities of investments		3,221
Capital expenditures	(400)	(145)
Net cash provided by (used in) investing activities	(6,344)	3,076
Cash flows from financing activities		
Proceeds from issuance of common stock, net	339	57
Net cash provided by financing activities	339	57
Effect of exchange rate changes on cash	23	
Net decrease in cash and cash equivalents	(13,251)	(2,392)
Cash and cash equivalents at beginning of period	33,734	4,621
Cash and cash equivalents at end of period	$ 20,483	$ 2,229

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

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CONCEPTUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to the instructions to Form 10-Q and Article 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, considered necessary for a fair presentation have been included.

The balance sheet at December 31, 2001 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. This financial data should be reviewed in conjunction with the audited consolidated financial statements and related notes included in the Company s Form 10-K for the year ended December 31, 2001. The results of operations for the three months ended March 31, 2002 may not necessarily be indicative of the operating results for the full 2002 fiscal year or any other future interim periods.

2. Inventories, net

Inventories are stated at the lower of cost or market. Cost is based on actual costs computed on a first-in, first-out basis. The components of inventories consist of the following:

	March 31, 2002	December 31, 2001
	(unaudited)	
	(in thousands)	
Raw materials	$ 326	$ 416
Work in process	876	664
Finished products	240	54
Total	$ 1,442	$ 1,134

3. Computation of Net Loss Per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted average number of common and dilutive common equivalent shares outstanding during each period. Under the requirements for calculating basic net loss per share, the effect of potentially dilutive securities such as stock options, common stock shares subject to repurchase, warrants and convertible securities are excluded. Basic and diluted net loss per share are equivalent for all periods presented due to the Company s net loss position.

During all periods presented, the Company had securities outstanding, which could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive. These outstanding securities consist of stock

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CONCEPTUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

options of 2,671,000 shares and 2,459,000 shares as of March 31, 2002 and December 31, 2001 respectively.

4. Comprehensive Loss

Total comprehensive loss for the three months ended March 31, 2002 consisted of foreign currency translation losses of $4,000 and net loss of $5.8 million, as unrealized gains and losses on available-for-sale securities were immaterial. For the three months ended March 31, 2001, total comprehensive loss approximates net loss as unrealized gains and losses were immaterial.

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

The following discussion should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in Part I-Item 1 of this Quarterly Report. In addition, the following discussion contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. We wish to alert readers that the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2001, as well as other factors, including those set forth in the following discussion, could in the future affect, and in the past have affected, our actual results and could cause our results for future periods to differ materially from those expressed or implied in any forward-looking statements made by us.

Overview

We develop, manufacture and market *Essure*, an innovative and proprietary non-incisional permanent birth control device for women. *Essure* is a soft and flexible micro-insert delivered into a woman s fallopian tubes and is designed to provide permanent birth control by causing a benign tissue in-growth that blocks the fallopian tubes. The procedure to place our *Essure* micro-insert, which we refer to as the *Essure* placement procedure, is typically performed as an outpatient procedure and is intended to be a less invasive and less costly alternative to tubal ligation, the leading form of birth control in the U.S. and worldwide. We currently market *Essure* in Australia, Singapore, Canada and eight European markets. Our primary focus is obtaining regulatory approval and commercializing *Essure* in the United States. We submitted our Premarket Approval, or PMA, application to the U.S. Food and Drug Administration, or FDA, on April 19, 2002, and intend to begin marketing *Essure* in the U.S. following FDA approval, which we expect to receive in 2003. The actual timing and substance of FDA action is not, however, within our control.

We commenced a multi-center, international Pivotal, or Phase III, trial in May 2000 designed to obtain 12-month safety, effectiveness and patient satisfaction data on 400 women to support the submission of a PMA application with the FDA. We also commenced a Phase II clinical study of the safety and effectiveness of *Essure* in November 1998. As of May 1, 2002, we had accumulated more than 940 woman-years of effectiveness data between our Phase II clinical study and Pivotal trial, and based on current data and zero reported pregnancies in women relying on *Essure* in these trials, statistical analysis supports an estimated one-year effectiveness rate of 99.84%. Based on zero reported pregnancies in women relying on *Essure* for contraception in our Pivotal trial, we submitted a proposal to the FDA requesting our PMA application be submitted with one-year data on 350 women instead of the previously agreed to 400 women. The FDA accepted this proposal in writing in March 2002. On April 19, 2002, we submitted our PMA application to the FDA with one-year data on 360 women in the Pivotal trial. As part of our original proposal to the FDA we agreed to follow with an update to the one-year data on an additional 40 women from the Pivotal trial later in the second quarter of 2002. As of May 1, 2002, we have not had any reported pregnancies in women relying on *Essure* in our clinical trials or in commercial use with our current product design. No method of birth control has proven 100% effective, and we expect women using *Essure* to report pregnancies in the future.

In Australia, we are continuing our sales, marketing and training effort. In March 2002, we established a call center staffed with healthcare professionals to provide women with information about permanent birth control options and to answer their questions about *Essure*. We are also continuing to market directly to the public hospitals in Australia and are now active in public hospitals in every major Australian region.

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In Europe, we have established distributor partnerships in the U.K., Northern Ireland, Spain, Portugal, Holland, Finland, Belgium, and Denmark. We have also established a team of clinical trainers and distribution managers to oversee the sales efforts and professional education programs of our distributors. We are continuing to focus our efforts in Europe on adding additional distributors, training physicians and obtaining reimbursement approval in certain European countries.

In the first quarter of 2002, we began to market our product in Canada. Our primary focus in Canada is the major metropolitan centers such as Montreal, Toronto, Ottawa and Vancouver.

Future revenues and results of operations may fluctuate significantly from quarter to quarter and will depend upon, among other factors, the progress of our clinical trials, actions relating to regulatory and reimbursement matters, the extent to which *Essure* gains market acceptance, the ability to attract marketing partners, the rate at which we establish our domestic and international distribution network, the timing and size of distributor purchases and introduction of competitive products.

Results of Operations Three Months Ended March 31, 2002 and 2001

Net sales were $0.3 million for the three months ended March 31, 2002 and zero for the three months ended March 31, 2001. The net sales for the first quarter of 2002 by country consisted of 40% to Europe, 34% to Australia, 22% to Canada and the remainder to Singapore.

Cost of sales and start-up manufacturing costs for the three months ended March 31, 2002 were $0.7 million and represented the costs of early stage product introduction and limited production volumes. There was no cost of sales for the same period in 2001.

Research and development expenses, which include product development, clinical, regulatory, quality assurance and process engineering, decreased to $2.0 million for the three months ended March 31, 2002 from $2.2 million for the same period in the prior year. This 9% decrease is primarily due to lower Pivotal trial costs.

Selling, general and administrative expenses increased to $3.2 million for the three months ended March 31, 2002, from $2.1 million for the same period in the prior year. This 56% increase is due to marketing efforts related to the commercial introduction of *Essure* in the U.K., Northern Ireland, Spain, Portugal, Finland, Holland, Belgium and Canada, and continued marketing activities in Australia.

Other expenses of $0.3 million included a one-time settlement charge in connection with a 1997 distribution agreement related to our discontinued product and a foreign currency transaction loss.

Interest and other income decreased to $0.1 million for the three months ended March 31, 2002, from $0.2 million for the same period in the prior year primarily as a result of lower average rate of return on investments.

We have experienced significant operating losses since inception and, as of March 31, 2002, had an accumulated deficit of $91.1 million. We expect our operating losses to continue at least through 2003 as we continue to expend substantial resources in the marketing of *Essure*, complete our clinical trials and prepare for a market launch of *Essure* in the United States pending FDA approval. Due to the unpredictable nature of these activities, we do not know whether we will achieve or sustain profitability in the future.

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Liquidity and Capital Resources

At March 31, 2002, cash, cash equivalents, short-term investments and restricted cash were $26.5 million, compared with $33.8 million at December 31, 2001. The decrease is due to $7.3 million of cash used in operating activities and $0.4 million of cash used for the purchase of capital equipment, partly offset by $0.3 million of cash received from the exercise of stock options.

Net cash used in operating activities was $7.3 million in the first three months of 2002, primarily a result of sales and marketing efforts related to the commercialization of *Essure* in Australia and Europe, payments related to our clinical trials, and scale up of our manufacturing and quality operations in order to transition from pilot to commercial manufacturing.

Net cash used in investing activities was $6.3 million in the first three months of 2002, primarily consisted of purchases of short-term investments and purchase of capital equipment.

Net cash provided by financing activities was $0.3 million in the first three months of 2002, primarily from exercise of stock options.

We estimate that our existing capital resources will be sufficient to meet our cash requirements into the first half of 2003 but will not be sufficient to support the large-scale commercialization of *Essure* in the United States. Our future liquidity and capital requirements will depend upon numerous factors, including the receipts of and the time required to obtain regulatory clearances and approvals, the rate at which we establish domestic and international distributors and marketing partners, the extent to which *Essure* gains market acceptance, the progress of our ongoing clinical trials, and the resources devoted to developing, manufacturing and marketing our product. Accordingly, we will require additional financing and, therefore, may in the future seek to raise additional funds through bank facilities, debt or equity offerings or other sources of capital. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive convenants. Additional funding may not be available when needed or on terms acceptable to us, which would have a material adverse effect on our business, financial condition and results of operations.

Item 3. ***Quantitative and Qualitative Disclosures About Market Risk***

Our cash balances in excess of short-term operating needs are invested in highly liquid short-term government securities and high quality commercial paper. Due to the short-term and high quality nature of these instruments, we believe these financial instruments are exposed to a low level of interest rate risk.

As of March 31, 2002, a fluctuation in exchange rates of 10% in the foreign currencies to which we are exposed would not have a material impact on our results of operations or financial condition. However, as we expand our international operations, exposure to foreign currency fluctuations will increase.

PART II. OTHER INFORMATION

Item 1. ***Legal Proceedings***

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We have commenced action against Ovion, Inc., a development-stage, privately held company, in the United States District Court, Northern District of California. We are pursuing a Declaratory Judgment of Patent Non-Infringement, Invalidity and Unenforceability against Ovion s United States Patent No. 6,096,052 entitled Occluding Device and Method of Use.

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.

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Item 5. ***Other Information***

None.

Item 6. ***Exhibits and Reports on Form 8-K***

(a) *Exhibits.*

None.

(b) *Reports on Form 8-K.*

On January 18, 2002, the Company filed a current report on Form 8-K under Item 4 (Changes in Registrant s Certifying Accountants) reporting that it had issued a press release announcing changes in Registrant s certifying accountants. The Company engaged PricewaterhouseCoopers LLP as its new independent accountant effective January 11, 2002.

On March 4, 2002, the Company filed a current report on Form 8-K under Item 5 (Other Events) reporting that it had issued a press release announcing financial results for the three and twelve months ended December 31, 2001.

On March 22, 2002, the Company filed a current report on Form 8-K under Item 5 (Other Events) reporting that it had issued a press release announcing plans to accelerate the submission of its Premarket Approval (PMA) application to the U.S. Food and Drug Administration (FDA).

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SIGNATURE

Pursuant to the requirements 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.

CONCEPTUS, INC

By: /s/ GLEN K. FURUTA

Glen K. Furuta
Vice President, Finance and Administration and Chief Financial Officer

Date: May 13, 2002