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CONCEPTUS INC
Form 10-Q
August 13, 2001

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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 June 30, 2001

[] 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
(State or other jurisdiction of
incorporation or organization)

94-3170244
(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 August 9, 2001, 13,690,784 shares of the registrant's Common Stock were outstanding.

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CONCEPTUS, INC.

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FORM 10-Q for the Quarter and Six Months Ended June 30, 2001

INDEX

	Facing sheet
	Index
Part I.	Financial Information (Unaudited)
Item 1.	a) Consolidated balance sheets at June 30, 2001 and December 31, 2000
	b) Consolidated statements of operations for the three and six month periods ended June 30, 2001 and June 30, 2000
	c) Consolidated statements of cash flows for the three and six month periods ended June 30, 2001 and June 30, 2000
	d) Notes to consolidated financial statements
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations
Item 3.	Quantitative and Qualitative Disclosures About Market Risk
Part II.	Other Information
	Signature
	Index to Exhibits

2

PART I: FINANCIAL INFORMATION

ITEM 1. Financial Statements

Conceptus, Inc.

Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	June 30, 2001	December 31, 2000
	-----	-----
	(Unaudited)	(Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,717	\$ 5,801
Short-term investments	5,801	163
Accounts receivable	163	483
Inventory	483	452
Other current assets	452	
	-----	-----
Total current assets	14,616	7,900
Property and equipment, net	1,288	1,288

2

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Other assets	398	

Total assets	\$ 16,302	\$
	=====	
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,514	\$
Clinical trial accruals	1,306	
Accrued compensation	537	
Other accrued liabilities	402	

Total current liabilities	3,759	

Commitments		
Stockholders' equity:		
Common stock, \$0.003 par value, 30,000,000 shares authorized, 13,574,316 and 11,701,733 shares issued and outstanding at June 30, 2001 and December 31, 2000, respectively	88,034	
Accumulated deficit	(75,491)	

Total stockholders' equity	12,543	

	\$ 16,302	\$
	=====	

See accompanying notes

3

Conceptus, Inc.

Consolidated Statements of Operations
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended		Six Mo
	June 30,		Ju
	2001	2000	2001
	----	----	----
Net sales	\$ 163	\$ --	\$ 163
Operating expenses:			
Cost of sales	646	--	646
Research and development	1,676	1,818	3,865
Selling, general and administrative	2,343	1,143	4,397
	-----	-----	-----
Total operating expenses	4,665	2,961	8,908
	-----	-----	-----
Operating loss	(4,502)	(2,961)	(8,745)
Recovery of legal defense costs	--	60	--
Interest and other income, net	215	11	402
	-----	-----	-----
Net loss	\$ (4,287)	\$ (2,890)	\$ (8,343)

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	=====	=====	=====
Basic and diluted net loss per share	\$ (0.32)	\$ (0.30)	\$ (0.67)
	=====	=====	=====
Shares used in computing basic and diluted net loss per share	13,300	9,692	12,521
	=====	=====	=====

See accompanying notes

4

Conceptus, Inc.

Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2001	2000
	----	----
Cash flows from operating activities		
Net loss	\$ (8,343)	\$ (4,649)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	342	249
Stock compensation expense	91	--
Changes in operating assets and liabilities		
Accounts receivable	(163)	(213)
Inventory	(416)	--
Other current assets	(393)	338
Other assets	(64)	123
Accounts payable	531	80
Clinical trial accruals	(604)	265
Accrued compensation	(450)	(52)
Other accrued liabilities	135	(49)
	-----	-----
Net cash used in operating activities	(9,334)	(3,908)
	-----	-----
Cash flows from investing activities		
Purchase of investments	(4,255)	--
Maturities of investments	6,326	3,992
Capital expenditures	(477)	(278)
	-----	-----
Net cash provided by investing activities	1,594	3,714
	-----	-----
Cash flows from financing activities		
Net proceeds from issuance of common stock	10,836	99
	-----	-----
Net cash provided by financing activities	10,836	99
	-----	-----
Net increase (decrease) in cash and cash equivalents	3,096	(95)
Cash and cash equivalents at beginning of period	4,621	3,494
	-----	-----
Cash and cash equivalents at end of period	\$ 7,717	\$ 3,399

4

See accompanying notes

5

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with Generally Accepted Accounting Principles for interim financial information and with the instruction 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. 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, 2000 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by Generally Accepted Accounting Principles for complete financial statements. This financial data should be reviewed in conjunction with the audited financial statements and notes thereto included in the Company's Form 10-K for the year ended December 31, 2000. The results of operations for the three months ended June 30, 2001 may not necessarily be indicative of the operating results for the full 2001 fiscal year.

Certain amounts in prior periods have been reclassified to conform with current period presentation. The reclassification had no impact on the Company's operating result or financial position.

2. Inventories

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

	June 30, 2001 -----	December 31, 2000 -----
Raw materials	\$ 193	\$ 31
Work in process	126	8
Finished products	164	28
	-----	-----
Total	\$ 483 =====	\$ 67 =====

3. Stockholders' Equity

In April 2001, the Company completed a private placement of approximately 1.64 million shares of newly issued common stock at \$7.00 per share, pursuant to

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Stock Purchase Agreements dated April 10, 2001. Gross proceeds to the Company were \$11.5 million.

4. Litigation Cost Recovery

In June 2000, the Company received an aggregate of \$513,000 from its Directors' and Officers' liability insurance policy for recovery of legal defense costs in connection with a sexual harassment lawsuit filed against the Company in December 1997. The payment was recorded as other income.

6

5. 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 is excluded. Basic and diluted net loss per share are equivalent for all periods presented due to the Company's net loss position.

6. Comprehensive Income

For all periods presented, total comprehensive loss approximates net loss as unrealized gains and losses were immaterial.

7

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 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, 2000, 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

Since inception on September 18, 1992, we have been engaged primarily in the design, development and marketing of innovative interventional medical devices for use in reproductive medicine. Our current focus is to develop Essure(TM) pbc, a non-incisional permanent birth control procedure for women, which was previously known as STOP (Selective Tubal Occlusion Procedure). The Essure procedure is designed to be a less invasive and less costly alternative to female surgical sterilization, more commonly known as tubal ligation.

Data from a 1998 United Nations report estimate that 33% of worldwide reproductive couples using contraception rely on tubal ligation. Furthermore, a survey performed by the Centers for Disease Control indicates that tubal ligation is the most prevalent form of birth control in the United States. According to the study, the prevalence increases with age and number of

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children, and 35% of women age 35 - 44 have had a surgical tubal sterilization. An estimated 700,000 surgical tubal ligations are performed annually in the U.S., of which 92% are performed in a hospital or surgi-center under general anesthesia which requires four to five hours of hospital recovery time and three to ten days before returning to regular activities. The Essure procedure is based on a unique and proprietary catheter delivery system for minimally invasive transcervical tubal access. It does not require surgical incisions or general anesthesia, and hence, it has a rapid recovery time and lower total cost when compared to tubal ligation.

We initiated a pivotal trial of Essure in May 2000 at 13 sites throughout the U.S., Australia and select European countries. The pivotal trial is designed to obtain 12-month safety, effectiveness and patient comfort data to support the filing of a Pre-Market Approval, or PMA, application with the FDA. Submission of the PMA is currently anticipated for the third quarter of 2002. To date, a total of 464 women have had device placement in both fallopian tubes in the pivotal trial. Interim data show that, excluding the day of the procedure, 92% of the employed women returned to work in one day or less. Further results indicate that nearly 60% of Essure pbc patients were back to their regular physical activities within one day, and within two days 76% had resumed regular activities. A comparison to laparoscopic tubal ligation was not performed in the pivotal trial; however, published reports show that women who undergo surgical tubal ligation - the only permanent birth control option currently available for women in the U.S. - return to regular physical activities in three to ten days.

To date, combining interim data from both the pivotal trial and a Phase II study of the current generation design, more than 400 women years of effectiveness testing have been achieved without a pregnancy. However, we note that no method of birth control is 100% effective and pregnancies are expected.

8

Essure is listed with Australia's Therapeutic Goods Administration, which allows us to market and sell in Australia. During the second quarter 2001, we have implemented an awareness program in Australia directed at general practitioners and gynecologists focused on patient counseling and referral. This was necessary because in Australia the general practitioner is required to make the referral to the gynecologist for woman to have this procedure. In addition, we initiated a media campaign in June 2001 that generated nationwide coverage of the Essure procedure in Australia and resulted in significant calls to the offices of trained specialists. To date, we have trained 40 physicians at 18 sites throughout Australia and expect to train 30 more physicians by the end of third quarter 2001.

Besides Australia, we have also received marketing clearance in Singapore and have begun to sell Essure to one of the largest public hospitals in Singapore. We will be training additional physicians in Singapore and anticipate modest revenues in that country through the remainder of 2001. In February 2001, we received approval to affix the CE Mark to the Essure device, which indicates that Essure is certified for sale throughout the European Union, subject to compliance with local regulations. We are currently evaluating marketing opportunities in Europe, and will select a distribution channel in the upcoming months. We have trained physicians at eight sites in the U.K. and France for reimbursement studies and anticipate the reimbursement process to be completed in early 2002. We expect to make our first commercial sales of Essure in select European markets in 2002. In the U.S., we intend to begin selling Essure following FDA approval, which is expected in 2003.

In addition to the pivotal trial and a Phase II study, we are continuing our histology studies to examine how the fallopian tube reacts to the Essure micro-insert and to support the theorized mechanism of action. The micro-insert elicits tissue in-growth throughout and around the device which blocks the fallopian tube. The tissue in-growth is expected to result in long-term device retention and pregnancy prevention.

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We have a limited history of operations and have experienced significant operating losses since inception. Operating losses are expected to continue for at least the next several years as we continue to expend substantial resources to fund clinical trials in support of regulatory and reimbursement approvals, to conduct research and product development and to develop appropriate marketing and distribution systems for Essure.

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 ability to scale up our commercial manufacturing capabilities and the introduction of competitive products.

Results of Operations - Three and Six Months Ended June 30, 2001 and 2000

Revenues were \$163,000 for the three and six months ended June 30, 2001 as compared to none for the same periods in the prior year. In May 2001, Conceptus initiated its first commercial launch in Australia and the revenues recorded primarily represent the first Essure pbc sales in Australia.

Cost of sales for the three and six months ended June 30, 2001 was \$646,000 as compared to none for the same periods in the prior year.

Research and development ("R&D") expenses decreased 8% to \$1,676,000 for the three months ended June 30, 2001, from \$1,818,000 for the same period in the prior year, due primarily to the

9

completion of pivotal trial patient enrollment. For the six months ended June 30, 2001, R&D expenses increased 14% to \$3,865,000, from \$3,386,000 for the same period in the prior year, due to increased activities to improve our manufacturing processes to enhance productivity, reduce cost, and increase automation in certain production processes.

Selling, general and administrative ("SG&A") expenses increased 105% to \$2,343,000 for the three months ended June 30, 2001, and 124% to \$4,397,000 for the six months ended June 30, 2001, from \$1,143,000 and \$1,965,000 for the same periods in the prior year, respectively. The increases were primarily due to marketing efforts to support the commercial introduction of Essure pbc in Australia and increased administrative costs required to support growth in marketing and manufacturing activities.

In June 2000, the Company received an aggregate of \$513,000 from its Directors' and Officers' insurance policy for legal defense costs reimbursement in connection with a sexual harassment lawsuit filed against the Company in December 1997. The receipt was recorded as other income.

Net interest and other income increased to \$215,000 and \$402,000 for the three and six months ended June 30, 2001, from \$11,000 and \$189,000 for the same periods in the prior year, respectively. The increases were primarily due to investment income on proceeds provided by the April 2001 private placement.

We have a limited history of operations. Since our inception in September 1992, we have been engaged primarily in research and development of our T-TAC and STARRT Falloposcopy systems and the Essure pbc device, and since 1996, the ERA and FUTURA product lines. In 1998, we suspended efforts on the T-TAC, STARRT, ERA and FUTURA products and focused our resources solely on the Essure pbc product. We have generated only limited revenues and have only limited experience in manufacturing, marketing or selling our products in

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commercial quantities. We have experienced significant operating losses since inception and, as of June 30, 2001, had an accumulated deficit of \$75.5 million. We expect our operating losses to continue for at least the next several years as we continue to expend substantial resources in research and product development, market development for Essure pbc and complete our clinical trials. Due to the expense and unpredictable nature of these activities, there can be no assurance that we will achieve or sustain profitability in the future.

Liquidity and Capital Resources

At June 30, 2001, cash, cash equivalents and investments were \$13.5 million, compared with \$12.5 million at December 31, 2000. The increase is due to the receipt of \$10.8 million of net proceeds from the April 2001 private placement, offset by \$9.3 million of cash used in operating activities and \$477,000 of cash used for the purchase of capital equipment.

We estimate that our existing capital resources will be sufficient to meet our requirements into the first quarter of 2002, but will not be sufficient to fund completion of the pivotal trial nor to commercialize our Essure pbc device on a wide-scale basis. Our future liquidity and capital requirements will depend upon numerous factors, including the progress of our clinical research and product development programs, execution and implementation of partnering arrangements, the receipt of and the time required to obtain regulatory clearances and approvals, and the resources devoted to developing, manufacturing and marketing our products. Accordingly, we will require additional financing and therefore, will in the future seek to raise additional funds through bank facilities, debt or equity offerings or other sources of capital. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. Additional funding may

10

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.

11

Part II. Other Information

Item 1. Legal Proceedings

There are no material pending or threatened legal proceedings against the Company. The Company from time to time is involved in routine legal matters incident to its business. While management currently believes the amount of ultimate liability, if any, with respects to these actions will not materially affect the financial position, results of operations, or liquidity of the Company, the ultimate outcome of any litigation is uncertain.

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Item 2. Changes in Securities and Use of Proceeds

On April 11, 2001, the Company sold and issued 1,642,858 million shares of its common stock (the "Shares") for \$7.00 per share to certain institutional and other accredited investors (the "Purchasers") in a private placement transaction (the "Private Placement") exempt from registration under Regulation D promulgated under the Securities Act of 1933, as amended (the "Securities Act"). Pursuant to the terms of certain Stock Purchase Agreements, dated as of April 10, 2001, by and among the Company and the Purchasers, on April 23, 2001, the Company filed a Registration Statement on Form S-3, SEC file no. 333-59368, with respect to certain resales of the Shares by the Purchasers on a delayed or continuous basis under Rule 415 of the Securities Act. The gross proceeds to the Company from the sale of the Shares were approximately \$11.5 million. These funds will be used for working capital and are currently invested in investment-grade instruments.

Item 3. Defaults upon Senior Securities

None.

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

The 2001 Annual Shareholders' Meeting was held on May 16, 2001 and the following votes were obtained, approving all matters proposed to stockholders:

Proposal 1 -----	Required Vote -----	Votes for Nominee -----		Votes Withhe -----
Nomination of Directors	Plurality of votes cast			
- Steven Bacich		8,398,382		1,201,204
- Richard Randall		9,430,494		169,092
Proposal 2 -----	Required Vote -----	For ---	Against -----	Abstain -----
Appointment of Ernst & Young as Independent Auditors	Majority of votes cast	9,550,986	23,100	25,500
Proposal 3 -----	Required Vote -----	For ---	Against -----	Abstain -----
Approval of 2001 Equity Incentive Plan	Majority of votes cast	3,683,196	1,637,922	13,775

Item 5. Other Information

In response to the SEC's recent adoption of Rule 10b5-1 under the Securities Exchange Act of 1934, certain officers of the Company have entered into trading plans for systematically selling of a portion of their shares of Common Stock. The officers who have entered into trading plans include Steven Bacich, Chief Executive Officer; Cindy Domecus, Sr. VP of Clinical Research and Regulatory Affairs; Ashish Khera, VP of Research and Development and Oliver

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Brouse, Director of Marketing. The Company anticipates that, as permitted by the new Rule 10b5-1 and the Company's inside trading policy, some or all of its officers, directors and other insiders may establish trading plans at some date in the future.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits.

None.

(b) Reports on Form 8-K.

On April 12, 2001, the Company filed a current report on Form 8-K under Item 5 ("Other Events") reporting that it had issued a press release announcing that it had completed a private placement of approximately 1,643,000 shares of its common stock to institutional and other accredited investors.

On April 26, 2001, 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 months ended March 31, 2001.

13

SIGNATURES

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: August 13, 2001

14