

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

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FILER

CONCEPTUS INC

CIK: **896778** | IRS No.: **973170244** | State of Incorpor.: **DE** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **000-27596** | Film No.: **1697134**
SIC: **3841** Surgical & medical instruments & apparatus

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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d) of The
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 26, 2001

CONCEPTUS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware

000-27596

97-3170244

State or Other Jurisdiction
of Incorporation)

(Commission File Number)

(I.R.S. Employer
Identification No.)

1021 Howard Avenue, San Carlos, California 94070

(Address of Principal Executive Offices) (Zip Code)

(650) 802-7240

(Registrant's telephone number, including area code)

N/A

(Former Name or Former Address, if Changed Since Last Report)

ITEM 5. OTHER EVENTS.

On July 26, 2001, Conceptus, Inc. issued a press release announcing financial results for the three and six months ended June 30, 2001. Text of the

press release follows:

SAN CARLOS, Calif. (July 26, 2001) - Conceptus, Inc. (NASDAQ NM: CPTS), developer of the non-incisional permanent birth control procedure Essure(TM) pbc, previously known as STOP (Selective Tubal Occlusion Procedure), today announced financial results for the three and six months ended June 30, 2001.

Net loss for the quarter was \$4.3 million, or \$0.32 per share, compared with a net loss of \$2.9 million, or \$0.30 per share, in the comparable period last year. Revenues for the second quarter of 2001 were \$163,000, representing the first commercial sales in Australia, where Essure pbc was recently launched, as well as \$23,000 of Essure pbc sales in Singapore. Cost of sales was \$646,000. The Company reported no sales or cost of sales for the comparable period last year. Research and development expenses for the quarter decreased slightly to \$1.7 million, from \$1.8 million in the prior-year second quarter. Selling, general and administrative expenses in the second quarter increased to \$2.3 million from \$1.1 million in 2000, as the Company ramped up its sales and marketing efforts in Australia.

For the six months ended June 30, 2001, net loss was \$8.3 million, or \$0.67 per share, compared with a net loss of \$4.6 million, or \$0.48 per share, for the six months ended June 30, 2000. The increase in net loss was primarily due to greater sales and marketing activities during the first half of 2001.

Cash, cash equivalents and short-term investments as of June 30, 2001 were \$13.5 million, compared with \$12.5 million as of December 31, 2000. On April 12, 2001, the Company announced the closing of an \$11.5 million private placement financing of approximately 1,643,000 newly issued shares of common stock.

"We are extremely encouraged by the early response we have received to Essure pbc in Australia among patients, physicians and the media alike," commented Steven Bacich, chief executive officer. "We have established a high-quality training and preceptorship program for qualified gynecologists. In addition, we implemented an awareness program directed at general practitioners (GP) and gynecologists focused on patient counseling and referral, including the contracting of a 6-person GP specialist sales force to complement our 4 direct sales representatives in Australia."

Mr. Bacich continued, "The data from the U.S. Pivotal Trial continue to support the Phase II data that formed the basis for marketing in Australia. In June, our media campaign resulted in nationwide coverage of the Essure pbc procedure in Australia, which was the final phase of the first commercial launch of the product worldwide. Following this widespread media coverage, patient calls sharply increased at the offices of the trained specialists for the Essure pbc procedure. Currently, we have trained 40 physicians at 18 sites throughout Australia, and expect

that another 30 physicians will have been trained by the end of the third quarter 2001. In addition, we have received our marketing clearance in Singapore and have begun selling product to one of the largest public hospitals there.

This quarter, we will be training more physicians in Singapore and expect modest yet growing sales in that country throughout the year."

In commenting on marketing plans in Europe, Mr. Bacich said, "An in-depth evaluation of the European opportunity is nearly complete and a decision regarding the optimal distribution channel is expected to be made in the upcoming months. In addition, we have been engaged in training physicians at eight sites in the U.K. and France for reimbursement studies with a final goal to have the reimbursement process completed in early 2002."

Combining data from both the Essure pbc Phase II and pivotal trial studies, to date more than 400 women years of effectiveness have been achieved without a pregnancy. The Company cautions, however, that no method of birth control is 100% effective and that pregnancies are expected. In addition, the success criteria for the pivotal trial allow for pregnancies to occur.

As previously announced, excluding the day of the procedure, data show that 92 percent of Essure pbc patients who are employed returned to work in one day or less of undergoing the procedure. Further results indicate that nearly 60 percent of Essure pbc patients were back to their regular physical activities within one day, and within two days 76 percent 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 3 to 10 days.

Conceptus has scheduled an investor conference call to discuss this announcement beginning at 4:30 p.m. Eastern Time today. Individuals interested in listening to the live conference call via the Internet may do so by logging on to the Company's Website, www.conceptus.com. A replay will be available on the Website for 30 days.

Permanent Birth Control

Surgical tubal ligation has become the most common form of birth control worldwide, despite the fact that it is invasive and costly. About 93 percent of the procedures in the U.S. are performed in a hospital or surgi-center under general anesthesia, requiring between four to five hours of hospital recovery time and 3 to 10 days before returning to regular activities. An Essure pbc procedure does not require cutting or penetrating the abdomen and can be performed in a less costly procedure setting without general anesthesia. Accordingly, a woman is expected to spend about two to three hours of her day for an Essure pbc procedure and have a rapid return to regular activities. Essure pbc does not involve taking drugs or hormones, which can interfere with the body's natural menstruation cycle.

About Conceptus

Conceptus, Inc. is developing Essure pbc, an investigational medical device and

procedure in the U.S., which is designed to provide a non-incisional alternative to tubal ligation, the leading form of contraception worldwide. Data from the United Nations show that worldwide, 33% of reproductive couples using contraception rely on surgical tubal ligation. Additionally, a survey performed by the United States Centers for Disease Control and Prevention indicates that surgical tubal ligation continues to be the most prevalent form of contraception in the United States, and that 35% of women age 35-44 have had a surgical tubal sterilization. An estimated 700,000 surgical tubal ligations are performed each year in the United States.

The Essure pbc procedure is based on a unique and proprietary catheter delivery system for minimally invasive transcervical tubal access.

Except for the historical information contained herein, the matters discussed in this press release are forward-looking statements, the accuracy of which is necessarily subject to risks and uncertainties. The receipt of regulatory approvals, results of product development programs, and clinical efficacy of and market demand for products, among other matters discussed in this release, may differ significantly from the discussion of such matters in the forward-looking statements. Such differences may be based upon factors within the Company's control, such as strategic planning decisions by management and re-allocation of internal resources, or on factors outside of the Company's control, such as delays by regulatory authorities, scientific advances by third parties and introduction of competitive products, as well as those factors set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2000 and other filings with the Securities and Exchange Commission.

(Tables to follow)

Conceptus, Inc.

Statement of Operations
(Unaudited)

(In thousands, except per share amounts)

<TABLE>
<CAPTION>

	Three Months Ended June 30,		Six Months Ended June 30,	
	2001	2000	2001	2000
<S>	<C>	<C>	<C>	<C>
Net Sales	\$ 163	\$ --	\$ 163	\$ --
Operating expenses:				
Cost of Sales	646	--	646	--
Research and development	1,676	1,818	3,865	3,386
Selling, general and administrative	2,343	1,143	4,397	1,965

Total operating expenses	4,665	2,961	8,908	5,351
	-----	-----	-----	-----
Operating loss	(4,502)	(2,961)	(8,745)	(5,351)
Recovery of legal defense costs	--	60	--	513
Interest and other income, net	215	11	402	189
	-----	-----	-----	-----
Net loss	\$ (4,287)	\$ (2,890)	\$ (8,343)	\$ (4,649)
	=====	=====	=====	=====
Basic and diluted net loss per share	\$ (0.32)	\$ (0.30)	\$ (0.67)	\$ (0.48)
	=====	=====	=====	=====
Shares used in computing basic and diluted net loss per share	13,300	9,692	12,521	9,686
	=====	=====	=====	=====

</TABLE>

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5

Conceptus, Inc.

Balance Sheet
(Unaudited)
(In thousands)

<TABLE>

<CAPTION>

	June 30, 2001	December 31, 2000
	-----	-----
	(Unaudited)	*
	<C>	<C>
Cash, cash equivalents and short-term investments	13,518	\$ 12,493
Accounts receivable	163	--
Inventory	483	67
Other current assets	452	59
	-----	-----
Total current assets	14,616	12,619
Property and equipment, net	1,288	1,153
Other assets	398	334
	-----	-----
Total assets	\$ 16,302	\$ 14,106
	=====	=====
Accounts payable and accruals	3,759	4,147
	-----	-----

Common stock	88,034	77,107
Accumulated deficit	(75,491)	(67,148)
	-----	-----
Stockholders' equity	12,543	9,959
	-----	-----
Total liabilities and stockholders' equity	\$ 16,302	\$ 14,106
	=====	=====

</TABLE>

* Derived from audited financial statements.

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6

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 hereunto duly authorized.

CONCEPTUS, INC.
(Registrant)

By: /s/ Glen K. Furuta

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

Dated: August 2, 2001

7