ORASURE TECHNOLOGIES INC
Form 8-K
October 28, 2003

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): October 28, 2003

ORASURE TECHNOLOGIES, INC.

(Exact name of issuer as specified in charter)

DELAWARE	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission file number)**	**(I.R.S. Employer Identification Number)**

220 East First Street

Bethlehem, Pennsylvania 18015-1360

(Address of principal executive offices)

(610) 882-1820

(Registrant s telephone number, including area code)

Item 5. Other Events and Required FD Disclosure.

Financial Results for Quarter and Nine Months Ended September 30, 2003

On October 28, 2003, OraSure Technologies, Inc. (the Company or OraSure) announced that its total revenues for the third quarter of 2003 increased 27% to $10.3 million, compared to $8.1 million for the quarter ended September 30, 2002. Product revenues for the third quarter increased 26% to $10.2 million, compared to $8.1 million in 2002. Both amounts represent record quarterly revenues for the Company. The Company also recorded a net profit for the quarter of $53,000, or $0.00 per share, compared to a net loss of $387,000, or $(0.01) per share, in the third quarter of 2002.

For the nine months ended September 30, 2003, the Company had total revenues of $28.6 million, a 20% increase over revenues of $23.8 million for the nine months ended September 30, 2002. Product revenues for the nine months ended September 30, 2003 were $28.0 million, or 19% higher than the $23.4 million in product revenues recorded during the comparable period in 2002. The Company recorded a net loss of $1.6 million, or $(0.04) per share, for the nine months ended September 30, 2003, compared to a net loss of $3.3 million, or $(0.09) per share, for the comparable period in 2002.

We had another great quarter and are pleased to announce the sixth consecutive quarter of increased revenues and that we had a small net profit, both of which are milestones in our efforts to achieve sustained profitability, said Mike Gausling, President and CEO of OraSure Technologies, Inc. We also made significant progress during the third quarter against our stated 2003 objectives, including the submission of an application for FDA approval of oral fluid and plasma claims for OraQuick®, receipt of FDA approval of our venous whole blood claim for OraQuick®, roll-out of our Freeze Off wart removal product, and submission of an application for 510(k) clearance for our UP*link*® analyzer and NIDA-5 panel of oral fluid drug assays. Additionally, shortly after the end of the quarter, we sold 5,000,000 shares of common stock and received over $42 million in net cash proceeds.

The revenue increase during the third quarter was primarily attributable to increased sales of the Company s OraQuick® rapid HIV-1 antibody test and greater than anticipated sales of Freeze Off, the Company s over-the-counter wart removal product, partially offset by lower sales of the Company s urine assays in the insurance risk assessment market.

Gross margin in the third quarter was 61%, compared to 59% in the same period in 2002. This increase resulted primarily from lower scrap and spoilage during the quarter compared to a year ago.

Operating expenses for the third quarter increased to $6.3 million, from $5.2 million in the comparable period in 2002. This increase was primarily attributable to increased advertising support and higher travel expenses for sales and marketing personnel, increased expenses associated with the occupancy of the Company s new corporate headquarters in Bethlehem, Pennsylvania, and increased clinical trial expenses. Operating expenses for the nine months ended September 30, 2003 were $18.8 million compared to $17.7 million for the comparable period in 2002.

Cash, cash equivalents and short-term investments totaled $17.7 million and working capital was $21.5 million at September 30, 2003, compared to $14.9 million in cash, cash equivalents and short-term investments and $18.9 million of working capital at December 31, 2002. During the third quarter, the Company renewed its existing credit facility with Comerica Bank and now has $8 million in available credit to finance future growth. With the closing of the stock offering in early October, the Company s cash, cash equivalents and short-term investments now approximate $60 million.

Cash flow from operations was $661,000 for the third quarter of 2003. This is the sixth consecutive quarter of positive cash flow from operations. Cash flow from operations for the nine months ended September 30, 2003 was $934,000.

Condensed Financial Data

(In thousands, except per-share

data and percentages)

Unaudited

	Three months ended September 30,		Nine months ended September 30,	
	2003	**2002**	**2003**	**2002**
Results of Operations				
Revenues	$ 10,331	$ 8,107	$ 28,571	$ 23,762
Cost of products sold	4,002	3,350	11,403	9,444
Gross profit	6,329	4,757	17,168	14,318
Operating expenses:				
Research and development	2,202	1,890	6,222	6,521
Sales and marketing	2,513	1,947	7,485	6,328
General and administrative	1,602	1,321	5,125	4,886
Total operating expenses	6,317	5,158	18,832	17,735
Operating income (loss)	12	(401)	(1,664)	(3,417)
Other income (expense), net	41	14	94	156
Net income (loss)	$ 53	$ (387)	$ (1,570)	$ (3,261)
Basic and diluted net income (loss) per share	$ 0.00	$ (0.01)	$ (0.04)	$ (0.09)
Weighted average shares:				
Basic	38,666	37,536	38,444	37,488
Diluted	39,777	37,536	38,444	37,488

	Three months ended September 30,				
	Dollars			Percentage of Total Revenues	
	2003	**2002**	**% Change**	**2003**	**2002**
Market Revenues					
Insurance risk assessment	$ 2,827	$ 2,987	(5)%	27%	37%
Infectious disease testing	2,294	1,472	56	22	18
Substance abuse testing	1,801	1,805		18	22
Cryosurgical systems*	3,298	1,840	79	32	23
Product revenues	10,221	8,104	26	99	100

Licensing and product development	110	3	3,567	1	
Total revenues	$ 10,331	$ 8,107	27	100%	100%

* Previously reported as physician s office therapies and includes sales of Histofreezer® in the physician s office market and Freeze Off in the over-the-counter market.

	Nine months ended September 30,				
	Dollars		%	Percentage of Total Revenues	
	2003	2002	Change	2003	2002
Market Revenues					
Insurance risk assessment	$ 8,285	$ 8,899	(7)%	29%	38%
Infectious disease testing	7,766	4,546	71	27	19
Substance abuse testing	5,234	4,768	10	18	20
Cryosurgical systems*	6,717	5,233	28	24	22
Product revenues	28,002	23,446	19	98	99
Licensing and product development	569	316	80	2	1
Total revenues	$ 28,571	$ 23,762	20	100%	100%

* Previously reported as physician s office therapies and includes sales of Histofreezer® in the physician s office market and Freeze Off in the over-the-counter market.

	September 30, 2003	December 31, 2002
Balance Sheets		
Assets		
Cash, cash equivalents and short-term investments	$ 17,692	$ 14,908
Accounts receivable, net	7,025	5,198
Inventories	4,012	4,088
Other current assets	772	926
Property and equipment, net	6,783	7,428
Other non-current assets	2,668	3,189
Total assets	$ 38,952	$ 35,737
Liabilities and Stockholders Equity		
Current portion of long-term debt	$ 1,125	$ 1,066
Accounts payable	1,776	1,802
Accrued expenses	5,105	3,321
Long-term debt, less current portion	2,739	3,409
Other liabilities	177	120
Stockholders equity	28,030	26,019
Total liabilities and stockholders equity	$ 38,952	$ 35,737

Recent Developments

Distribution Strategy Hospital Market

Abbott Laboratories has been a co-exclusive distributor of the Company s OraQuick® rapid HIV-1 antibody test in the United States under a five-year agreement, which requires minimum monthly purchases totaling approximately $4 million during a 15-month period following initial FDA approval of the product. As previously reported, Abbott s purchases through the first 10 months of this period have been substantially below these minimum obligations, totaling only $1.5 million.

The Company notified Abbott of this deficiency and requested that it be cured. The Company has been working with Abbott, in the context of negotiating an amendment to the agreement

affecting minimum purchase requirements and other terms, to correct this deficiency and to relieve Abbott of the consequences of its breach, which include termination of its distribution rights under the agreement.

As a result of Abbott s failure to cure its purchase deficiency and recently stalled efforts to reach agreement on an amendment, the Company has declared the agreement terminated. At the same time, the Company has invited Abbott to continue negotiations toward an amended distribution arrangement and offered to continue supplying OraQuick® devices to Abbott on terms acceptable to the Company. However, there is no assurance that the agreement will be reinstated and amended or that Abbott will continue to purchase OraQuick® devices.

Abbott has advised the Company that it disputes the termination of the agreement and has initiated discussions under the alternative dispute resolution procedures in the agreement. Pursuant to these procedures, if the parties are not able to reach resolution through good faith negotiations, either party may submit the matter to binding arbitration for final resolution. Although OraSure believes that the agreement with Abbott has been lawfully terminated, there is no assurance that it will prevail if this matter is submitted to arbitration.

The Company is evaluating alternative distribution arrangements, including expanding its internal sales force to sell directly to hospitals, which was a primary market targeted by Abbott. The Company believes that expanding its direct sales efforts will provide greater control over distribution, a higher margin contribution from this product and a channel for distributing other high value-added products to these customers. The Company estimates that the available market for HIV testing in the United States is currently 17 million potential tests, consisting of 10 million tests in hospitals, 3 million in physician office labs, 3 million in the public health market, and roughly 1 million to the military and Centers for Disease Control and Prevention (CDC) markets. Additional testing is also anticipated due to the CDC s new initiatives for advancing HIV prevention entitled, Advancing HIV Prevention: New Strategies for a Changing Epidemic.

The Company currently intends to establish a small, but highly effective sales force focusing on the top metropolitan areas in the country, possibly supplemented with selective telemarketing and outside sales forces. The Company would also have the potential to develop, purchase or license additional products to be sold by this sales force in the future.

In the event the Company is unsuccessful in deploying its own sales force or is unable to implement an alternative distribution arrangement in a timely manner or at all, the sales volume of its OraQuick® devices may decrease.

HIV-2 Patent License

The Company believes it is important that it offer its OraQuick® product for the detection of the HIV-2 virus in order to fully develop a global sales strategy for OraQuick®. Consequently, the Company approached BioRad Laboratories about securing a world-wide non-exclusive license for HIV-2 and has completed negotiation of a license agreement that the Company believes is complete to the satisfaction of both parties. BioRad is now in the process of securing the necessary signatures and approval from several other licensees and other relevant parties. Although there can be no assurance that the Company will secure all of the necessary signatures, the Company remains cautiously optimistic that the license agreement will be executed by all required parties.

Sales of Freeze-Off

In February 2003, the Company received FDA clearance to market and sell its Histofreezer® product in the retail or over-the-counter market for the removal of common and planter warts. The Company entered into an agreement with Medtech Holdings, Inc., the owner of the Compound W® wart removal product line, for the distribution of Freeze Off, a cryosurgical wart removal product similar to Histofreezer®, in the over-the-counter market in the United States. This product is being sold under the name, Freeze Off.

The Company initially expected Medtech to purchase about $2 million of this product in 2003, based on minimum purchase obligations in the agreement. However, the roll-out of this product has gone extremely well, and the Company now expects sales to top $4 million this year based on orders received to date from Medtech.

Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.

(c) Exhibits

Exhibit No.	Description
99	Press Release dated October 28, 2003, in which OraSure Technologies, Inc. announced its financial results for the quarter and nine months ended September 30, 2003, provided an update on its strategy for distributing OraQuick® to the hospital market, and reaffirmed its financial guidance for 2003 and 2004.

Item 12. Results of Operations and Financial Condition.

On October 28, 2003, OraSure Technologies, Inc. issued a press release in which it announced its financial results for the quarter and nine months ended September 30, 2003, provided an update on its strategy for distributing OraQuick® to the hospital market, and reaffirmed its financial guidance for 2003 and 2004. A copy of the press release is attached as Exhibit 99 to this Form 8-K and is incorporated herein by reference.

Signatures

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

ORASURE TECHNOLOGIES, INC.

Date: October 28, 2003 By: /s/ JACK E. JERRETT

Jack E. Jerrett

Senior Vice President, General Counsel

and Secretary

Index to Exhibits

Exhibit No.	Description
99	Press Release dated October 28, 2003, in which OraSure Technologies, Inc. announced its financial results for the quarter and nine months ended September 30, 2003, provided an update on its strategy for distributing OraQuick® to the hospital market, and reaffirmed its financial guidance for 2003 and 2004.