ORASURE TECHNOLOGIES INC Form 10-Q August 06, 2009 Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2009.

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 Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE(State or Other Jurisdiction of

36-4370966 (IRS Employer

Incorporation or Organization)

Identification No.)

220 East First Street, Bethlehem, Pennsylvania (Address of Principal Executive Offices)

18015 (Zip code)

(610) 882-1820

(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 "

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes "No"

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer "

Accelerated filer

X

Non-accelerated filer "

Smaller reporting company

Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes "No x

Number of shares of Common Stock, par value \$.000001 per share, outstanding as of August 5, 2009: 45,876,186

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

(Unaudited)

ASSETS	JUNE 30, 2009	DECEMBER 31, 2008
CURRENT ASSETS:	Φ (2.010.2(1	Φ 20.565.210
Cash and cash equivalents Short-term investments	\$ 63,019,261 16,143,003	\$ 39,565,218 42,957,467
Accounts receivable, net of allowance for doubtful account of \$334,038 and \$163,100	11,071,032	11,571,048
Inventories	8,662,672	10,704,088
Prepaid expenses and other	1,272,738	1,418,171
- Proceedings of the Control of the	, , ,,,,,	, , ,
Total current assets	100,168,706	106,215,992
PROPERTY AND EQUIPMENT, net	20,774,959	21,235,367
PATENTS AND PRODUCT RIGHTS, net	956,252	4,380,540
OTHER ASSETS	79,816	86,290
	\$ 121,979,733	\$ 131,918,189
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	\$ 538,854	\$ 557,897
Accounts payable	2,086,258	3,925,662
Accrued expenses and other	8,223,191	10,795,955
Total current liabilities	10,848,303	15,279,514
LONG-TERM DEBT	8,041,679	8,301,440
OTHER LIABILITIES	5,008	11,985
STOCKHOLDERS EQUITY Preferred stock, par value \$.000001, 25,000,000 shares authorized, none issued Common stock, par value \$.000001, 120,000,000 shares authorized, 45,876,186 and 45,769,221 shares		
issued and outstanding	46	46
Additional paid-in capital	237,352,061	235,862,999
Accumulated other comprehensive loss	(214,358)	(262,442)
Accumulated deficit	(134,053,006)	(127,275,353)
Total stockholders equity	103,084,743	108,325,250
	\$ 121,979,733	\$ 131,918,189

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months 2009	Ended June 30, 2008	Six Months E	nded June 30, 2008	
REVENUES:					
Product	\$ 16,748,235	\$ 18,141,842	\$ 33,669,437	\$ 35,777,453	
Licensing and product development	525,326	804,356	860,575	1,257,564	
	17,273,561	18,946,198	34,530,012	37,035,017	
COST OF PRODUCTS SOLD	7,393,657	7,802,893	13,678,036	15,248,744	
C	0.070.004	11 142 205	20.051.07/	21.797.272	
Gross profit	9,879,904	11,143,305	20,851,976	21,786,273	
OPERATING EXPENSES:					
Research and development	2,432,640	6,099,501	5,785,138	10,697,132	
Sales and marketing	5,289,032	4,961,853	10,311,797	10,177,842	
General and administrative	4,434,679	3,889,960	8,891,730	7,730,741	
Impairment of patent and product rights	3,028,375		3,028,375		
	15 10 4 50 6	14051 214	20.017.040	20 (05 515	
	15,184,726	14,951,314	28,017,040	28,605,715	
Operating loss	(5,304,822)	(3,808,009)	(7,165,064)	(6,819,442)	
INTEREST EXPENSE	(90,285)	(72,074)	(179,949)	(155,200)	
INTEREST INCOME	236,624	822,639	574,504	1,840,444	
OTHER INCOME				4,883,714	
FOREIGN CURRENCY LOSS	(1,209)	(6,344)	(7,144)	(79,344)	
Total of Containe Loop	(1,20))	(0,511)	(7,111)	(75,511)	
Loss before income taxes	(5,159,692)	(3,063,788)	(6,777,653)	(329,828)	
INCOME TAX BENEFIT		(820,494)		(88,271)	
MET LOCC	¢ (5 150 (02)	¢ (2.242.204)	¢ (6 777 (52)	¢ (241.557)	
NET LOSS	\$ (5,159,692)	\$ (2,243,294)	\$ (6,777,653)	\$ (241,557)	
LOSS PER SHARE:					
BASIC AND DILUTED	\$ (0.11)	\$ (0.05)	\$ (0.15)	\$ (0.01)	
SHARES USED IN COMPUTING LOSS PER SHARE					
BASIC AND DILUTED	45,870,720	46,847,027	45.854.255	46,815,277	
DASIC AND DILUTED	45,670,720	40,047,027	45,654,255	40,013,477	

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

(Unaudited)

	Six Months Ended June 30, 2009 2008	
OPERATING ACTIVITIES:		
Net loss	\$ (6,777,653)	\$ (241,557)
Adjustments to reconcile net loss to net cash used in operating activities:	2.020.277	
Impairment of patent and product rights	3,028,375	• 000 400
Stock-based compensation	2,093,697	2,838,190
Deferred income taxes	1 (72 704	(81,723)
Depreciation and amortization	1,672,784	1,386,854
Reserve for excess and obsolete inventories	(220,971)	(263,972)
Changes in assets and liabilities:	507.072	(1.405.500)
Accounts receivable Inventories	507,273	(1,485,580)
	2,262,387 151,907	(611,992) 753,110
Prepaid expenses and other assets Accounts payable	(1,786,392)	(1,340,127)
Accrued expenses and other liabilities	(2,572,764)	(2,867,795)
Accrued expenses and other natimues	(2,372,704)	(2,807,793)
Net cash used in operating activities	(1,641,357)	(1,914,592)
INVESTING ACTIVITIES:		
Purchase of short-term investments	(5,986,000)	(59,396,670)
Proceeds from maturities and redemptions of short-term investments	32,713,000	51,829,880
Purchase of property and equipment	(741,184)	(1,314,472)
Payments of patents and licenses		(200,000)
Net cash provided by (used in) investing activities	25,985,816	(9,081,262)
FINANCING ACTIVITIES:		
Repayments of long-term debt	(278,804)	(236,566)
Proceeds from issuance of common stock	17,898	92,517
Withholding and retirement of common stock	(320,905)	(849,311)
Purchase and retirement of common stock	(308,605)	
Net cash used in financing activities	(890,416)	(993,360)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	23,454,043	(11,989,214)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	39,565,218	32,229,697
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 63,019,261	\$ 20,240,483

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: Cash paid for:

Interest	\$ 182,840	\$ 221,539
Income taxes	\$ 32,500	\$ 386,284

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements

(Unaudited)

1. The Company

We develop, manufacture and market oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products, including *in vitro* diagnostic tests that are used on other specimen types, and other medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our diagnostic products include tests which are performed on a rapid basis at the point of care and tests which are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians offices, and commercial and industrial entities. One of our products has been sold in the over-the-counter or consumer retail markets in the United States, Canada, Europe, Central and South America, and Australia.

The current economic downturn, including disruptions in the capital and credit markets, may continue indefinitely and intensify, and could adversely affect our results of operations, cash flows and financial condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct acquisitions or make other discretionary investments. These circumstances may also adversely impact the capital needs of our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. In addition, demand for our products by consumers may also be adversely affected by the economic downturn. All of these factors could adversely affect our results of operations, cash flows and financial condition. A weakening business climate could cause longer sales cycles and slower growth, and could expose us to increased business or credit risk in dealing with customers or suppliers adversely affected by economic conditions. Our ability to collect accounts receivable may be delayed or precluded if our customers are unable to pay their obligations.

2. Summary of Significant Accounting Policies

<u>Basis of Presentation</u>. The accompanying financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. Results of operations for the three months and six months ended June 30, 2009 are not necessarily indicative of the results of operations expected for the full year. We have evaluated all subsequent events through the date that we filed our financial statements with the SEC on August 6, 2009.

<u>Use of Estimates</u>. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the valuation of accounts receivable, inventories and intangible assets, as well as calculations related to contingencies, accruals and indemnifications, among others. These estimates and assumptions are based on management s best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors, which management believes to be reasonable under the circumstances, including the current economic environment. We adjust such estimates and assumptions when facts and circumstances dictate. Illiquid credit markets, volatile equity, foreign currency, and energy markets, and declines in consumer spending have combined to increase the uncertainty inherent in such estimates and assumptions. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in those estimates resulting from continuing changes in the economic environment will be reflected in the financial statements in those future periods.

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<u>Cash and Cash Equivalents</u>. We consider all highly liquid investments with a purchased maturity of ninety days or less to be cash equivalents. As of June 30, 2009 and December 31, 2008, cash equivalents consisted of money market accounts, commercial paper and U.S. government agency obligations.

<u>Short-term Investments</u>. We consider all short-term investments to be available-for-sale securities, in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, Accounting for Certain Investments in Debt and Equity Securities. These securities are comprised of certificates of deposits, commercial paper, U.S. government and agency obligations, and corporate bonds, all with purchased maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses reported in stockholders equity as a component of accumulated other comprehensive income (loss).

The following is a summary of our available-for-sale securities at June 30, 2009 and December 31, 2008:

	Gross	Gross	
Amortized	Unrealized	Unrealized	Fair
Cost	Gains	Losses	Value