

WRIGHT MEDICAL GROUP INC

Form 10-Q

November 02, 2011

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011

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: 000-32883

WRIGHT MEDICAL GROUP, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction

of Incorporation or Organization)

13-4088127

(IRS Employer

Identification Number)

5677 Airline Road

Arlington, Tennessee

(Address of Principal Executive Offices)

38002

(Zip Code)

(901) 867-9971

(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 ☒ 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 ☐ Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting
company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐

Yes ☒ No

As of October 27, 2011, there were 39,326,861 shares of common stock outstanding.

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SAFE-HARBOR STATEMENT

This quarterly report contains “forward-looking statements” as defined under U.S. federal securities laws, including statements regarding potential actions by the United States Attorney’s Office for the District of New Jersey, independent monitor, Office of Inspector General and other agencies or their potential impact. These statements reflect management’s current knowledge, assumptions, beliefs, estimates, and expectations and express management’s current views of future performance, results, and trends and may be identified by their use of terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” and other similar terms. Forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements. The readers should not place undue reliance on forward-looking statements. Such statements are made as of the date of this quarterly report, and we undertake no obligation to update such statements after this date.

Risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking

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statements include those discussed in our filings with the Securities and Exchange Commission (including those described in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2010, under the heading, “Risk Factors” and in Item 1A of Part II and elsewhere in this report), and the following:

future actions of the FDA or any other regulatory body or government authority that could delay, limit or suspend product development, manufacturing or sale or result in seizures, injunctions, monetary sanctions or criminal or civil liabilities;

the impact of any such future actions of the FDA or any other regulatory body or government authority on our settlement of the federal investigation into our consulting arrangements with orthopaedic surgeons relating to our hip and knee products in the United States, and the impact of such settlement of the federal investigation into our consulting arrangements with orthopaedic surgeons relating to our hip and knee products in the United States, including our compliance with the Deferred Prosecution Agreement (“DPA”) through September 2012 and the Corporate Integrity Agreement (“CIA”) through September 2015. Our failure to comply with the DPA or the CIA could expose us to significant liability including, but not limited to, extension of the term of the DPA, exclusion from federal healthcare program participation, including Medicaid and Medicare, which would have a material adverse effect on our financial condition, results of operations and cash flows, potential prosecution, including under the previously-filed criminal complaint, civil and criminal fines or penalties, and additional litigation cost and expense. In addition, a breach of the DPA or the CIA could result in an event of default under the Senior Credit Facility, which in turn could result in an event of default under the Indenture;

the possibility of litigation brought by stockholders, including private securities litigation and stockholder derivative suits, which, if initiated, could divert management’s attention, harm our business and/or reputation and result in significant liabilities;

demand for and market acceptance of our new and existing products;

recently enacted healthcare reform legislation and its future implementation, possible additional legislation, regulation and other governmental pressures in the United States or globally, which may affect pricing, reimbursement, taxation and rebate policies of government agencies and private payers or other elements of our business;

tax reform measures, tax authority examinations and associated tax risks and potential obligations;

our ability to identify business development and growth opportunities for existing or future products;

product quality or patient safety issues, leading to product recalls, withdrawals, launch delays, sanctions, seizures, litigation, or declining sales;

individual, group or class action alleging products liability claims, including an increase in the number of claims during any period;

our ability to enforce our patent rights or patents of third parties preventing or restricting the manufacture, sale or use of affected products or technology;

the impact of geographic and product mix on our sales;

retention of our sales representatives and independent distributors;

inventory reductions or fluctuations in buying patterns by wholesalers or distributors;

our ability to realize the anticipated benefits of restructuring initiatives;

any impact of the commercial and credit environment on us and our customers and suppliers; and

the implementation of our new compliance enhancements, including the duration and severity of delays related to medical education, research and development and clinical studies, and the impact of any such delays on our relationships with customers.

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (unaudited).

WRIGHT MEDICAL GROUP, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

(unaudited)

	September 30, 2011	December 31, 2010
Assets:		
Current assets:		
Cash and cash equivalents	\$ 156,141	\$ 153,261
Marketable securities	15,740	19,152
Accounts receivable, net	97,328	105,336
Inventories	171,690	166,339
Prepaid expenses	8,039	5,333
Deferred income taxes	32,097	32,026
Other current assets	21,933	16,143
Total current assets	502,968	497,590
Property, plant and equipment, net	163,361	158,247
Goodwill	54,192	54,172
Intangible assets, net	16,064	16,501
Marketable securities	6,989	17,193
Deferred income taxes	4,247	4,125
Other assets	5,747	7,411
Total assets	\$ 753,568	\$ 755,239
Liabilities and Stockholders' Equity:		
Current liabilities:		
Accounts payable	\$ 17,001	\$ 15,862
Accrued expenses and other current liabilities	65,027	54,409
Current portion of long-term obligations	8,550	1,033
Total current liabilities	90,578	71,304
Long-term debt and capital lease obligations	168,975	201,766
Deferred income taxes	4,488	5,705
Other liabilities	20,838	5,492
Total liabilities	\$ 284,879	\$ 284,267
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, \$0.01 par value, authorized: 100,000,000 shares; issued and outstanding: 39,324,406 shares at September 30, 2011 and 39,171,501 shares at December 31, 2010	384	379
Additional paid-in capital	394,423	390,098
Accumulated other comprehensive income	21,866	22,173
Retained earnings	52,016	58,322
Total stockholders' equity	468,689	470,972
Total liabilities and stockholders' equity	\$ 753,568	\$ 755,239

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

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WRIGHT MEDICAL GROUP, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net sales	\$118,184	\$121,708	\$386,075	\$380,686
Cost of sales ¹	36,185	37,989	116,457	118,064
Cost of sales - restructuring	1,900	—	1,900	—
Gross profit	80,099	83,719	267,718	262,622
Operating expenses:				
Selling, general and administrative ¹	83,581	64,877	229,227	209,089
Research and development ¹	6,769	8,779	23,783	28,398
Amortization of intangible assets	721	708	2,088	1,991
Restructuring charges	12,132	134	12,132	1,139
Total operating expenses	103,203	74,498	267,230	240,617
Operating (loss) income	(23,104)	9,221	488	22,005
Interest expense, net	1,464	1,532	4,774	4,550
Other expense, net	59	313	4,775	270
(Loss) income before income taxes	(24,627)	7,376	(9,061)	17,185
(Benefit) provision for income taxes	(8,582)	2,726	(2,755)	8,213
Net (loss) income	\$(16,045)	\$4,650	\$(6,306)	\$8,972
Net (loss) income per share (Note 9):				
Basic	\$(0.42)	\$0.12	\$(0.16)	\$0.24
Diluted	\$(0.42)	\$0.12	\$(0.16)	\$0.24
Weighted-average number of shares outstanding-basic	38,406	37,935	38,228	37,748
Weighted-average number of shares outstanding-diluted	38,406	38,011	38,228	37,923

¹ These line items include the following amounts of non-cash, stock-based compensation expense for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Cost of sales	\$356	\$314	\$1,063	\$980
Selling, general and administrative	1,715	2,261	5,083	7,700
Research and development	150	492	542	1,500

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

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WRIGHT MEDICAL GROUP, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2011	2010
Operating activities:		
Net (loss) income	\$(6,306)	\$8,972
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	29,214	26,073
Stock-based compensation expense	6,688	10,180
Amortization of intangible assets	2,088	1,991
Amortization of deferred financing costs	768	777
Deferred income taxes	(3,333)	(3,470)
Write off of deferred financing costs	2,926	—
Excess tax benefit from stock-based compensation arrangements	(40)	(288)
Non-cash restructuring charges	4,090	246
Other	(1,125)	1,170
Changes in assets and liabilities (net of acquisitions):		
Accounts receivable	10,349	3,384
Inventories	(7,599)	(2,736)
Prepaid expenses and other current assets	(8,020)	2,527
Accounts payable	1,079	2,949
Accrued expenses and other liabilities	18,007	8,221
Net cash provided by operating activities	48,786	59,996
Investing activities:		
Capital expenditures	(35,198)	(35,950)
Acquisitions of businesses	—	(2,072)
Purchase of intangible assets	(1,624)	(1,598)
Maturities of held-to-maturity marketable securities	4,748	—
Investment in held-to-maturity marketable securities	—	(4,674)
Sales and maturities of available-for-sale marketable securities	31,909	104,049
Investment in available-for-sale marketable securities	(23,093)	(81,067)
Proceeds from sale of assets	5,500	—
Net cash used in investing activities	(17,758)	(21,312)
Financing activities:		
Issuance of common stock	338	461
Financing under factoring agreement, net	—	5
Payments of long term borrowings	(4,610)	(968)
Redemption of convertible senior notes	(170,889)	—
Proceeds from term loan borrowings	150,000	—
Payments of deferred financing costs	(2,887)	—
Excess tax benefit from stock-based compensation arrangements	40	288
Net cash used in financing activities	(28,008)	(214)
Effect of exchange rates on cash and cash equivalents	(140)	291
Net increase in cash and cash equivalents	2,880	38,761
Cash and cash equivalents, beginning of period	153,261	84,409

Cash and cash equivalents, end of period	\$156,141	\$123,170
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The accompanying notes are an integral part of these condensed consolidated financial statements.

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WRIGHT MEDICAL GROUP, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Summary of Significant Accounting Policies

Basis of Presentation. The unaudited condensed consolidated interim financial statements of Wright Medical Group, Inc. have been prepared in accordance with accounting principles generally accepted in the United States (U.S.) for interim financial information and the instructions to Quarterly Report on Form 10-Q and Rule 10-01 of Regulation S-X. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the U.S. have been condensed or omitted pursuant to these rules and regulations. Accordingly, these unaudited condensed consolidated interim financial statements should be read in conjunction with our consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the U.S. Securities and Exchange Commission (SEC). In the opinion of management, these unaudited condensed consolidated interim financial statements reflect all adjustments necessary for a fair presentation of our interim financial results. All such adjustments are of a normal and recurring nature. The results of operations for any interim period are not indicative of results for the full fiscal year. The accompanying unaudited condensed consolidated interim financial statements include our accounts and those of our wholly-owned domestic and international subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation.

The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the dates of the financial statements and the amounts of revenues and expenses during the reporting periods. Actual amounts realized or paid could differ from those estimates.

Product Liability Claims and Other Litigation. Periodically, claims arise involving the use of our products. We make provisions for claims specifically identified for which we believe the likelihood of an unfavorable outcome is probable and an estimate of the amount of loss has been developed. As additional information becomes available, we reassess the estimated liability related to our pending claims and make revisions as necessary.

In the third quarter of 2011, as a result of an increase in the number of claims associated with fractures of our long PROFEMUR® titanium modular necks in North America and an increase in the monetary amount of those claims, management recorded a provision for current and future claims associated with fractures of this product. See Note 12 for further description of this provision.

Future revisions in our estimates of these provisions could materially impact our results of operation and financial position. We maintain insurance coverage that limits the severity of any single claim as well as total amounts incurred per policy year, and we believe our insurance coverage is adequate. We use the best information available to us in determining the level of accrued product liabilities, and we believe our accruals are adequate.

We are also involved in legal proceedings involving other product liability claims and contract, patent protection and other matters. We make provisions for claims specifically identified for which we believe the likelihood of an unfavorable outcome is probable and an estimate of the amount of loss can be developed.

Revenue Recognition. Our revenues are primarily generated through two types of customers, hospitals and surgery centers, and stocking distributors, with the majority of our revenue derived from sales to hospitals. Our products are primarily sold through a network of employee sales representatives and independent sales representatives in the U.S. and by a combination of employee sales representatives, independent sales representatives, and stocking distributors outside the U.S. Revenues from sales to hospitals are recorded when the hospital takes title to the product, which is generally when the product is surgically implanted in a patient. We record revenues from sales to our stocking distributors outside the U.S. at the time the product is shipped to the stocking distributor.

In 2011, we entered into a trademark license agreement (License Agreement) with KCI Medical Resources, a subsidiary of Kinetic Concepts, Inc (KCI). The License Agreement provides KCI Medical Resources with a non-transferable license to use our trademarks associated with our GRAFTJACKET® line of products in connection with the marketing and distribution of KCI Medical Resources' soft tissue graft containment products used in the

wound care field, subject to certain exceptions. License revenue is being recognized over the life of the agreement on a straight line basis.

Derivative Instruments. We account for derivative instruments and hedging activities under Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) Topic 815, Derivatives and Hedging (FASB ASC 815). Accordingly, all of our derivative instruments are recorded in the accompanying condensed consolidated balance sheets as either an asset or liability and are measured at fair value. The changes in the derivative's fair value are recognized currently in earnings unless specific hedge accounting criteria are met.

We employ a derivative program using 30-day foreign currency forward contracts to mitigate the risk of currency fluctuations on

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WRIGHT MEDICAL GROUP, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(UNAUDITED)

our intercompany receivable and payable balances that are denominated in foreign currencies. These forward contracts are expected to offset the transactional gains and losses on the related intercompany balances. These forward contracts are not designated as hedging instruments under FASB ASC 815. Accordingly, the changes in the fair value and the settlement of the contracts are recognized in the period incurred in the accompanying consolidated statements of operations.

Additionally, we entered into an interest rate swap to hedge a portion of our variable interest rate obligations. The interest rate swap has been accounted for as a cash flow hedge in accordance with FASB ASC Topic 815. See Note 6 for further disclosure on our interest rate swap.

Fair Value of Financial Instruments. The carrying values of cash and cash equivalents, accounts receivable, and accounts payable approximate the fair values of these financial instruments as of September 30, 2011 and December 31, 2010 due to their short maturities.

The carrying amount of debt outstanding pursuant to our credit facility approximates fair value as interest rates on these instruments approximate current market rates. See Note 5 for additional information regarding the credit facility. The \$29.1 million of our convertible senior notes are carried at cost. The estimated fair value of the senior notes was approximately \$27 million at September 30, 2011 based on a limited number of trades and does not necessarily represent the value at which the entire convertible note portfolio can be retired.

Pursuant to the requirements of the FASB ASC Topic 820, Fair Value Measurements and Disclosures, our financial assets and liabilities measured at fair value on a recurring basis are classified and disclosed in one of the following three categories:

Level 1: Financial instruments with unadjusted, quoted prices listed on active market exchanges.

Level 2: Financial instruments determined using prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.

Level 3: Financial instruments that are not actively traded on a market exchange. This category includes situations where there is little, if any, market activity for the financial instrument. The prices are determined using significant unobservable inputs or valuation techniques.

We use a third-party provider to determine fair values of our available-for-sale marketable securities. The third-party provider receives market prices for each marketable security from a variety of industry standard data providers, security master files from large financial institutions and other third-party sources with reasonable levels of price transparency. The third-party provider uses these multiple prices as inputs into a pricing model to determine a weighted average price for each security. We classify our U.S. Treasury bills and bonds as Level 1 based upon quoted prices in active markets. All other marketable securities are classified as Level 2 based upon the other than quoted prices with observable market data. These include municipal debt securities, U.S. agency debt securities, corporate debt securities, certificates of deposits and time deposits. During the three months ended March 31, 2011, we began investing in commercial paper with original maturity dates of three months or less. Our commercial paper is classified as a Level 2 and is included in our Cash and cas