Integra LifeSciences Reports Third Quarter 2023 Financial Results

Oct 25, 2023

PRINCETON, N.J., Oct. 25, 2023 (GLOBE NEWSWIRE) -- Integra LifeSciences Holdings Corporation (NASDAQ: IART), a leading global medical technology company, today reported financial results for the third quarter ending September 30, 2023.

Third Quarter 2023 Highlights

- Third quarter revenues of $382.4 million declined 0.7% on a reported basis and declined 0.4% on an organic basis compared to the prior year and increased 7.1% on an organic basis excluding Boston
- Third quarter GAAP earnings per diluted share of $0.24, compared to $0.60 in the prior year; adjusted earnings per diluted share of $0.76, compared to $0.86 in the prior year
- Successfully completed all interim external inspections in preparation for the Boston manufacturing facility restart and remain on track to committed timelines
- Relaunched CereLink® ICP Monitor in select international markets and submitted a 510(k) premarket notification in the U.S.
- Completed $125 million accelerated share repurchase initiated in the third quarter
- Updating full-year 2023 revenue and adjusted earnings per share guidance with a range of $1.541 billion to $1.547 billion and $3.10 to $3.14 respectively, which reflects the impact of third quarter Boston recall returns, strong organic growth of the business excluding Boston, strengthening U.S. dollar and tax favorability

"Although the Boston returns weighed further on our third quarter results, we are on track to restart the Boston facility by the end of the year, and we also met two significant CereLink milestones with the relaunch in international markets and submission for regulatory approval in the U.S.," said Jan De Witte, Integra LifeSciences' president and chief executive officer. "At the same time, our strong organic growth performance in the Codman Specialty Surgical and Tissue Technologies businesses, excluding Boston, plus advances across our product pipeline, give us confidence in our long-range growth commitments."

Third Quarter 2023 Consolidated Performance

Total reported revenues of $382.4 million declined 0.7% on a reported basis and declined 0.4% on an organic basis compared to the prior year.

The Company reported GAAP gross margin of 57.1%, compared to 61.5% in the third quarter of 2022. Adjusted gross margin was 64.6%, compared to 66.7% in the prior year.

Adjusted EBITDA for the third quarter of 2023 was $88.1 million, or 23.0% of revenue, compared to $105.3 million, or 27.3% of revenue, in the prior year.

The Company reported GAAP net income of $19.5 million, or $0.24 per diluted share, in the third quarter of 2023, compared to a GAAP net income of $49.9 million, or $0.60 per diluted share, in the prior year.

Adjusted net income for the third quarter of 2023 was $60.5 million, or $0.76 per diluted share, compared to $71.7 million or $0.86 per diluted share, in the prior year.

Third Quarter 2023 Segment Performance

Codman Specialty Surgical (~70% of Revenues)

- Total revenues were $268.2 million, representing reported growth of 7.4% and organic growth of 7.4% compared to the third quarter of 2022, attributable to low-double digit growth in CSF management and Neuro Monitoring driven by Certas® Plus valves, BactiSeal® catheters and ICP microsensors; high-single-digit growth in Dural Access and Repair driven by DuraGen® DuraSeal® and Mayfield®; low single-digit decline in Advanced Energy due to timing of CUSA® capital orders; and mid single-digit growth in Instruments.

Tissue Technologies (~30% of Revenues)

- Total revenues were $114.2 million, representing reported decline of 15.6% and organic decline of 15.1% compared to the third quarter of 2022, due to the impact of the lost revenue and increase in the return provision related to the Boston product recall which was partially offset by double digit growth from MicroMatrix®, Cytal®, Gentrix® and amniotics.

- Tissue Technologies organic growth excluding Boston products was 6.7%.

Key Products and Business Highlights

- **Boston Restart**
  - Project team driving progress on Boston remediation plan with external inspections confirming quality of execution
  - Expect to restart manufacturing in Boston by end of Q4'23 and resume commercial distribution in mid-to late Q2'24
- **Advancing our portfolio**
  - Relaunched CereLink in select international markets and submitted a 510(k) premarket notification to the U.S. Food and Drug Administration for CereLink.
  - Submitted 510(k) premarket notification for next generation Aurora® 8mm Surgiscope
  - Continued international expansion of CUSA platform with the launch of Clarity Stage 3, Laparoscopic tip and Single Sided Bone Tip in Saudi Arabia
  - Launched DuraGen Plus in China
  - Completed international registrations of DuraGen, DuraSeal, Mayfield, Duo LED lighting, electrosurgery and nerve products primarily in LATAM and EMEA
  - Extended the Urinary Bladder Matrix platform by obtaining 510(k) clearance for MicroMatrix Flex
- Progressed In-China-for-China strategy by beginning buildout of leased manufacturing facility
- Issued 2022 ESG report
- Further strengthened executive leadership team with the appointment of Chantal Veillon as chief human resources officer

Balance Sheet, Cash Flow and Capital Allocation

The Company generated cash flow from operations of $26.8 million in the quarter. Total balance sheet debt and net debt at the end of the quarter were $1.52 billion and $1.24 billion, respectively, and the consolidated total leverage ratio was 3.0x.

As of quarter end, the Company had total liquidity of approximately $1.48 billion, including $273.7 million in cash and the remainder available under its revolving credit facility.

2023 Outlook

For the full year 2023, the Company is updating its revenue and adjusted EPS expectations to $1.541 to $1.547 billion and $3.10 to $3.14, respectively. The revenue range represents reported growth of -1.1% to -0.7%, with organic growth of 0.1% to 0.5%, reflecting the impact of higher-than-expected Boston recall returns, strong organic growth excluding Boston, the strength of the U.S. dollar, and an updated tax rate.

For the fourth quarter 2023, the Company expects reported revenues in the range of $397 million to $403 million, representing reported growth of -0.4% to +1.1% and organic growth of -0.8% to +0.7%. Adjusted earnings per diluted share are expected to be in the range of $0.89 to $0.93, including the impact of the Boston recall, the strength of the U.S. dollar, and an updated tax rate.

The Company's guidance for the fourth quarter and full-year organic sales growth excludes acquisitions and divestitures, the effects of foreign currency and the year-over-year change in revenue from discontinued products. Organic growth excludes sales from the divestiture of the Company's traditional wound care (TWC) business as of September 1, 2022, and sales from the acquisition of Surgical Innovation Associates, Inc. (SIA) through December 1, 2023. Adjusted earnings per share guidance reflects the impacts of the divestiture of the TWC business, the SIA acquisition, and foreign currency.

Conference Call and Presentation Available Online

Integra has scheduled a conference call for 8:30 a.m. ET on Wednesday, October 25, 2023, to discuss third quarter 2023 financial results and forward-looking financial guidance. The conference call will be hosted by Integra's senior management team and will be open to all listeners. Additional forward-looking information may be discussed in a question-and-answer session following the call. Integra's management team will reference a presentation during the conference call, which can be found on the Investor section of the website at investor.integralife.com.

A live webcast will be available on the Investors section of the Company's website at investor.integralife.com. For those planning to participate on the call, register here to receive dial-in details and an individual pin. While not required, it is recommended to join 10 minutes prior to the event's start. A webcast replay of the conference call will be available on the Investors section of the Company's website following the call.

About Integra

At Integra LifeSciences, we are driven by our purpose of restoring patients' lives. We innovate treatment pathways to advance patient outcomes and set new standards of surgical, neurologic and regenerative care. We offer a comprehensive portfolio of high quality, leadership brands that include

AmnioExcel®, Aurora®, Bactiseal®, BioD™, CerebroFlo®, CereLink® Certas® Plus, Codman®, CUSA®, Cytal®, DuraGen®, DuraSeal®, DuraSorb®, Gentrix®, ICP Express®, Integra®, Licox®, MAYFIELD®, MediHoney®, MicroFrance®, MicroMatrix®, NeuraGen®, NeuraWrap™, PriMatrix®, SurgiMend®, TCC-EZ® and VersaTru®. For the latest news and information about Integra and its products, please visit www.integralife.com.

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties and reflect the Company's judgment as of the date of this release. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements. Some of these forward-looking statements may contain words like “will,” “believe,” “may,” “could,” “would,” “might,” “possible,” “should,” “expect,” “intend,” "forecast," "guidance," “plan,” “anticipate,” "target," or “continue,” the negative of these words, other terms of similar meaning or they may use future dates. Forward-looking statements contained in this news release include, but are not limited to, statements concerning future financial performance, including projections for revenues, expected revenue growth (both reported and organic), GAAP and adjusted net income, GAAP and adjusted earnings per diluted share, non-GAAP adjustments such as divestiture, acquisition and integration-related charges, intangible asset amortization, structural optimization charges, EU Medical Device Regulation-related charges, charges related to the voluntary global recall of all products manufactured at the Company's facility in Boston, Massachusetts, and income tax expense (benefit) related to non-GAAP adjustments and other items, expectations and plans with respect to strategic initiatives, product development and regulatory approvals, including the status of the Company’s 510(k) premarket notification for Cerelink, and expectations concerning the resumption of manufacturing at the Company’s Boston, Massachusetts facility. It is important to note that the Company’s goals and expectations are not predictions of actual performance. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from predicted or expected results. Such risks and uncertainties include, but are not limited, to the following: the ongoing and possible future effects of global challenges, including macroeconomic uncertainties, inflation, supply chain disruptions, trade regulation and tariffs, other economic disruptions and U.S. and global recession concerns, on the Company’s customers and on the Company’s business, financial condition, results of operations and cash flows; the Company's ability to execute its operating plan effectively; the Company’s ability to successfully integrate acquired businesses; the Company’s ability to achieve sales growth in a timely fashion; the Company's ability to manufacture and ship sufficient quantities of its products to meet its customers' demands; the ability of third-party suppliers to supply us with raw materials and finished products; global macroeconomic and political conditions, including the war in Ukraine and the conflict in Israel and Gaza; the Company's ability to manage its direct sales channels effectively; the sales performance of third-party distributors on whom the Company relies to generate revenue for certain products and geographic regions; the Company's ability to access and maintain relationships with customers of acquired entities and businesses; physicians' willingness to adopt and third-party payors' willingness to provide or maintain reimbursement for the Company's recently launched, planned and existing products; initiatives launched by the Company's competitors; downward pricing pressures from customers; the Company's ability to secure regulatory approval for products in development; the Company's ability to remediate quality systems violations; fluctuations in hospitals' spending for capital equipment; the Company's ability to comply with regulations regarding products of human origin and products containing materials derived from animal source; difficulties in controlling expenses, including costs to procure and manufacture our products; the impact of changes in management or staff levels; the impact of goodwill and intangible asset impairment charges if future operating results of acquired businesses are significantly less than the results anticipated at the time of the acquisitions, the Company's ability to leverage its existing selling organizations and administrative infrastructure; the Company's ability to increase product sales and gross margins, and control non-product costs; the Company’s ability to achieve anticipated growth rates, margins and scale and execute its strategy generally; the amount and timing of divestiture, acquisition and integration-related costs; the geographic distribution of where the Company generates its taxable income; new U.S. and foreign government laws and regulations, and changes in existing laws, regulations and enforcement guidance, which affect areas of our operations including, but not limited to, those affecting the health care industry, including the EU Medical Devices Regulation; the scope, duration and effect of additional U.S. and international governmental, regulatory, fiscal, monetary and public health responses to the COVID-19 pandemic and any future public health crises; fluctuations in foreign currency exchange rates; the amount of our bank borrowings outstanding and other factors influencing liquidity; potential negative impacts resulting from environmental, social and governance matters; and the economic, competitive, governmental, technological, and other risk factors and uncertainties identified under the heading “Risk Factors” included in Item 1A of Integra's Annual Report on Form 10-K for the year ended December 31, 2022 and information contained in subsequent filings with the Securities and Exchange Commission.

These forward-looking statements are made only as of the date hereof, and the Company undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, future events, or otherwise.

Discussion of Adjusted Financial Measures

In addition to our GAAP results, we provide certain non-GAAP measures, including organic revenues, organic revenues excluding Boston, adjusted earnings before interest, taxes, depreciation and amortization (EBITDA), adjusted net income, adjusted earnings per diluted share, free cash flow, adjusted free cash flow conversion, and net debt. Organic revenues consist of total revenues excluding the effects of currency exchange rates, revenues from current-period acquisitions and product divestitures and discontinuances. Organic revenues excluding Boston consist of total revenues, excluding (i) the effects of currency exchange rates, revenues from current-period acquisitions and product divestitures and discontinuances and (ii) revenues associated with Boston produced products including sales reported prior to the recall and the impact of sales return provisions recorded. Adjusted EBITDA consists of GAAP net income excluding: (i) depreciation and amortization; (ii) other income (expense); (iii) interest income and expense; (iv) income tax expense (benefit); and (v) those operating expenses also excluded from adjusted net income. The measure of adjusted net income consists of GAAP net income, excluding: (i) structural optimization charges; (ii) divestiture, acquisition and integration-related charges; (iii) EU Medical Device Regulation-related charges; (iv) charges related to the voluntary global recall of products manufactured at the Company’s Boston, Massachusetts facility; (v) intangible asset amortization expense; and (vi) income tax impact from adjustments. The adjusted earnings per diluted share measure is calculated by dividing adjusted net income attributable to diluted shares by diluted weighted average shares outstanding. The measure of free cash flow consists of GAAP net cash provided by operating activities less purchases of property and equipment. The adjusted free cash flow conversion measure is calculated by dividing free cash flow by adjusted net income. The measure of net debt consists of GAAP total debt (excluding deferred financing costs) less cash and cash equivalents.

Reconciliations of GAAP revenues to organic revenues, GAAP revenues to organic revenues excluding Boston, GAAP net income to adjusted EBITDA, and adjusted net income, GAAP total debt to net debt and GAAP earnings per diluted share to adjusted earnings per diluted share all for the quarter ended September 30, 2023 and 2022, and the free cash flow and adjusted free cash flow conversion for the quarter ended September 30, 2023 and 2022, appear in the financial tables in this release.

The Company believes that the presentation of organic revenues and the other non-GAAP measures provide important supplemental information to

management and investors regarding financial and business trends relating to the Company's financial condition and results of operations. For further information regarding why Integra believes that these non-GAAP financial measures provide useful information to investors, the specific manner in which management uses these measures, and some of the limitations associated with the use of these measures, please refer to the Company's Current Report on Form 8-K regarding this earnings press release filed today with the Securities and Exchange Commission. This Current Report on Form 8-K is available on the SEC's website at www.sec.gov or on our website at www.integralife.com.

Investor Relations Contact:

Chris Ward
(609) 772-7736
chris.ward@integralife.com

Media Contact:

Laurene Isip
(609) 208-8121
laurene.isip@integralife.com

INTEGRA LIFESCIENCES HOLDINGS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

(In thousands, except per share amounts)

	Three Months Ended Sept. 30,	
	2023	2022
Total revenues, net	$ 382,421	$ 385,191
Costs and expenses:		
Cost of goods sold	164,076	148,445
Research and development	26,596	24,736
Selling, general and administrative	161,948	143,820
Intangible asset amortization	3,208	3,141
Total costs and expenses	355,828	320,142
Operating income	26,593	65,049
Interest income	4,607	3,264
Interest expense	(13,062)	(12,809)
Gain from sale of business	—	644
Other income, net	471	2,648
Income before income taxes	18,609	58,796
Income tax expense (benefit)	(888)	8,881
Net income	$ 19,497	$ 49,915
Net income per share:		
Diluted net income per share	$ 0.24	$ 0.60
Weighted average common shares outstanding for diluted net income per share	79,811	83,399

The following table presents revenues disaggregated by the major sources for the three months ended September 30, 2023 and 2022 (amounts in thousands):

	Three Months Ended Sept 30,		
	2023	2022	Change
Neurosurgery	209,229	193,848	7.9%
Instruments	58,976	55,948	5.4%
Total Codman Specialty Surgical	268,205	249,796	7.4%
Wound Reconstruction and Care	88,071	104,625	(15.8)%
Private Label	26,145	30,770	(15.0)%
Total Tissue Technologies	114,216	135,395	(15.6)%
Total reported revenues	382,421	385,191	(0.7)%
Impact of changes in currency exchange rates	(994)	0	
Less contribution of revenues from acquisitions	(2,934)	—	
Less contribution of revenues from divested products	(13)	(4,556)	

Less contribution of revenues from discontinued products	(1,403)	(1,933)		
Total organic revenues[(1)]	$ 377,077	$ 378,702		(0.4)%
Boston Revenue impact	$ 6,232	$ (20,952)		
Total organic revenues[(1)] excl. Boston	$ 383,309	$ 357,750		7.1%

[(1)] Organic revenues have been adjusted to exclude foreign currency (current period), acquisitions and to account for divested and discontinued products.

Items included in GAAP net income and location where each item is recorded are as follows:

(In thousands)

Three Months Ended September 30, 2023

Item	Total Amount	COGS(a)	SG&A(b)	R&D(c)	Amort (d)	OI&E(e)	Tax(f)
Acquisition, divestiture and integration-related charges	5,832	407	6,638	(1,090)	—	(123)	—
Structural Optimization charges	5,893	4,011	1,909	(27)	—	—	—
EU Medical Device Regulation charges	13,490	1,263	5,661	6,565	—	—	—
Boston Recall	5,636	5,542	94	—	—	—	—
Intangible asset amortization expense	20,869	17,661	—	—	3,208	—	—
Estimated income tax impact from above adjustments and other items	(10,677)	—	—	—	—	—	(10,677)
Depreciation expense	9,670	—	—	—	—	—	—

a) COGS - Cost of goods sold
b) SG&A - Selling, general and administrative
c) R&D - Research & development
d) Amort. - Intangible asset amortization
e) OI&E - Other income & expense
f) Tax - Income tax expense (benefit)

Items included in GAAP net income and location where each item is recorded are as follows:

(In thousands)

Three Months Ended Sept 30, 2022

Item	Total Amount	COGS(a)	SG&A(b)	R&D(c)	Amort.(d)	OI&E(e)	Tax(f)
Acquisition, divestiture and integration-related charges	(13,841)	177	(12,151)	(547)	—	(1,320)	—
Structural Optimization charges	10,112	2,765	7,356	(9)	—	—	—
EU Medical Device Regulation charges	13,208	1,257	5,672	6,279	—	—	—
Intangible asset amortization expense	19,192	16,051	—	—	3,141	—	—
Estimated income tax impact from above adjustments and other items	(6,892)	—	—	—	—	—	(6,892)
Depreciation expense	10,275	—	—	—	—	—	—

a) COGS - Cost of goods sold
b) SG&A - Selling, general and administrative
c) R&D - Research & development
d) Amort. - Intangible asset amortization
e) OI&E - Other income & expense
f) Tax - Income tax expense (benefit)

RECONCILIATION OF NON-GAAP ADJUSTMENTS - GAAP NET INCOME TO ADJUSTED EBITDA
(UNAUDITED)

(In thousands)

	Three Months Ended Sept 30,	
	2023	2022
GAAP net income	19,497	49,915
Non-GAAP adjustments:		
Depreciation and intangible asset amortization expense	30,538	29,467
Other (income) expense, net	(348)	(1,972)
Interest expense, net	8,455	9,545

Income tax expense	(888)	8,881
Structural optimization charges	5,893	10,112
EU Medical Device Regulation charges	13,490	13,208
Boston Recall	5,636	—
Acquisition, divestiture and integration-related charges	5,832	(13,842)
Total of non-GAAP adjustments	68,608	55,400
Adjusted EBITDA	$ 88,105	$ 105,315

RECONCILIATION OF NON-GAAP ADJUSTMENTS - GAAP NET INCOME TO MEASURES OF ADJUSTED NET INCOME AND ADJUSTED EARNINGS PER SHARE
(UNAUDITED)

(In thousands, except per share amounts)

	Three Months Ended Sept 30,	
	2023	2022
GAAP net income	19,497	49,915
Non-GAAP adjustments:		
Structural optimization charges	5,893	10,112
Acquisition, divestiture and integration-related charges(1)	5,832	(13,841)
EU Medical Device Regulation charges	13,490	13,208
Boston Recall	5,636	—
Intangible asset amortization expense	20,869	19,192
Estimated income tax impact from adjustments and other items	(10,677)	(6,892)
Total of non-GAAP adjustments	41,042	21,779
Adjusted net income	$ 60,539	$ 71,694
Adjusted diluted net income per share	$ 0.76	$ 0.86
Weighted average common shares outstanding for diluted net income per share	79,811	83,399

CONDENSED BALANCE SHEET DATA
(UNAUDITED)

(In thousands)

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 273,732	$ 456,661
Trade accounts receivable, net	256,270	263,465
Inventories, net	366,251	324,583
Current and long-term borrowing under senior credit facility	859,776	771,274
Borrowings under securitization facility	75,700	104,700
Long-term convertible securities	569,527	567,341
Stockholders' equity	$ 1,579,221	$ 1,804,403

CONDENSED STATEMENT OF CASH FLOWS
(UNAUDITED)

(In thousands)

	Nine Months Ended Sept 30,	
	2023	2022
Net cash provided by operating activities	$ 81,205	$ 179,135
Net cash used in investing activities	(36,949)	(3,760)
Net cash used by financing activities	(223,035)	(154,254)
Effect of exchange rate changes on cash and cash equivalents	(4,150)	(22,632)

Net decrease in cash and cash equivalents	$ (182,929)	$ (1,511)

RECONCILIATION OF NON-GAAP ADJUSTMENTS - GAAP OPERATING CASH FLOW TO MEASURES OF FREE CASH FLOW AND ADJUSTED FREE CASH FLOW CONVERSION
(UNAUDITED)
(In thousands)

	Three Months Ended Sept 30,	
	2023	2022
Net cash provided by operating activities	$ 26,770	$ 68,310
Purchases of property and equipment	$ (13,063)	$ (9,157)
Free cash flow	13,707	59,153
Adjusted net income[(1)]	$ 60,539	$ 71,694
Adjusted free cash flow conversion	22.6%	82.5%

	Twelve Months Ended Sept 30,	
	2023	2022
Net cash provided by operating activities	$ 166,539	$ 248,418
Purchases of property and equipment	(56,868)	(55,315)
Free cash flow	$ 109,671	$ 193,103
Adjusted net income[(1)]	$ 257,514	$ 274,183
Adjusted free cash flow conversion	42.6%	70.4%

[(1)] Adjusted net income for quarters ended September 30, 2023 and 2022 are reconciled above. Adjusted net income for remaining quarters in the trailing twelve months calculation have been previously reconciled and are publicly available in the Quarterly Earnings Call Presentations on our website at investor.integralife.com under Events & Presentations.

The Company calculates adjusted free cash flow conversion by dividing its free cash flow by adjusted net income. The Company believes this measure is useful in evaluating the significance of the cash special charges in its adjusted earnings measures.

RECONCILIATION OF NON-GAAP ADJUSTMENTS - NET DEBT CALCULATION
(UNAUDITED)

(In thousands)

	September 30, 2023	December 31, 2022
Short-term borrowings under senior credit facility	9,687	$ 38,125
Long-term borrowings under senior credit facility	850,089	733,149
Borrowings under securitization facility	75,700	104,700
Long-term convertible securities	569,527	567,341
Deferred financing costs netted in the above	10,697	11,385
Cash & Cash Equivalents	(273,732)	(456,661)
Net Debt	$ 1,241,968	$ 998,039