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Riverain software gives clearer picture for lung cancer detection

By OMAR FORD

Medical Device Daily Staff Writer

Riverain Medical (Miamisburg, Ohio) is providing clinicians and radiologists with the perfect back-up plan to detect lung cancer in patients – and it has a peer-reviewed study to prove it.

Earlier this week, the firm reported the results of the study that shows radiologists using the SoftView bone suppression application with chest X-rays significantly increased their detection of lung nodules proven to be primary lung cancer.

FDA cleared in March 2010, SoftView is an image enhancement technology designed to increase the clarity of chest X-rays by suppressing bone. Using advanced bone suppression and image enhancement algorithms, SoftView automatically provides a soft tissue image for more See Riverain, Page 5

Healthcare industry may soon see increased M&A activity

By AMANDA PEDERSEN

Medical Device Daily Senior Staff Writer

The healthcare industry, including the device sector, should continue to see an increase in mergers and acquisitions if current trends continue, according to the latest healthcare M&A report from the **Walden Group** (Tarrytown, New York). The firm's IQII report suggests that stronger balance sheets, unit price pressures and slow, incremental organic growth are leading many larger healthcare companies to rely on M&As to achieve growth, obtain new technology and position themselves for the future.

Interestingly, one of the reasons the industry is seeing this trend stems from the economic recession from the last three years. While it's been a very difficult time from an employment point of view for people who were laid off in See Walden, Page 6

Washington roundup

FDA strategic plan still lacks details on enforcement plans

BV MARK McCARTY

Medical Device Daily Washington Editor

FDA has published its strategic plan for the years 20Il-20I5, and while enforcement of regulations is high on the agency's list of priorities, the document does not go much further in explaining what the agency has in mind than was revealed in the agency's announcement last year.

In a statement released yesterday with the priorities document, FDA commissioner Margaret Hamburg, MD, states that the document "marks a renewal of our commitment to creating a stronger, more effective agency," and that the agency's announcement of the intent to forge the strategic priorities list, which appeared in the Oct. 1, 2010, edition of the Federal Register, "generated more than 200 See Washington, Page 7

IHE Connectathon

Shared EHRs are blocked by incompatibility of med-tech

BV IOHN BROSKY

Medial Device Daily European Editor

PISA, Italy – Connecting healthcare systems is proving to be as complex as it is mission-critical.

Even as the political will that has so long been missing is finally being applied to the effort in the United States and Europe, advocates of electronic health records (EHRs) continue to confront infuriating roadblocks to progress.

Anyone with a personal computer knows that the technology already exists to support a seamless exchange of patient records.

So the finger of blame quickly points to people and processes as the culprits that are holding up the promised cost savings, enhanced productivity and improved patient See Connectathon, Page 8

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Walden

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the last three years, Richard Cohen, president of the Walden Group, a strategic investment banking firm for the healthcare industry, told *Medical Device Daily* that the recession created some discipline in operations and forced larger companies in particular to become more efficient. "So those efficiencies have now translated into higher levels of cash flow and cash but that's sort of a one time event," Cohen says. "Now to grow they can only do so much with the product lines and technologies in hand and what's in research and development internally so larger companies are actively looking for companies to acquire, not just for the top line but for R&D and new technologies and innovations for the future."

Larger companies have come to realize that because of slower hospital market, capital budget constraints, reimbursement issues, and a tougher regulatory environment, core product lines are just slower to grow, Cohen said. "Overall it is harder to grow organically." So these companies have larger balance sheets, cash in the bank swelling, difficulties growing organically, plus Wall Street is watching the stock prices quarterly, "it's really not possible to grow on one's own and there are ample opportunities to grow by acquisition."

M&A offers companies an opportunity to enter new sectors as well as new geographic markets, Cohen added.

Meanwhile, smaller companies are facing challenges as well. "Many small companies, before the recession, had expectations of getting to the next level, to growing to much higher levels," Cohen said. Then comes along the recession and now reality has set in and smaller companies are realizing that it is much more difficult to grow without a huge sales force. "I think smaller companies are reassessing their independence and not necessarily selling in desperation . . . but analyzing when is the best time to do this," he said.

For smaller companies, according to the Walden report, the challenging healthcare landscape puts a premium on having sufficient financial wherewithal to fund regulatory and sales and marketing requirements. Clearly the more stringent 5l0(k) process that is expected, along with the need for a substantial sales force to properly sell new products, smaller companies - especially those with new technology - will find it more expensive and risky to remain an independent company, according to the report. "With the recession dampening the growth expectations of many smaller companies, many will want to realistically assess their future and devise strategies for obtaining value for investments that have yet to hit stride in the market," the report says.

The report notes several significant deals that were made during IQII and even highlighted the fact that **Johnson** & **Johnson** (New Brunswick, New Jersey) is rumored to be in talks to acquire **Synthes** (Solothurn, Switzerland) for \$20 billion, which would be J&J's largest ever acquisition – not to mention one of the largest med-tech deals in history

(Medical Device Daily, April 19, 2011). The Wall Street Journal first shed light about the possible merger late last week. As mentioned in the Walden Report, J&J was in a bidding war several years ago with **Boston Scientific** (Natick, Massachusetts) to buy **Guidant** (Indianapolis). Boston Scientific ended up paying \$27.2 billion for Guidant (MDD, Jan. 26, 2006). The Walden report notes that medical devices and diagnostics accounted for 40% of J&J's \$61 billion in 2010 sales but due to competition, recalls, and lower margins, the company said it may consider major acquisitions to bolster growth as its cash balance rises to record highs.

Among the most noteworthy deals from this past quarter that are mentioned in the report, **Accuray** (Sunnyvale, California) says it is buying **TomoTherapy** (Madison, Wisconsin) for \$277 million (*MDD*, March 8, 2010) in an effort to become a leading image guided radiation therapy company. The Walden Group report calls this a "transformative" transaction that creates a company with offerings from high-precision radiosurgery to imageguided, intensity-modulated radiation therapy. The report further notes that this deal significantly increases Accuray's global market presence, creates financial benefits from operating efficiencies and overhead reductions, and opens up new revenue opportunities.

Also, Boston Scientific is buying **Intelect Medical** (Boston) for \$60 million (*MDD*, Jan. 7, 2011); **Artritech** (Plymouth, Minnesota) for \$100 million, plus up to \$275 million in milestones (*MDD*, March 4, 2010), and **ReVascular Therapeutics** (Sunnyvale, California) (*MDD*, Feb. 17, 2011). Boston Scientific "continues to reposition itself for higher growth, higher margin lines," the Walden Report says.

The report also notes that Edwards LifeSciences (Irvine, California) is paying \$43 million for Embrella Cardiovascular (Wayne, Pennsylvania) (MDD, March 15, 2011); Hologic (Bedford, Massachusetts) is buying Interlace Medical (Farmingham, Massachusetts) for \$125 million (MDD, Jan. 10, 2011), and Microwave Endometrial Ablation Systems from Microsuils Medical (Denmead, England) (MDD, Feb. 7, 2011); **Medline** (Mundelein, Illinois) is buying Carefusion's (San Diego) international surgical products unit in a \$440 million deal (MDD, Feb. 4, 2011); Medtronic (Minneapolis) is paying \$800 million for Ardian (Mountain View, California) (MDD, Feb. 4, 2011); and Terumo (Tokyo) is seeking to become the biggest maker of bloodtransfusion equipment with its \$2.6 billion purchase of The **CaridianBCT** (Lakewood, Colorado) blood transfusion equipment business of **Gambro** (Stockholm, Sweden) (*MDD*, April 15, 2011).

In the diagnostics sector, the report notes that the largest deal in terms of dollar amount is between **Danaher** (Washington) and **Beckman Coulter** (Brea, California) for \$6.8 billion (*MDD*, Feb. 9, 2011). ■

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