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# Integra Buys Acclarent From J&J To Expand ENT 'Footprint'

by Reed Miller

Integra will pay \$275m in cash plus \$5m more in potential milestone incentive payments to add Acclarent's ear, nose, and throat surgery devices to its existing neurosurgery portfolio.

[Editor's Note: This article was updated on 14 December with additional commentary from securities analysts that arrived after publication of the original version on 13 December.]

<u>Integra LifeSciences</u> has agreed to acquire <u>Acclarent</u> from <u>Johnson & Johnson/Ethicon</u>, adding Acclarent's ear, nose, and throat surgery (ENT) product lines to the <u>Codman</u> specialty neurosurgery business Integra bought from J&J about six years ago.

"The Acclarent business is a unique asset that enables Integra to effectively address the attractive ENT market with established commercial scale, own brand recognition, a differentiated portfolio and a robust innovation pipeline and class-leading R&D capabilities," Integra CEO Jan De Witte said on 13 December. (See box)

The ENT specialty surgery market is worth more than \$1bn in the US alone and is growing at least 6% annually, according to Integra.

Acclarent pioneered balloon sinus dilation to treat patients suffering from chronic sinus disease. It launched the Acclarent Aera tube balloon, the first dilation device for persistent eustachian tube dysfunction, in Europe in 2014 and in the US in 2016.

#### **Terms Of The Deal**

Integra has agree to acquire Acclarent from J&J/Ethicon or \$275m in cash at closing, plus \$5m upon the achievement of certain regulatory milestones.

The companies expect to close the deal in the

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Last year, Acclarent introduced the TruDi electromagnetically navigated shaver blade for precision surgery in the nasopharynx. (Also see "Acclarent Expects TruDi Shaver Blade To Prevent Repeat ENT Surgeries" - Medtech Insight, 16 Aug, 2022.)

Acclarent also markets the TruDi surgical navigation platform specifically for sinus and skull base surgery.

Integra already participates in ENT surgery with its MicroFrance line of surgical instruments, but Integra expects the addition of Acclarent to expand its total addressable annual market from about \$5bn to more than \$6bn.

Acclarent's total revenue in 2022 was about \$110m, and its revenue is growing almost 10% annually. Integra expects the deal's return on investment to reach 10% by 2028.

By comparison, Integra expects its 2023 revenue to reach \$1.54bn with earnings per-share around \$3.12. Codman represents about 70% of Integra's total revenue. In the third quarter, the Codman division reported revenue of \$268.2m, up 7.4% year-over-year.

# "Immediate Leadership"

According to Michael McBreen, the president of the Integra's Codman business, neurosurgery and ENT surgery represent "clear anatomical adjacencies." Neurosurgeons and ENT surgeons often work together directly, especially in procedures that require finding the right

second quarter of 2024.

Integra expects the deal's impact on earnings to be neutral in the first year and accretive thereafter.

To minimize disruptions while Integra integrates Acclarent's operations, the companies have signed agreements for transition services, including transition manufacturing services, for up to four years.

Lee Daniels Knight, Integra's chief financial officer, said Integra will finance the deal through its existing revolving credit line, which will take the company's overall leverage ratio to the upper end of its preferred range, between 2.5x to 3.5x.

"But we do see an opportunity through the cash generated off of our core business ... to drive that leverage ratio down, back down to kind of where we anticipate ending this year by the same time next year," Knight said.

Irvine, CA-based Acclarent was founded in 2004 and acquired by Ethicon for \$785m in 2009. However, the company's value at that time may have been at least slightly inflated by illegal sales techniques.

In 2016, two Acclarent executives were convicted of promoting Acclarent products off-label in the years before they sold the company to J&J. (Also see "Fines, But No Prison Time For Ex-Acclarent Execs" - Medtech

pathway to access a brain tumor.

"Acquiring Acclarent gives us an immediate leadership position with the relevant scale to accelerate growth in this market, while also building important capabilities," McBreen said.

Insight, 21 Jan, 2021.)

Both ENT and neurosurgery are highly specialized markets that address "high-impact" disease states. In these markets, highly specialized companies have an advantage over companies trying to sell a broader range of products because ENT and neurosurgeons usually have significant influence over their centers' device purchasing decisions.

Acclarent's direct sales force will help Integra reach new surgeon customers.

"[Acclarent has] strong brand equity and best-in-class sales channel, giving the Integra an expanded footprint into adjacent sites of care such as outpatient surgery, ambulatory surgical centers and physicians' offices." – Michael McBreen

"They have strong brand equity and best-in-class sales channel, giving the Integra an expanded footprint into adjacent sites of care such as outpatient surgery, ambulatory surgical centers and physicians' offices," McBreen said.

He suggested Integra may seek more acquisitions to expand its ENT business, saying, "We're very interested in future M&A, but we feel this deal on its own for scale allows us a long runway."

Integra is also looking to expand its reach outside the US. "This is a US business," McBreen said. "There are some [international] opportunities that we're in the early stages [of investigating] and we've got a select group of categories that we're starting to work through and we'll certainly be reporting back progress on that."

# **Strategic Roadmap**

De Witte said the Acclarent deal "not only aligns with our strategic roadmap for growth and financial commitments, it also supports our mission to innovate treatment pathways to advance

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patient outcomes and set new standards for surgical care."

It is the latest of major moves for the company over the past six years. Integra bought Codman from J&J/DePuy Synthes for \$1.05bn in 2017. (Also see "Integra Aims To Bolster Neurology Portfolio With J&J Codman Buy" - Medtech Insight, 16 Feb, 2017.)

In 2020, Integra bought wound care firm Derma Sciences for \$201m and regenerative medicine company ACell for \$400m. (Also see "Integra LifeSciences Returns To Organic Growth After Rough Year With COVID-19" - Medtech Insight, 29 Apr, 2021.)

Around the same time, Integra sold its extremity orthopedics business to Smith & Nephew for \$240m. (Also see "Smith & Nephew Pays \$240M For Integra's Extremities Business" - Medtech Insight, 30 Sep, 2020.)

Wells Fargo analyst Vik Chopra expects Integra's investors to support the Acclarent acquisition. "Investors will view the deal positively as it positions the company in a stable end market," Chopra wrote in a 13 December note. "More importantly, we do not believe that investors would have been pleased with another deal in wound care."

BTIG analyst Ryan Zimmerman is not certain there is as much overlap between Acclarent and Integra's customer bases as Integra suggested.

## **Integra Restarts In Boston**

Integra has been struggling to resume manufacturing at its Boston facility since <u>it</u> <u>failed a US Food and Drug Administration</u> <u>inspection last summer.</u> (Also see "<u>FDA Sends Warning Letter To Integra Following Recall Of Surgical Repair Products</u>" - Medtech Insight, 22 Aug, 2023.)

The agency concluded that wound-care products produced by Integra's TEI Biosciences subsidiary were susceptible to bacterial contamination.

During Integra's third-quarter 2023 earnings call on 25 October, Integra CEO Jan De Witte said the company will resume manufacturing at the facility by the end of 2023 and resume commercial distribution of those products by the middle of 2024.

Integra expects to complete the final external audit of its updated quality system in early 2024.

"Over the past four months, we have worked diligently on the remediation of our quality system in Boston, consistent with the holistic plan we built in alignment with FDA expectations," he said.

"We've bolstered our Boston operations leadership, quality expertise, project management capabilities and capacity with internal resources, and we further engaged external subject matter experts as well."

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"The bulk of [Acclarent's] portfolio is balloon sinus dilation, and the synergies are less obvious for Integra as balloon sinus dilation will require an entirely separate sales force," he wrote in a 13 December note.

Although ENT surgery is a large, fastgrowing market it is also extremely competitive, Zimmerman said.

"We believe there are cross-sell opportunities with ENT instrumentation and the rest of the Codman portfolio, areas such as navigation and shavers are also going up against companies such as Medtronic, and Stryker who have very established presences in these peripheral ENT growth areas."

"It remains to be seen whether this will be a favorable acquisition," Zimmerman wrote, but he noted, "J&J bought Acclarent for \$785m, so for Integra to pick this up for \$275m isn't a bad price."

Kristen Stewart of CL King and Associates accepts Integra's justification for the deal. "Overall, we view the deal as positive as the Acclarent is a high-single digit growth business, is highly complementary

BTIG analyst Ryan Zimmerman believes the company should be focused on its Boston problem rather than new ventures.

"While Integra has restarted manufacturing in Boston, it is going to be another six months before those products are commercial again, and we wonder if [the Acclarent] transaction might not distract from the focus necessary to ensure Integra retains its position in tissue technologies.

In a 13 December note, Truist Securities analyst Richard Newitter agrees that the acquisition "could add some execution risk as management now has to focus on integrating the asset while it continues to work through remediation issues at its Boston manufacturing facility."

On the same day, Raymond James' Jayson Bedford wrote, "The deal was opportunistic and provides the potential for solid accretion in 2025, but our near term focus remains on the completion of the remediation and return to full operations of the Boston manufacturing facility."

to the neurosurgery segment and the transaction, is expected to be accretive to Integra's [long-range plan,]" Stewart wrote on 14 December.