

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 30, 2022

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

0-26224
(Commission File Number)

51-0317849
(IRS Employer Identification No.)

1100 Campus Road
Princeton, NJ 08540
(Address of principal executive offices) (Zip Code)
Registrant's telephone number, including area code: (609) 275-0500

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class
Common Stock, Par Value \$.01 Per Share

Trading Symbol
IART

Name of Exchange on Which Registered
Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

ITEM 7.01 REGULATION FD DISCLOSURE

On December 1, 2022, Integra LifeSciences Holdings Corporation (the “Company”) issued a corporate presentation containing additional information related to the other events as detailed in Item 8.01 of this Current Report on Form 8-K, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference. This presentation will also be available on the Company’s investor relations website at <https://investor.integralife.com/> under the “Events & Presentations” tab.

As provided in General Instruction B.2 of Form 8-K, the information in this Item 7.01 and Exhibit 99.1 incorporated herein shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

ITEM 8.01 OTHER EVENTS

On November 30, 2022, the Company entered into a definitive agreement to acquire Surgical Innovation Associates, Inc. The transaction is expected to close during the fourth quarter of 2022, subject to the satisfaction of customary closing conditions.

On December 1, 2022, the Company announced it is planning a \$150 million share repurchase as a part of a previous approval by the board of directors. The Company may repurchase shares at its discretion, subject to applicable regulatory and other legal requirements. The number of shares to be repurchased and the timing of such transactions will depend on a variety of factors, including market conditions, regulatory requirements, and other corporate considerations, and could be suspended or discontinued at any time as determined by management. Commencement of share repurchases is expected to occur in early 2023 and the Company may utilize various methods to effect the repurchases, including open market transactions, privately negotiated transactions, transactions structured through investment banking institutions, including accelerated share repurchases, or a combination of the foregoing, some of which may be effected through Rule 10b5-1 plans.

On December 1, 2022, the Company issued a press release announcing the transaction and the Company’s share repurchase plans, a copy of which is filed as Exhibit 99.2 and is incorporated herein by reference.

Cautionary Note Regarding Forward-Looking Statements.

This Form 8-K contains forward-looking statements, including statements related to the Company’s expectations with respect to the closing of the transaction and repurchase of common stock, including the timing and manner of any purchases under the Company’s authorized stock repurchase program. These forward-looking statements are covered by the “Safe Harbor for Forward-Looking Statements” provided by the Private Securities Litigation Reform Act of 1995. The Company has tried to identify these forward looking statements by using words such as “expect,” “anticipate,” “estimate,” “plan,” “will,” “would,” “should,” “could,” “intend” or similar expressions, but these words are not the exclusive means for identifying such statements. The Company cautions that a number of risks, uncertainties and other factors could cause the Company’s plans and actual results to differ materially from those expressed in, or implied by, the forward-looking statements. Such factors include, but are not limited to, changes in the market price of the Company’s common stock, general market conditions, access to credit or debt capital markets, applicable securities laws and alternative uses of capital. For a detailed discussion of factors that could affect the Company’s future operating results, please see the Company’s filings with the Securities and Exchange Commission, including the disclosures under “Risk Factors” in those filings. Except as expressly required by the federal securities laws, the Company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, changed circumstances or future events or for any other reason.

Item 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

99.1 [Presentation, dated December 1, 2022, of Integra LifeSciences Holdings Corporation](#)

99.2 [Press Release, dated December 1, 2022, issued by Integra LifeSciences Holdings Corporation](#)

104 Cover Page Interactive Data File (embedded within the inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

Date: December 1, 2022

By: /s/ Eric I. Schwartz
Eric I. Schwartz
Title: Executive Vice President, Chief Legal Officer and
Secretary



**ACQUISITION OF
SURGICAL INNOVATION
ASSOCIATES (SIA), INC.**
DECEMBER 01, 2022

Confidential - For internal use only

Legal Information

Forward-Looking Statements

This presentation 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," "can," "could," "would," "might," "project," "possible," "should," "expect," "intend," "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 the anticipated satisfaction of the customary closing conditions of the acquisition of Surgical Innovation Associates, Inc. ("SIA"), the expected strategic and financial benefits of the SIA acquisition; the Company's business plans, objectives, expectations, opportunities and intentions following the acquisition; the Company's liquidity and financial position; future financial performance, including projections for revenues, expected revenue growth (both reported and organic) and GAAP and adjusted earnings per diluted share and other items. Statements of past performance, efforts, or results about which assumptions or inferences may be made can also be forward-looking statements and are not indicative of future performance or results. 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 impact of COVID-19 (and any subsequent variants) and its effects on our employees, customers, patients, suppliers and distributors, including the economic impacts of the various recommendations, orders and protocols issued by governmental agencies and other regulatory bodies (including any periodic reimplementation of preventative measures in various global locations) in response to the continual evolution of the pandemic; macroeconomic conditions, including inflation, disruptions to the global supply chain, fluctuations in currency exchange rates, weakness in general economic conditions and recessions; the Company's ability to execute its operating plan effectively; the Company's ability to execute the acquisition of SIA and successfully integrate SIA and its other acquired businesses; the Company's ability to achieve sales growth in a timely fashion and execute on its channel reorganization in its Tissue Technologies segment; 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; 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 hospital spending for capital equipment; the Company's ability to comply with and obtain approvals for products of human origin and comply with regulations regarding products containing materials derived from animal sources; 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; fluctuations in foreign currency exchange rates; the amount of our bank borrowings outstanding and other factors influencing liquidity; 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, 2021 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.

Non-GAAP Financial Measures

This presentation includes anticipated changes to our adjusted earnings per diluted share, which is a non-GAAP measure, in connection with the announced transaction. 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 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) intangible asset amortization expense; and (v) income tax impact from adjustments.

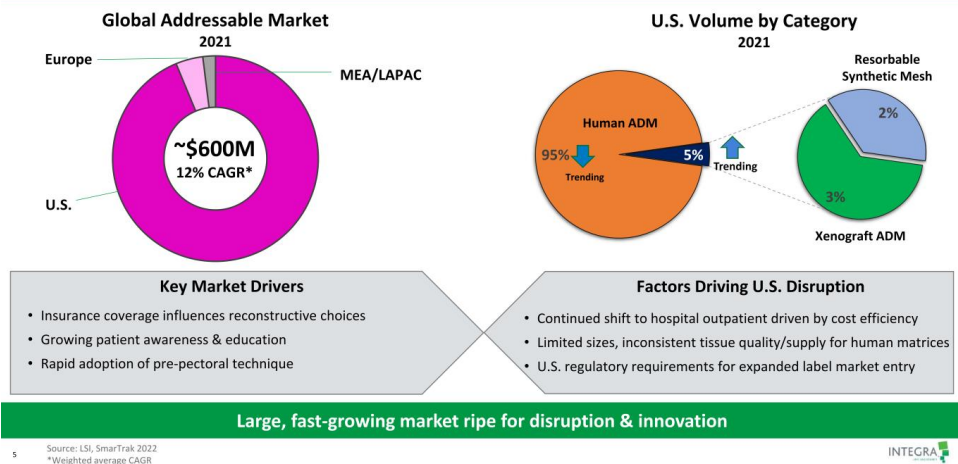
The Company believes that the presentation of adjusted earnings per diluted share measure provides important supplemental information to management and investors regarding financial and business trends relating to the Company's financial condition and results of operations. Management uses such non-GAAP financial measure when evaluating operating performance because we believe that the inclusion or exclusion of the items described above, for which the amounts and/or timing may vary significantly depending upon the Company's divestiture, acquisition, integration, and restructuring activities, for which the amounts are non-cash in nature, or for which the amounts are not expected to recur at the same magnitude, provides a supplemental measure of our operating results that facilitates comparability of our financial condition and operating performance from period to period, against our business model objectives, and against other companies in our industry. This measure should be considered in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

The Company provided the foregoing forward-looking expectations regarding adjusted earnings per diluted share but has not provided a reconciliation to GAAP earnings per share, because certain GAAP expense items are highly variable and management is unable to predict them with reasonable certainty and without unreasonable effort. Specifically, the financial impact and timing of divestitures, acquisitions, integrations, structural optimization and efforts to comply with the EU Medical Device Regulation are uncertain, depend on various dynamic factors and are not reasonably ascertainable at this time. These expense items could have a material impact on GAAP results.

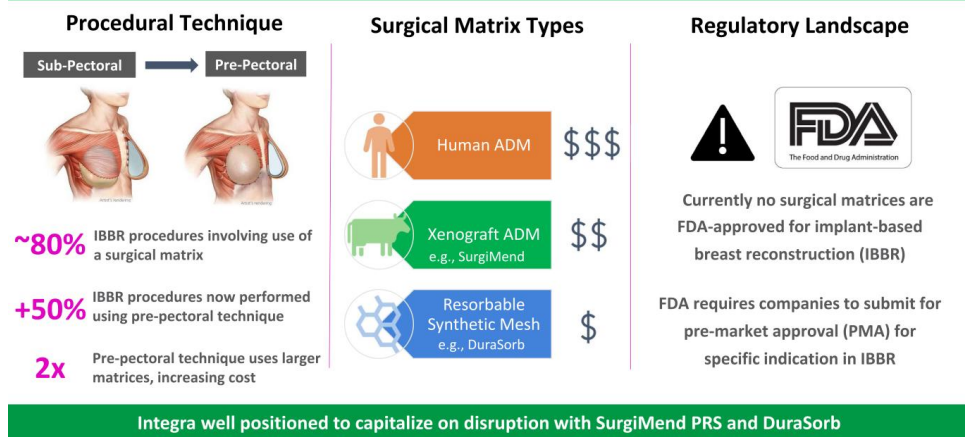
Acquisition overview & strategic rationale

<p>SIA Business Description</p>	<ul style="list-style-type: none"> Private company headquartered in Chicago, IL, founded in 2016 by plastic surgeons and entrepreneurs Founded to commercialize resorbable synthetic mesh for use in plastic and reconstructive surgery DuraSorb® monofilament mesh 510k cleared for reinforcement of soft tissue; 2022E revenue ~\$5M SIA is only company with an active enrolling U.S. Investigational Device Exemption (IDE) trial for soft tissue support in implant-based breast reconstruction (IBBR)
<p>Strategic Rationale</p>	<ul style="list-style-type: none"> Breast reconstruction represents an attractive growth opportunity for surgical matrix business; historically dominated by human derived surgical matrices Today, there are no FDA-approved surgical matrices for IBBR Integra's SurgiMend® PRS (a xenograft) is subject of the 1st premarket approval (PMA) application for an IBBR surgical matrix; we submitted and held a panel review meeting with FDA in 2021, and anticipate amendment submission in mid-2023 with approval for sub-pectoral IBBR in 2024 DuraSorb (a resorbable synthetic matrix) expected to be 2nd to receive PMA, in 2025/2026, for both sub-pectoral and pre-pectoral IBBR As U.S. market faces potential for disruption through shifting surgical techniques, value-based care trends, and regulatory actions, we anticipate a shift towards xenograft and resorbable synthetic surgical matrix solutions By offering two distinct product solutions to plastic and reconstructive surgeons, Integra can build a leading position by addressing various clinical, contracting and economic needs across different sites of care
<p>Key Deal Terms</p>	<ul style="list-style-type: none"> Acquisition structured as a merger \$50M at closing, and up to \$90M in milestones Deal expected to be accretive in Year 3 (2025); ROIC to exceed 10% in year 5 (2027) Subject to the satisfaction of customary conditions; acquisition expected to close in December 2022

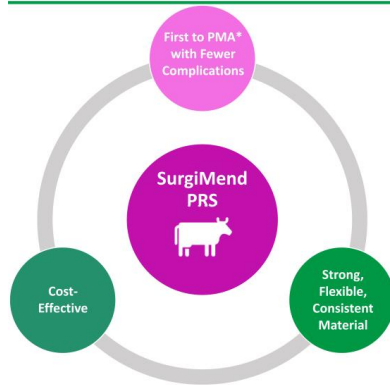
Global breast reconstruction market represents attractive opportunity for surgical matrix business, historically dominated by human derived surgical matrices



Anticipated disruption in U.S. breast reconstruction landscape via shifting surgical techniques, value-based care trends, and regulatory actions



SurgiMend PRS collagen matrix targeting expanded-label market entry in 2024



Product

- **Acellular dermal matrix** derived from **fetal bovine**
- Currently indicated for soft tissue reinforcement where weakness exists

Affordability & Site of Care

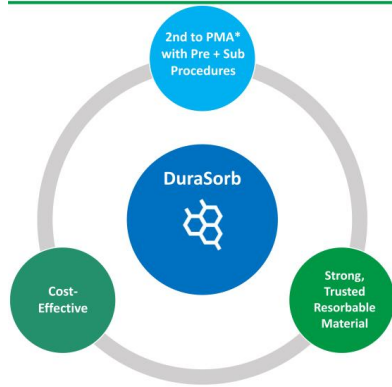
- **30%** more affordable than human derived surgical matrices
- **Higher acuity** sites of care (i.e., hospital outpatient)

Clinical & Regulatory

- **First and only** manufacturer to have submitted a PMA (2021 submission and panel meeting)
- Under active review for **sub-pectoral IBBR**; amendment submission planned for mid-2023, approval expected in 2024
- Leverages a real world, historic dataset from the **Mastectomy Research Outcomes Consortium (MROC)** study

With SurgiMend PRS, Integra is a leading contender today to capture opportunity in this market

DuraSorb monofilament mesh targeting expanded-label market entry in 2025/2026



Product

- Soft, warp-knit monofilament **macro-porous resorbable mesh**
- Indicated for reinforcement of soft tissue where weakness exists

Affordability & Site of Care

- **60%** more affordable than human derived surgical matrices
- Accessible to **lower acuity** sites of care (i.e., ambulatory surgical center)

Clinical & Regulatory

- **First and only active, prospective**, multi-center enrolling **IDE trial** in the U.S. with enrollment ~70% complete
- Evaluating use in two stage **sub-pectoral and pre-pectoral** IBBR to obtain PMA, expected in 2025/2026
- Additional 500 patient registry active with up to 3 years follow up

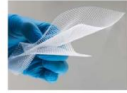
DuraSorb poised to become the clinical leader in the resorbable synthetic mesh category for IBBR

Integra poised for leadership position in IBBR with both xenograft and resorbable synthetic portfolio offerings



SurgiMend

Portfolio Advantages



DuraSorb



Clinical & Cost Efficacy

- Clinical advantages across a **broader range of procedures**
- Enables delivery of **cost-effective solutions** to distinct segments **across varied sites of care**



First Mover Advantage

- SurgiMend PRS PMA **Expected First** (Sub-Pectoral)
- DuraSorb PMA **Next** (Sub-Pectoral and **Pre-Pectoral**)
- No other companies have submitted a PMA



Commercial Synergy

- Expanded sales & marketing footprint
- Strengthens contracting position across categories

Two distinct solutions to address varying clinical, contracting, and economic needs across different sites of care

SIA acquisition adds resorbable synthetic technology to Integra's strong capabilities in soft tissue reconstruction

1

Brings us closer to reaching our ambition of becoming a global leader in breast reconstruction with future FDA approvals, evidence generation and pipeline investments with revenue opportunity of ~\$200M by 2030 for SurgiMend and DuraSorb

2

Transaction expected to be \$0.06 dilutive in Year 1, and turn accretive by Year 3 (2025)

- ROIC to exceed 10% by Year 5 (2027)
- 2022E Sia revenue ~\$5M; gross margin > 75%

3

Plans to initiate a \$150M share repurchase in early 2023;
Benefit to adjusted EPS expected to largely offset Year 1 dilution of Sia acquisition

Highly strategic acquisition that advances our market leadership ambitions

Integra LifeSciences Announces Definitive Agreement to Acquire Surgical Innovation Associates (SIA) and Plans for \$150 Million Share Repurchase

Acquisition will add distinct new product solution for plastic and reconstructive surgery to address clinical needs and improve patient outcomes

Deploys capital to support strong profitable growth and greater returns for our shareholders

PRINCETON, N.J., December 1, 2022 (GLOBE NEWSWIRE) -- [Integra LifeSciences Holdings Corporation](#) (NASDAQ:IART), a leading global medical technology company, today announced that it entered into a definitive agreement to acquire [Surgical Innovation Associates](#) (SIA), which develops, markets and sells [DuraSorb](#)[®], a resorbable synthetic matrix for plastic and reconstructive surgery. This acquisition will advance Integra's global strategy in breast reconstruction, expanding plans to access the U.S. market with devices specifically approved by the FDA for use in implant-based breast reconstruction (IBBR) procedures. The transaction is expected to close by the end of the year, subject to the satisfaction of customary conditions.

The addition of DuraSorb's resorbable synthetic technology will further strengthen Integra's plastic and reconstructive surgery portfolio, which includes [SurgiMend](#)[®] PRS, a xenograft surgical matrix. Today, there are no surgical matrices approved by the FDA specifically for use in IBBR. With SurgiMend[®] PRS, Integra is the first and, to date, the only manufacturer to submit a pre-market approval (PMA) application for a surgical matrix for use as soft tissue support in IBBR. Integra's PMA application for SurgiMend is currently under review with the FDA. Concurrently, SIA is conducting an investigational device exemption study in the U.S. evaluating the safety and effectiveness of DuraSorb with the goal of obtaining a PMA in IBBR.

"The global breast reconstruction market represents an attractive growth opportunity for our surgical reconstruction business," said Robert T. Davis, Jr., executive vice president and president, Tissue Technologies, Integra LifeSciences. "By offering two distinct product solutions, SurgiMend and DuraSorb, to plastic and reconstructive surgeons, we aim to address various clinical, contracting, and economic needs across different sites of care. We look forward to welcoming the SIA leadership and colleagues who will continue to drive the team's success."

According to Breastcancer.org, one in eight women will develop breast cancer in her lifetime. For women undergoing a mastectomy and opting for a breast reconstruction procedure today, surgical matrices are commonly used to provide support in a majority of IBBR procedures. Shifts in procedural techniques and trends towards value-based care are expected to increasingly favor xenograft and resorbable synthetic matrices in IBBR surgeries.

"We are excited to work with Integra and contribute our resorbable synthetic technology to its strong soft tissue reconstruction capabilities, with a view to providing surgeons with greater access to FDA-approved devices to support breast reconstruction," said Josh Vose, M.D., chief executive officer, SIA. "Integra's global reach and commercial strength will help enable us to achieve our joint mission to improve outcomes in women's health."

Financial Highlights

Integra will purchase SIA for \$50 million at closing, subject to customary purchase price adjustments, and pay up to an additional \$90 million upon the achievement of certain revenue and regulatory milestones. The acquisition is expected to support Integra's long-term organic growth and financial goals. Integra does not expect this acquisition to have a material financial impact in 2022. The transaction is expected to be dilutive to adjusted earnings per share by approximately \$0.06 in Year 1 and accretive to earnings in Year 3, with a return on invested capital greater than 10% by Year 5.

2022 revenue for DuraSorb is expected to be approximately \$5 million. Following closing of the transaction, DuraSorb sales will be reported within Integra's Tissue Technologies segment as part of its Wound Reconstruction and Care franchise along with Integra's SurgiMend product, which is expected to record 2022 revenues of approximately \$45 million.

Share Repurchase Program

The company is planning a \$150 million share repurchase as a part of a previous approval by the board of directors. The company may repurchase shares at its discretion, subject to applicable regulatory and other legal requirements. The number of shares to be repurchased and the timing of such transactions will depend on a variety of factors, including market conditions, regulatory requirements, and other corporate considerations, and could be suspended or discontinued at any time as determined by management.

Commencement of share repurchases is expected to occur in early 2023 and the company may utilize various methods to make the repurchases. The benefit of the share repurchases to adjusted earnings per share is expected to largely offset the first year of earnings dilution from the acquisition of SIA.

"The SIA acquisition will bring us another step closer to reaching our ambition of becoming a global segment leader and innovator in breast reconstruction with future FDA approvals, investment in pipeline and evidence generation," said Jan De Witte, president and CEO, Integra LifeSciences. "Moreover, our ability to reinvest for growth and repurchase shares reflects the strength of our balance sheet and our commitment to creating shareholder value."

Advisors

BofA Securities acted as exclusive financial advisor to SIA.

Wyrick Robbins acted as legal advisor to Integra and Proskauer served as legal advisor to SIA.

About Integra LifeSciences

Integra LifeSciences is a global leader in regenerative tissue technologies and neurosurgical solutions dedicated to limiting uncertainty for clinicians so they can focus on providing the best patient care. Integra offers a comprehensive portfolio of high quality, leadership brands that include AmnioExcel®, Bactiseal®, BioD™, CerebroFlo®, CereLink® Certas® Plus, Codman®, CUSA®, Cytal®, DuraGen®, DuraSeal®, Gentrix®, ICP Express®, Integra®, Licox®, MAYFIELD®, MediHoney®, MicroFrance®, MicroMatrix®, NeuraGen®, PriMatrix®, SurgiMend®, TCC-EZ® and VersaTru®. For the latest news and information about Integra and its products, please visit integralife.com.

About Surgical Innovation Associates (SIA)

Surgical Innovation Associates, Inc (SIA) is a Northwestern University spin-out founded in 2016 by Alexei Mlodinow, Todd Cruikshank, and technology inventor Dr. John Kim. The company is focused on introducing a new gold standard for soft tissue support in plastic and reconstructive surgery. Having achieved a 510k for DuraSorb Monofilament Mesh in 2018, a CE mark in 2019, and an Investigational Device Exemption in 2020, the company has both commercial and experimental products in the United States and several other markets. Learn more at sia.health

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, including statements related to the Company's expectations with respect to the closing of the transaction, the anticipated financial and operational impact and benefit of the acquisition and the repurchase of the Company's common stock, including the timing of any purchases under the Company's authorized stock repurchase program and the expected benefits realized from any such share repurchase. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ from predicted results. These risks and uncertainties include the price of the Company's common stock, general market conditions, access to credit or debt capital markets, applicable securities laws and alternative uses of capital and other factors beyond the Company's control and the economic, competitive,

governmental, technological, and other factors 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, 2021, and information contained in subsequent filings with the Securities and Exchange Commission. These forward-looking statements are made only as the date thereof, 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.

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