

**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): January 8, 2024**

**SI-BONE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**001-38701**  
(Commission  
File Number)

**26-2216351**  
(I.R.S. Employer  
Identification No.)

**471 El Camino Real  
Suite 101  
Santa Clara, CA 95050**  
(Address of principal executive offices) (Zip Code)

**(408) 207-0700**  
(Registrant's telephone number, include area code)

N/A  
(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:

- 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 \$0.0001 per share

Trading Symbol(s)  
SIBN

Name of each exchange on which registered  
The Nasdaq Global 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 2.02 Results of Operations and Financial Condition.**

On January 8, 2024, SI-BONE, Inc. (the "Company") issued a press release (the "Press Release") announcing preliminary unaudited revenue for the fourth quarter and full year 2023. A copy of the Press Release is attached as Exhibit 99.1 to this current report on Form 8-K and is incorporated by reference herein.

**Item 7.01 – Regulation FD Disclosure.**

Members of the Company's management team expect to meet with investors and analysts the week of January 8, 2024, to discuss the Company performance, using presentation materials which are furnished and attached as Exhibit 99.2.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release dated January 8, 2024</a>
99.2	<a href="#">Presentation dated January 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The information in Items 2.02 and 7.01 and Exhibits 99.1 and 99.2, of this Current Report on Form 8-K are being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 as amended (Exchange Act), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (Securities Act). The information in Items 2.02 and 7.01, and Exhibits 99.1 and 99.2 shall not be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**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.

**SI-BONE, INC.**

Date: January 8, 2024

By: /s/ Anshul Maheshwari  
Anshul Maheshwari  
Chief Financial Officer  
(Principal Financial and Accounting Officer)



**SI-BONE Announces Preliminary Revenue for the Fourth Quarter and Full Year 2023**  
*Fiscal Year 2023 revenue of \$138.5 - \$138.7 million representing growth of over 30%*

SANTA CLARA, Calif., January 8, 2024 – SI-BONE, Inc. (Nasdaq: SIBN), a medical device company dedicated to solving musculoskeletal disorders of the sacropelvic anatomy, today announced its preliminary and unaudited revenue for fourth quarter and full year 2023.

**Fourth Quarter 2023 Summary**

- Worldwide revenue expected to be in the range of \$38.5-\$38.7 million, representing growth of approximately 21% compared to the prior year period
- U.S. revenue expected to be in the range of \$36.5-\$36.6 million, representing growth of approximately 22% compared to the prior year period
- Ended the quarter with approximately 1,130 active surgeons in the U.S., representing growth of approximately 22% compared to the prior year period

**Fiscal Year 2023 Summary**

- Worldwide revenue expected to be in the range of \$138.5-\$138.7 million, representing growth of approximately 30% compared to the prior year period
- U.S. revenue expected to be in the range of \$130.5-\$130.6 million, representing growth of approximately 32% compared to the prior year period

Cash and marketable securities are expected to be approximately \$166.0 million as of December 31, 2023, implying net cash usage of \$0.8 million in the fourth quarter.

The fourth quarter and full year 2023 revenue and cash and marketable securities included in this release are preliminary and prior to the completion of SI-BONE's financial closing procedures and audit procedures by its external auditors and therefore may be subject to adjustment. SI-BONE expects to provide fourth quarter and full year 2023 financial results during its fourth quarter 2023 earnings call in February 2024.

**About SI-BONE, Inc.**

SI-BONE (NASDAQ: SIBN) is a global leader in technology for surgical treatment of musculoskeletal disorders of the sacropelvic anatomy. Since pioneering minimally invasive SI joint surgery in 2009, SI-BONE has supported over 3,600 surgeons in performing a total of over 95,000 sacropelvic procedures. A unique body of clinical evidence supports the use of SI-BONE's technologies, including two randomized controlled trials and over 125 peer reviewed publications. SI-BONE has leveraged its leadership in minimally invasive SI joint fusion to commercialize novel solutions for adjacent markets, including adult deformity, spinopelvic fixation and pelvic trauma.

For additional information on the company or the products including risks and benefits, please visit [www.si-bone.com](http://www.si-bone.com).

#### **Forward Looking Statements**

The statements in this press release regarding expectations of future events or results, including SI-BONE's expectations of continued revenue and procedure growth and financial outlook, contained in this press release are "forward-looking" statements. These forward-looking statements are based on SI-BONE's current expectations and inherently involve significant risks and uncertainties. These risks include preliminary fourth quarter and full year 2023 revenue and cash and marketable securities, which is subject to continued review by SI-BONE and its auditors and significant adjustments may be made before final results are determined, SI-BONE's ability to introduce and commercialize new products and indications, SI-BONE's ability to maintain favorable reimbursement for procedures using its products, the impact of any future economic weakness on the ability and desire of patients to undergo elective procedures including those using SI-BONE's devices, SI-BONE's ability to manage risks to its supply chain, and future capital requirements driven by new surgical systems requiring instrument tray investment. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these and other risks and uncertainties, many of which are described in the company's most recent filings on Form 10-K and Form 10-Q, and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)), especially under the caption "Risk Factors." SI-BONE does not undertake any obligation to update forward-looking statements and expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein, except as required by law.

#### **Investor Contact**

Saqib Iqbal  
Sr. Director, FP&A and Investor Relations  
[investors@SI-BONE.com](mailto:investors@SI-BONE.com)



# SI-BONE Corporate Overview

January 2024

# Safe Harbor Statement

This presentation contains "forward-looking statements," which are statements related to events, results, activities or developments that SI-BONE expects, believes or anticipates will or may occur in the future. Forward-looking often contain words such as "intends," "estimates," "anticipates," "hopes," "projects," "plans," "expects," "seek," "believes," "see," "should," "will," "would," "target" and similar expressions and the negative versions thereof. Such statements are based on SI-BONE's experience and perception of current conditions, trends, expected future developments and other factors it believes are appropriate under the circumstances, and speak only as of the date made. Forward-looking statements are inherently uncertain and actual results may differ materially from assumptions, estimates or expectations reflected or contained in the forward-looking statements as a result of various factors. Risks to SI-BONE's results include preliminary fourth quarter and full year 2023 revenue and cash and marketable securities, which is subject to continued review by SI-BONE and its auditors and significant adjustments may be made before final results are determined, the company's ability to introduce and commercialize new products and indications, its ability to maintain favorable reimbursement for procedures using its products, the impact of any future economic weakness on the ability and desire of patients to undergo elective procedures including those using SI-BONE's devices, its ability to manage risks to its supply chain, and future capital requirements driven by new surgical systems requiring instrument tray investment. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these and other risks and uncertainties, many of which are described in the company's most recent filings on Form 10-K and Form 10-Q, and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)), especially under the caption "Risk Factors". SI-BONE does not undertake any obligation to update forward-looking statements and expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein, except as required by law.

This presentation includes certain non-GAAP measures, including Adjusted EBITDA. For a reconciliation of such non-GAAP measures to GAAP accounting metrics, please refer to the final page of this presentation or SI-BONE's most recent earnings release. This presentation also includes preliminary fourth quarter and full-year 2024 revenue and cash and marketable securities, which remain subject to review and finalization as part of SI-BONE's year end financial audit.



# Identifying Unmet Clinical Needs in the Sacropelvic Space



## Innovation

3 Differentiated Product Families  
77 WW Patents



## Evidence

2 Randomized Controlled Trials  
125+ Peer-reviewed Publications



## Education

3,600+ WW Surgeons <sup>1</sup>  
95,000+ Procedures Performed <sup>2</sup>



## Commercialization

82 Territory Managers  
150+ CSS and Agents

Market Leader | >\$3B Opportunity | Breakthrough Products | Differentiated Health Economics | Scalable Infrastructure

Note: As of January 8, 2024

1. Trained and performed at least one procedure since inception of the company.

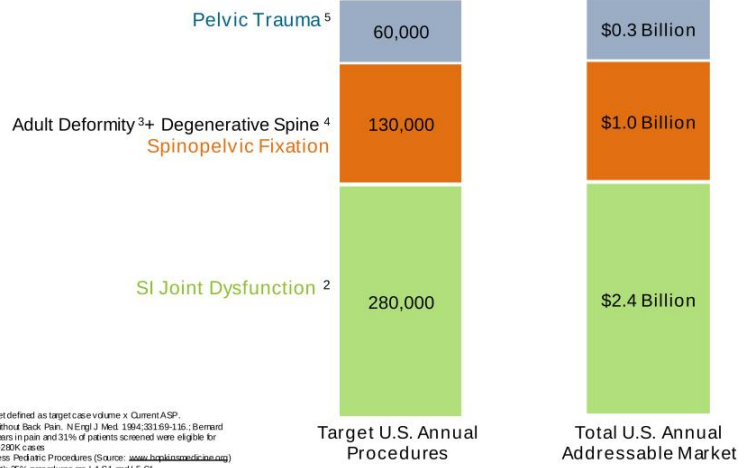
2. Since inception.



# Large Addressable Markets with Attractive Fundamentals

~470,000  
Target U.S. Annual  
Procedures<sup>1</sup>

> \$3 Billion  
Total U.S. Addressable  
Market<sup>1</sup>



1. Management estimate for existing and potential products in 2024. Total addressable market defined as target case volume x Current ASP.  
 2. Sources: Jensen M, et al. Magnetic Resonance Imaging of the Lumbar Spine in People Without Back Pain. N Engl J Med. 1994;331:159-166; Bernard 1997; Schwazer 1995; Magne 1996; Iwin 2007; Sembrano 2009. ; INSITE RCT data. 5 years in pain and 31% of patients screened were eligible for surgery. ; 4. 1,200 therapeutic injections per year with average patient in 15 years of pain = ~280K cases  
 3. 30K target procedures; 70K Deformity Procedures (Source: U.S.2020 Wallstreet Report) less Pediatric Procedures (Source: [www.hipinmedicine.org](http://www.hipinmedicine.org))  
 4. 100K target procedures; 400K Lumbar Fusion Procedures (Source: 2020 Wallstreet Report); 25% procedures are L4-S1 and L5-S1 (Source: Orthopedic Network News, October 2023)  
 5. US Fragility FX TAM: 136K incidence x 40% surgical candidates = 54K; High Energy FX TAM: 6K Pelvic Trauma Surgeries = 6K Source: Management estimates based on internal research; Melton, et al. (1993). Epidemiologic features of pelvic fractures. Clin Orthop Relat Res; Rommens, et al. (2017). Fragility fractures of the pelvis. JBJS; Demetriades, et al. (2002). Pelvic fractures with abdominal injuries. J Am Coll Surg.

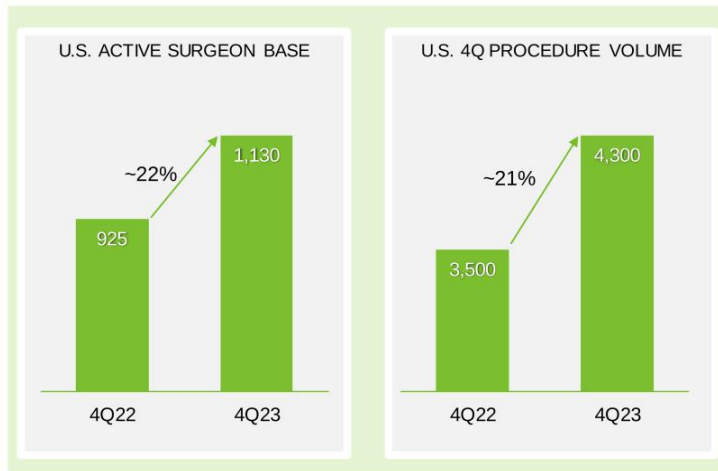
## Strong Demand Drove Record Revenue in 2023



Note: As of January 8, 2024

Note: The fourth quarter and full year 2023 revenue and cash and marketable securities included in this release are preliminary and prior to the completion of SI-BONE's financial closing procedures and audit procedures by its external auditors and therefore may be subject to adjustment. SI-BONE expects to provide fourth quarter and full year 2023 financial results during its fourth quarter 2023 earnings call in February 2024.

## Continued Record Surgeon Engagement



12<sup>th</sup> consecutive quarter of double-digit U.S. active surgeon growth

7<sup>th</sup> consecutive quarter of 20%+ U.S. procedure volume growth

Note: Rounded numbers as of January 8, 2024.

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## Entering 2024 With a Strong Balance Sheet



Continued improvement in cash outflow while investing in the business

- 4Q23 net cash usage estimated to be ~\$0.8 million

Entering 2024 with strong liquidity

- ~\$166 million in expected cash and equivalents

Note: As of January 8, 2024

Note: The fourth quarter and full year 2023 revenue and cash and marketable securities included in this release are preliminary and prior to the completion of SI-BONE's financial closing procedures and audit procedures by its external auditors and therefore may be subject to adjustment. SI-BONE expects to provide fourth quarter and full year 2023 financial results during its fourth quarter 2023 earnings call in February 2024.



# Pioneering Sacropelvic Solutions™

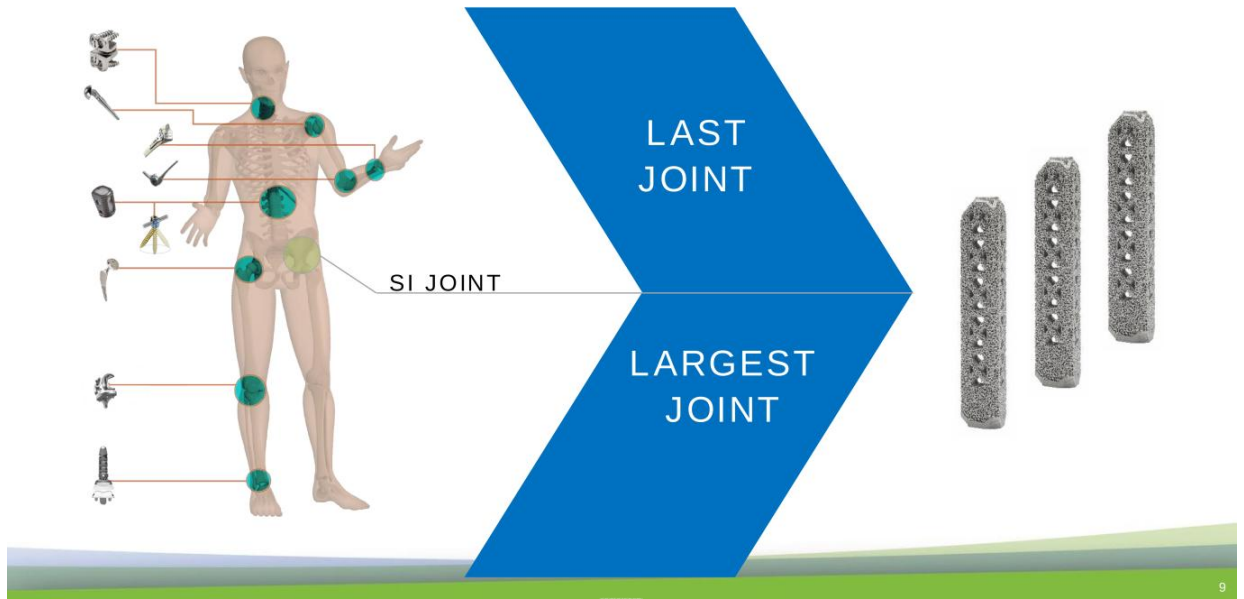
>95,000  
Procedures

>3,600  
Surgeons





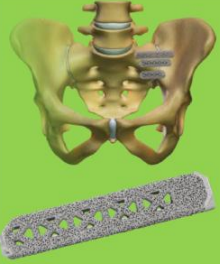
>300M  
U.S. Covered Lives

Note: As of January 8, 2024

## Major Joints Market



## A Major Gap in Sacroiliac Joint Therapy

NON-SURGICAL MANAGEMENT			SURGERY	
MEDICATIONS, PHYSICAL THERAPY	THERAPEUTIC INJECTIONS	RADIO-FREQUENCY ABLATION	OPEN SI JOINT FUSION	MIS SI JOINT FUSION
 An image showing a spilled pill bottle with various colored pills and a photograph of a patient walking on a treadmill with a physical therapist's assistance.	 An anatomical diagram of the sacroiliac joint with a needle and syringe labeled 'Medication' injecting into the joint space.	 An anatomical diagram of the sacroiliac joint with a needle and probe emitting a yellow glow, representing radio-frequency ablation.	 A grayscale medical image showing a surgical incision and the internal structure of the sacroiliac joint during an open fusion procedure.	 An anatomical diagram of the sacroiliac joint with a minimally invasive surgical approach, and a separate image of a porous, cylindrical interbody fusion cage.

# Diagnostic Algorithm Acceptance and Adoption

Accuracy equals or exceeds other lumbar spine diagnoses



Source: Petersen, et al. BMC Musculoskeletal Disorders. 2017;18(1):188. DOI 10.1186/s12891-017-1549-6



# Comprehensive Sacropelvic Solutions Portfolio

## iFuse / iFuse 3D

Market Leader in  
SI Joint Fusion



SI Joint Fusion | Pelvic Trauma | Adult Deformity

## iFuse TORQ

Disruptive Technology for  
Fragility Fractures



## iFuse Bedrock Granite

Breakthrough Fixation and  
Fusion Solution



Adult Deformity | Degenerative Spine

Enabling  
Technologies

iFuse Navigation

iFuse Neuromonitoring

iFuse Robotics

iFuse Bone

## Patent Protected Differentiated Platform

- 77 issued patents: U.S. (59), OUS (18)
- 56 pending patents: U.S. (34), OUS (22)

- iFuse implant patent until Dec 2025
- Triangular broach instrument patent until Feb 2034
- iFuse-3D™ implant patents until Sept 2035

### INSTRUMENT



Triangular broach instrument and the methods of using the instrument

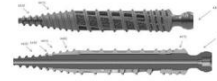
### 3-D TECHNOLOGY



Rectilinear profile, longitudinal struts, and struts connecting the longitudinal struts

- iFuse Bedrock Granite implant patent until Feb 2039
- iFuse TORQ implant patent until Nov 2040

### iFuse Bedrock Granite



Inner shank with external distal threads and an outer sleeve with threads, surface growth features, and fenestrations



### iFuse TORQ



Helical threads, porous network of struts disposed between the threads, and the porous height is less than the major thread diameter

Note: As of January 8, 2024.

# Proprietary, Differentiated iFuse Technology®

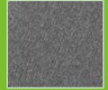
	
Rotation	▲ 6x resistance (vs. 12mm Rialto screw) <sup>1</sup>
Strength	▲ 3x strength (vs. stand 8.0mm cannulated screw) <sup>2</sup>
Safety	▲ Low complication rate <sup>3,4</sup>
Revision	▲ 3.5% (4-year) <sup>5</sup>
Clinical Evidence	▲ 125+ publications (2 RCTs) <sup>6</sup>
Surface	▲ Porous 

- ▶ Proven triangular design and procedure
- ▶ Porous, 3D-printed titanium implant
- ▶ Bony on-growth, in-growth, and through-growth<sup>7</sup>

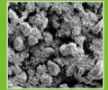
1. SI-BONE Technical Study 3006L0-TS. Torsional Rigidity of the iFuse Implant Compared with a SI Joint Screw in a Sawbones Model.  
 2. SI-BONE Report. Strength of materials of the SI-BONE iFuse Implant vs. 8.0 mm Cannulated Screw. Maudlin RG. December 2009.  
 3. SI-BONE Corporate Records, Complaining Handling & Post-market Surveillance, December 2022.

4. Whang P, et al. Int J Spine Surg. 2023 Oct 58543.  
 5. Cher DJ, et al. Med Devices (Auckl). 2015;8:465-92.  
 6. <https://doi.org/10.1007/s10067-019-01601-0>  
 7. MacBarb RF, et al. Int J Spine Surg. 2017;11:16 (Part 2).

REPRESENTATIVE COMPETITOR



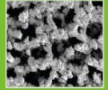
TPS-COATED IFUSE



CANCELLOUS BONE



3D-PRINTED iFuse 3D



3 MONTH SHEEP STUDY 7



## Robust Clinical Evidence

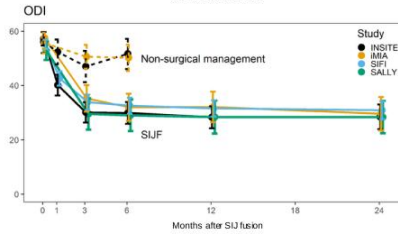
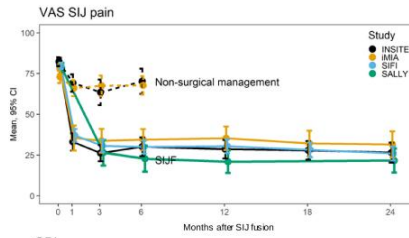
- 125+ peer-reviewed published papers
- 5-year long-term, prospective data
- Two Level 1 randomized studies

[www.s-bone.com/results](http://www.s-bone.com/results)



# SALLY Prospective Clinical Trial: iFuse-3D 2-year Outcomes<sup>1</sup>

## Rapid, marked and durable improvements in pain, patient function and quality of life



VAS Pain Reduction	57-point improvement (MCID 20 points)
ODI Disability Improvement	25-point improvement (MCID 15 points)
Decreased Opioid Use	59% at baseline vs. 18% at follow-up
Patient Satisfaction	91% satisfied / very satisfied at follow-up



1. Patel V, et al. Prospective Trial of Sacroiliac Joint Fusion Using 3D-Printed Triangular Titanium Implants: 24-Month Follow-Up. Med Devices (Auckl). 2021;14:211-16. (Published June 29, 2021). [51 subjects enrolled and treated between October 2017 and January 2019. 24-month follow-up was obtained in 43 (84%)]

2. Similar results to RCTs (INSITE and iMIA) and Prospective trial SIFI.  
 3. Three tests (active straight leg raise, 5x sit-to-stand, transitional timed up-and-go)  
 4. CT at 6 and 12 months [Patel V, et al. Med Devices (Auckl). 2022;13:173-82]

# iFuse TORQ®: Cutting-Edge Pelvic Fixation and Fusion™

## Large, Adjacent Market <sup>1</sup>

~\$350 million Pelvic Trauma opportunity

~120K Sacral Fragility fracture incidence / yr.

~\$40 million revenue synergy opportunity

## Differentiated Technology

FuSlon 3D™ Surface for Osseointegration

IntelliHarvest® Technology self harvests host bone

## Competitive Advantages

TORQLock™ Threads<sup>2</sup>  
10x rotational resistance on insertion vs. trauma screws

Compression Lag Implant and washer



1. Based on internal estimates.
2. Internal clinical reports. Data on file.

# iFuse Bedrock Granite®: Optimized for Fusion and Fixation



## Differentiated Technology



Microporous Lattice Surfaces



Macroporous Fenestrations  
IntelliHarvest® Cutting Flutes



OMNIGapture™ Tulip & Set Screw



EZDrive® Tip

## Large, Adjacent Market

~\$1 billion Adult Spinal Deformity and Degenerative Spine pelvic fixation opportunity<sup>1</sup>

## Competitive Advantages

Breakthrough Device Designation by the FDA

Expanded Rod Combability allows use with wide variety of pedicle screw systems

Up to \$9,828 New Technology Add-On Payment (NTAP)<sup>2</sup>

1. Based on management estimate of total addressable market for existing and potential products in 2024.

2. In August 2022, the Center for Medicare and Medicaid Services issued a final decision for a New Technology Add-on Payment of up to \$9,828 for eligible cases using iFuse Bedrock Granite.

# Long-Term Business Drivers

## Platform Set-up to Deliver Strong Revenue Growth and Operating Leverage

<b>Expand Access to Solutions</b> Accelerate market expansion	Selectively expand sales force headcount Deploy hybrid case coverage solutions
<b>Increase Surgeon Engagement</b> Drive surgeon penetration and adoption	Leverage training and comprehensive portfolio to drive active surgeon growth Expand residents and fellows academic training programs
<b>Expand Addressable Markets</b> Build differentiated portfolio	Accelerate penetration of iFuse Bedrock Granite in adult deformity and degeneration market Build pelvic trauma market with TORQ
<b>Gain Operational Efficiency</b> Achieve Adjusted EBITDA breakeven over time <sup>(1)</sup>	Increase territory productive Expand and optimize surgical capacity to support growth

>\$3B Opportunity | Breakthrough Products | Differentiated Health Economics | Scalable Infrastructure | Strong Liquidity

1. Adjusted EBITDA defined as Earnings Before Interest, Taxes, Depreciation, Amortization and Stock Based Compensation.



## Differentiated Portfolio Complemented By Strong Fundamentals

Robust Data	<ul style="list-style-type: none"><li>▪ 125+ published papers</li><li>▪ 2 randomized controlled trials</li></ul>
Reimbursement Advantage	<ul style="list-style-type: none"><li>▪ &gt;300 million U.S. covered lives</li><li>▪ NTAP for iFuse Bedrock Granite</li></ul>
Large, Underpenetrated Markets	<ul style="list-style-type: none"><li>▪ 470,000 annual target procedures, for a total annual opportunity &gt; \$3 billion</li><li>▪ &lt;10% SI joint fusion market penetrated</li></ul>
Proven Execution Track Record	<ul style="list-style-type: none"><li>▪ ~30% worldwide y/y revenue growth in FY2023</li><li>▪ 12 consecutive quarters of double-digit U.S. active surgeon base growth</li></ul>
Strong Balance Sheet	<ul style="list-style-type: none"><li>▪ ~\$166 million in estimated cash and equivalents</li></ul>

Note: As of January 8, 2024

Note: The fourth quarter and full year 2023 revenue and cash and marketable securities included in this release are preliminary and prior to the completion of SI-BONE's financial closing procedures and audit procedures by its external auditors and therefore may be subject to adjustment. SI-BONE expects to provide fourth quarter and full year 2023 financial results during its fourth quarter 2023 earnings call in February 2024.



# Pioneering Sacropelvic Solutions™

>95,000  
Procedures

>3,600  
Surgeons

>300M  
U.S. Covered Lives

Note: As of January 8, 2024

## Disclosures

The iFuse Bedrock Granite® Implant System is intended for sacroiliac joint fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

When connected to compatible pedicle screw systems with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloy the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Spinal tumor
- Pseudarthrosis
- Failed previous fusion

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic® StealthStation® System.

## Disclosures

The iFuse Implant System® is intended for sacroiliac fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

If present, a pelvic fracture should be stabilized prior to the use of iFuse implants.

The iFuse TORQ® Implant System is indicated for:

- Fusion of the sacroiliac joint for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures.

The iFuse TORQ Implant System is also indicated for fracture fixation of the pelvis, including acute, non-acute, and non-traumatic fractures.

The iFuse TORQ Navigation instruments are intended to be used with the iFuse TORQ Implant System to assist the surgeon in precisely locating anatomical structures in iFuse TORQ Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse TORQ Navigation instruments are intended to be used with the Medtronic® StealthStation® System.

Healthcare professionals please refer to the Instructions For Use for indications, contraindications, warnings, and precautions at [www.si-bone.com/label](http://www.si-bone.com/label).

There are potential risks associated with iFuse procedures. They may not be appropriate for all patients and all patients may not benefit.

For information about the risks, visit [www.si-bone.com/risks](http://www.si-bone.com/risks).

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# SI-BONE®

Sacropelvic Solutions™

- SI Joint Dysfunction
- Pelvic Trauma
- Spinopelvic Fixation

iFuse 3D.  
Implant System

iFuse TORQ.  
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Implant System

