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Medical Technology

# JNJ Electrophysiology update – trial timelines and view of market

**Industry Overview**

## JNJ provided an Electrophysiology update call today

JNJ hosted an Electrophysiology investor event this morning and we walked away with more clarity on PFA trial timelines and JNJ's view of the EP market. JNJ notes more patients are self-diagnosing with smart watches / have increased awareness of afib and are seeking treatment, contributing to the recent strength in the market. Varipulse CE Mark should come any day/week now. Varipulse US PMA submission is expected soon (FDA approval likely this year). JNJ feels ready on the supply side to meet demand for both consoles and catheters in Europe once CE Mark comes as well as in the US if needed by year end. No comments on pricing were made but JNJ feels its PFA will be priced accordingly to the benefit it brings to the market.

## Updates on JNJ's PFA clinical trials; US approval 2024

The complete 12-month results from the admIRE trial (US Varipulse study) are expected to be presented in May. The afIRE study (Varipulse in China) has completed enrollment. The European trial for the dual energy (RF/PFA) Thermocool SmartTouch SF has completed enrollment and the US trial is currently enrolling (SmartPulse trial began enrollment in Dec 2023). The Omnypulse trial in EMEA and Canada is currently enrolling and US enrollment is to come. The Omnypulse catheter is a large tip catheter, in between focal and single shot, which JNJ believes will be versatile with use in PVI ablations and other areas of the atrium and potentially for VT. See inside for our PFA trials tracker and device landscape.

## JNJ's view of the afib mkt; seeing RF still have a place

JNJ sizes the global afib market at 38m people of which less than 5% of eligible patients are treated with ablation. The market is expected to continue to grow double digits as more patients become aware of their afib and the population ages. PFA may be the opportunity to get ablation penetration beyond 5% as it brings down procedure times and can increase accessibility of procedures. A potential bottleneck could be the number of labs and doctors there are to treat these patients globally but JNJ thinks there could be more investment from hospitals to drive up the number of cath labs and EPs coming into the field as patient awareness of afib and those seeking treatment increases. JNJ has programs with hospitals to improve referral patterns and drive awareness while also focusing on the safety, efficiency, and effectiveness of its PFA developments to increase treatment by docs. JNJ is excited about PFA but also believes RF is here to stay given the familiarity among docs and known longer term outcomes. JNJ believes the initial patients to be treated with PFA will be those with paroxysmal afib getting a de novo PVI and RF will be preferred when ablation in other areas of the heart is needed or in re-do ablations. No split of de novo vs re-do ablations was shared but JNJ notes there is an increasing amount of newly diagnosed patients who are getting treated earlier.

The changing landscape in EP is important for MDT, ABT, JNJ, and BSX. We continue to see BSX being the biggest beneficiary from the changing landscape in EP given their early lead and lower starting share along with excellent doc feedback on the Farapulse device.

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AFib = atrial fibrillation

PMA = premarket approval

RF = radiofrequency

PFA = pulse field ablation

PVI = pulmonary vein isolation

VT = ventricular tachycardia

MDT = Medtronic

ABT = Abbott Labs

BSX = Boston Scientific

# PFA trials tracker and PFA device landscape

**Exhibit 1: PFA trials tracker**
The next data we expect to see is the full 12 month data from the admIRE US Varipulse trial in May and Sphere-9 (Affera) US trial data in the Spring.

| Trial | Device | Patient # | Start Date | Est Completion Date | Trial Details | Next Update |
|---|---|---|---|---|---|---|
| **BSX** | | | | | | |
| ADVENT | Farapulse | 900 | March 2021 | June 2023 | Pivotal study comparing Farapulse with force-sensing RF catheters and cryoballoon catheters for persistent afib | FDA approval expected in Q1'24 |
| PersAFOne III | Farapulse | 60 | Feb 2022 | Jul 2024 | Feasibility study for persistent afib | - |
| RWS of the Farapulse | Farapulse | 30 | Jan 2023 | Apr 2023 | Real world study of Farapulse for treatment of Paroxysmal afib in a Chinese population | - |
| ADVANTAGE AF | Farapulse/Farapoint | 755 | Feb 2023 | Feb 2025 | Pivotal study for persistent afib. First phase evaluating Farapulse for treatment of persistent AF. Extension arm evaluating Farapoint, a point-by-point PFA focal catheter for CTI ablations, used to treat atrial flutter. | First cohort completed enrollment in Q3'23. Second phase with Farapoint, expect to complete enrollment in Q1'24. |
| AVANT GUARD | Farapulse | 500 | Dec 2023 | - | PFA as front line therapy for persistent AF. Outcomes will show PFA vs AAD therapy | Trial initiated Dec 2023 |
| **MDT** | | | | | | |
| PULSED-AF | PulseSelect | 418 | Dec 2019 | Nov 2022 | Pilot phase followed sequentially by a pivotal consisting of 3 arms enrolling: Roll-in, Paroxysmal AF, Persistent AF | Results were presented at ACC on Mar 6, 2023 |
| SPHERE Per-AF | Sphere-9 (Affera) | 477 | Dec 2021 | Nov 2023 | Study comparing Sphere-9 vs the THERMOCOOL SMARTTOUCH SF RF ablation on persistent afib | Complete 12 mo follow up in US 2023 year end, FDA submission to follow. Data to be presented in Spring 2024. |
| SpherePVI | SpherePVI | 50 | July 2021 | July 2023 | Single-arm study to evaluate SpherePVI catheter for treating paroxysmal AF | - |
| **JNJ** | | | | | | |
| inspIRE | Varipulse | 550 | Aug 2020 | May 2023 | EU pivotal study on paroxysmal afib | CE Mark expected early 2024E |
| admIRE | Varipulse | 362 | Apr 2022 | Jan 2024 | US pivotal study on paroxysmal afib. First patient enrolled in May 2022. Company said enrollment completed in April 2023.Last patient 12 mo follow up visit in November '23. FDA submission to follow. | 2024? |
| afIRE | Varipulse | 135 | Dec 2022 | Dec 2024 | Varipulse study in China | Completed enrollment as of Feb 2024 |
| smartfIRE | Thermocool SmartTouch SF | 135 | Feb 2023 | Nov 2024 | European clinical trial on paroxysmal afib | European trial completed enrollment in July 2023. |
| SmartPulse | Thermocool SmartTouch SF | 250 | Dec 2023 | Apr 2025 | US trial for thermocool smarttouch SF | Enrollment ongoing as of Feb 2024 |
| Omny-IRE | Omnypulse | 160 | Sept 2023 | Apr 2025 | Europeans tiral to demonstrate safety and effectiveness of Omnypulse in treatment of participants with paroxysmal afib | Currently enrolling as of Feb 2024 |
| **Private Companies** | | | | | | |
| Kardium (PULSAR) | Globe | 435 | Mar 2023 | Jan 2025 | Pivotal study on Globe PFA for treating patients with paroxysmal or persistent afib | 12 mo follow up data by Jan 2025 then can submit to FDA. |
| Kardium (PULSE EU) | Globe | 110 | Aug 2021 | Dec-23 | EU study on Globe PFA for treating AF | Data at AF Symposium Feb 2024 |
| Adagio (PARALELL) | CryoPulse PFCA | 78 | Oct 2022 | Mar 2024 | First-in-human clinical study on Adagio PFA and PFCA Systems for persistent afib | - |

**Source:** clinicaltrials.gov, company materials

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**Exhibit 2: PFA device landscape**
Varipulse CE Mark is expected in the next few weeks and US PMA submission is expected very soon (could receive FDA approval by year end)

| Company | Device | FDA Approval | CE Mark | Energy | Type of Afib | Technique | Tissue Contact | Type of Energy | Waveform |
|---|---|---|---|---|---|---|---|---|---|
| BSX | Farapulse | Approved Jan 2024, immediate LMR | CE Mark in 2021; full market release in 2H22 | PFA | Paroxysmal; running trial for Persistent | Single shot | Independent | Bipolar | Biphasic or Monophasic |
| MDT (internal) | PulseSelect | Approved Dec 2023 and commercialization early 2024 | CE Mark in Nov 23 | PFA | Paroxysmal or Persistent | Single shot | Independent | Bipolar | Biphasic |
| MDT (Affera) | Sphere-9 | Potentially 2H'24. 12 month data from US trial to be presented in Spring | CE Mark in March 2023 | PFA / RF | Paroxysmal or Persistent | Point-by-point | Dependent | Bipolar | Biphasic |
| JNJ | Varipulse | Potentially by end of 2024. 12 mo data from admIRE trial to be presented in May '24 | CE Mark expected early 2024E. Japan approval in Jan 2024. | PFA | Paroxysmal | Single shot | - | Bipolar | Biphasic |
| JNJ | Thermocool SmartTouch | US SmartPulse trial began enrollment in Dec '23 | First cases in Europe Feb '23 in smartfIRE trial, enrollment completed as of Aug'23 | PFA / RF | Paroxysmal | Contact force–guided radiofrequency | Dependent | - | - |
| JNJ | Omnypulse | US enrollment likely begins this year | Enrollment in Omny-IRE trial in Europe & Canada began in Sept '23 and enrollment ongoing as of Feb '24 | PFA | Paroxysmal | Large focal | Dependent | - | - |
| ABT | Volt | IDE trial approval expected 1H24. Our estimate is late 2026/early 2027 | As of Jan 2024, 30 patients treated in CE Mark study | PFA | Paroxysmal or Persistent | Single shot | Dependent | Bipolar | Biphasic |
| Adagio | iCLAS | Plans to initiate a pivotal study | Plans to initiate a trial to support CE Mark | PFA / Cryo | Paroxysmal or Persistent | - | Dependent | - | - |
| Kardium | Globe PF System | Initiated IDE study in March '23, US data for paroxysmal cohort in Jan 2025, FDA approval in late 2025/early 2026 | European data to be presented at AF Symposium Feb 2024 | PFA | Paroxysmal or Persistent | Single shot | - | - | - |

**Source:** Company materials, BofA Global Research.

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## Price objective basis & risk

**Boston Scientific (BSX: B-1-9: $66.43)**
Our PO of $70 is derived from 28x our 2025E EPS estimate, which is a premium to the large cap medtech comp group. We believe this multiple is justified given our view of BSX's accelerating earnings growth outlook based on opportunities to drive above average top line growth.

Downside risks to our PO are: 1) Watchman slowdown if ABT becomes more competitive than expected, 2) supply chain/inflationary pressures impact margins more than expected, 3) BSX sees a major setback in a clinical trial or product pipeline failure, 4) unexpected COVID related headwinds.

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| | Bausch & Lomb | BLCO | BLCO US | Craig Bijou |
| | Becton Dickinson | BDX | BDX US | Travis Steed |
| | Boston Scientific | BSX | BSX US | Travis Steed |
| | Dexcom | DXCM | DXCM US | Travis Steed |
| | Inari Medical | NARI | NARI US | Travis Steed |
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| | Intuitive Surgical | ISRG | ISRG US | Travis Steed |
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| | Teleflex Incorporated | TFX | TFX US | Craig Bijou |
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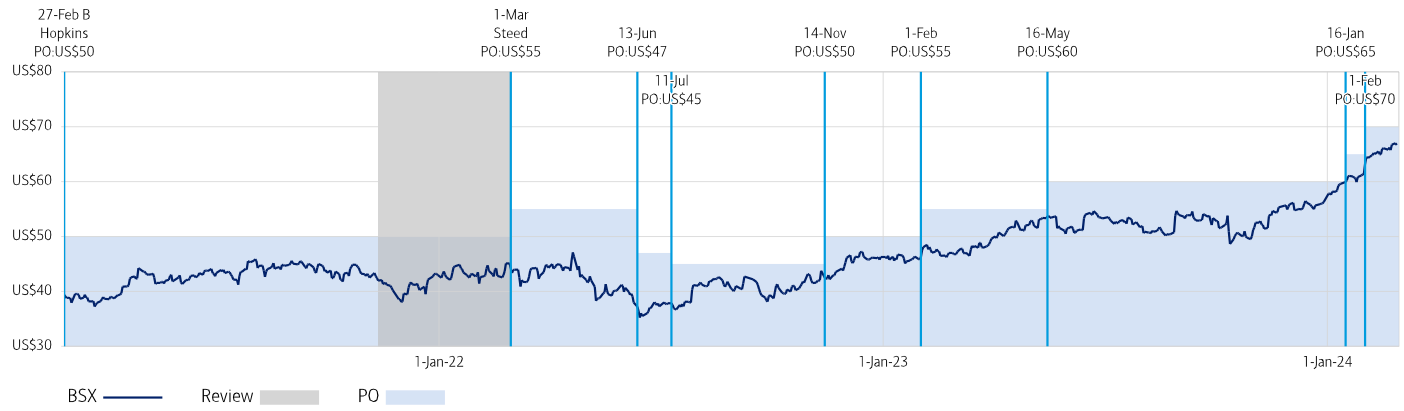
**Boston Scientific (BSX) Price Chart**

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**Boston Scientific (BSX) Price Chart**

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| Coverage Universe | Count | Percent | Inv. Banking Relationships [R1] | Count | Percent |
|---|---|---|---|---|---|
| Buy | 234 | 60.94% | Buy | 115 | 49.15% |
| Hold | 80 | 20.83% | Hold | 36 | 45.00% |
| Sell | 70 | 18.23% | Sell | 29 | 41.43% |

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|---|---|---|---|---|---|
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| Hold | 832 | 23.54% | Hold | 454 | 54.57% |
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| Neutral | ≥ 0% | ≤ 30% |
| Underperform | N/A | ≥ 20% |

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