BofA SECURITIES

Medical Technology

Prep packet for next week – medtech questions and catalysts

Industry Overview

Medtech questions and catalysts by company

Next week medtech companies will be meeting investors and talking more about 4Q23 and 2024. To help prep for next week, inside we go through company-specific questions we would be asking each company and include our list of catalysts for each company as well. The big picture topics for the sector likely revolve around sustainability of 2023 growth (see note) into 2024, Q1 comps, margin recovery, China, interest expense (see note), FX, Pillar Two (see note), appetite for M&A (see note), and GLP-1s. PFA timelines moving up (see link) and ISRG procedure guide (see note) will likely be topical. We doubt we will learn much next week on a new ISRG system, but we have thought about how a new robot could impact the model (see note). We also think investors will be trying to get a better sense for BAX's earnings power (see note). See inside for all the details.

04 January 2024

Equity
United States
Medical Technology

Travis Steed
Research Analyst
BofAS
+1 404 607 3251
travis.steed@bofa.com

Craig Bijou
Research Analyst
BofAS
+1 646 855 2590
craig.bijou@bofa.com

Stephanie Piazzola
Research Analyst
BofAS
+1 646 855 4568
stephanie.piazzola@bofa.com

Carolyn Huszagh
Research Analyst
BofAS
+1 312 259 7414
carolyn.huszagh@bofa.com

Acronym glossary
BAX = Baxter
FX = foreign currency
GLP-1 = Glucagon-like peptide-1
ISRG = Intuitive Surgical
M&A = mergers and acquisitions
PFA = pulsed field ablation

Refer to important disclosures on page 40 to 41.

Contents

History of pre-announcement and guidance at competitor conference in Jan

Exhibit 1: History of Q4 pre-announcements and guidance at competitor conference in January

In 2023 GE Healthcare, Intuitive Surgical, Axonics, Dexcom, Inari, Nevro, Outset Medical, and Tandem pre-announced Q4 and gave guidance while Inspire Medical, Integer, Integra LifeSciences, Paragon28, Procept, RxSight, and Si Bone just pre-announced Q4 and did not provide guidance.

	2020A		2021A		2022A		2023A	
Company	Pre-Announced Q4?	Gave Guidance?	Pre-Announced Q4?	Gave Guidance?	Pre-Announced Q4?	Gave Guidance?	Pre-Announced Q4?	Gave Guidance?
Abbott	No	No	No	No	No	No	No	No
Baxter	Yes	Yes	Yes	No	No	No	No	No
Becton Dickinson	No	No	Yes	Yes	No	No	No	No
Boston Scientific	Yes	No	Yes	No	No	No	No	No
Cooper Companies	Q4 call in Dec	Q4 call in Dec	Q4 call in Dec	Q4 call in Dec	Q4 call in Dec	Q4 call in Dec	Q4 call in Dec	Q4 call in Dec
Edwards Lifesciences	No	No	No	No	No	At AD	No	At AD
GE Healthcare	NR	NR	NR	NR	NR	NR	Yes	Yes
Intuitive Surgical	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Medtronic	No	No	No	No	No	No	No	No
Teleflex	No	No	No	No	No	No	No	No
Stryker	No	No	No	No	No	No	No	No
Zimmer Biomet	No	No	No	No	No	No	No	No
Axonics	Yes	No	Yes	No	Yes	No	Yes	Yes
Bausch & Lomb	NR	NR	NR	NR	NR	NR	No	No
Conmed	No	No	No	No	No	No	No	No
Dexcom	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Embecta	NR	NR	NR	NR	NR	NR	Q4 call in Dec	Q4 call in Dec
Globus Medical	Yes	Yes	No	No	No	No	No	No
Inari	NR	NR	Yes	No	Yes	No	Yes	Yes
Inspire Medical	No	No	No	No	Yes	No	Yes	No
Insulet	No	No	No	No	No	No	No	No
Integer	No	No	No	No	No	No	Yes	Q3 call in Oct
Integra LifeSciences	Yes	No	Yes	No	Yes	No	Yes	No
Nevro	Yes	No	Yes	No	Yes	No	Yes	Yes
Outset Medical	NR	NR	No	No	No	No	Yes	Yes
Paragon 28	NR	NR	NR	NR	Yes	No	Yes	No
Penumbra	No	No	Yes	No	No	No	No	No
Procept	NR	NR	NR	NR	Yes	No	Yes	No
RxSight	NR	NR	NR	NR	Yes	No	Yes	No
Shockwave Medical	No	No	No	No	No	No	No	No
Si Bone	Yes	No	Yes	No	Yes	No	Yes	No
Silk Road	No	No	No	No	No	No	No	No
Tandem	No	No	No	No	No	No	Yes	Yes

Source: Company filings

BofA GLOBAL RESEARCH

Exhibit 2: 2023 Guidance provided at competitor conference in January last year

Below we outline what 2023 guidance was given for those that pre-announced/provided guidance at competitor conference in January last year

2023 Guidance Provided at JPM last year	
Large Caps	
ISRG	- WW da Vinci procedure growth ~12% to 16%
GEHC	- Organic revenue growth 5%-7% - Adjusted EBIT margin of 15.0%-15.5%, reflecting an expansion of 50 basis points to 100 basis points versus its 2022 Pro forma Adjusted EBIT margin - Free cash flow conversion 85%+
SMIDs	
AXNX	- Total company net revenue $342 million, which is based on sacral neuromodulation and Bulkamid revenue each growing 25% compared to fiscal year 2022 - Sacral neuromodulation revenue of $277.5 million - Bulkamid revenue of $64.5 million

Exhibit 2: 2023 Guidance provided at competitor conference in January last year
Below we outline what 2023 guidance was given for those that pre-announced/provided guidance at competitor conference in January last year

	2023 Guidance Provided at JPM last year
DXCM	- Total revenue of ~$3.35 billion to $3.49 billion (15%-20% y/y revenue growth) - Non-GAAP Gross Profit Margin of 62%- 63% - Non-GAAP Operating Margin of approximately 16.5%
NARI	- Revenue of $470 million to $480 million, reflecting growth of approximately 23% to 25% over 2022
NVRO	- Worldwide revenue of approximately $445 million to $455 million, an increase of 10% to 12% over prior year - $75 million to $85 million of PDN revenue
OM	- Revenue to be between $140 million to $150 million, growing approximately 22% to 30% - Non-GAAP gross margin is expected to expand to approximately 20% for the full year 2023 and exit the year in the mid-20% range for the fourth quarter of 2023
TNDM	- non-GAAP sales are estimated to be an increase of 11 to 12 percent over 2022

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Key questions/catalysts – Large cap medtech

Abbott Laboratories (ABT)

1. **Acceleration of base organic growth in 2024:** Expect base organic revenue growth to accelerate from the pre-pandemic ~7% growth to 7.5%-8% in 2024. In Established Pharmaceuticals expecting 7.5% growth vs pre-covid (2017-2019) avg of ~8%, in Nutrition expecting 6.5-7% vs pre-covid avg of ~4%, in Diagnostics expecting growth of 6.5% vs pre-covid avg of 6% and in Devices expecting growth of 9-10% vs pre-covid avg of 8%. What is driving the growth/acceleration within each segment? How should we think about growth in 1H vs 2H given some of the puts and takes from covid testing last year and the nutrition comp?

2. **Gross margin expansion in 2024:** Street modeling ~60bps of gross margin expansion in 2024 to 56.2% from current 2023 estimate of 55.5%. With inflation pressures easing, why can't it be more than the Street is currently modeling? What has gotten better and what is still pressured from an inflation standpoint? What about other factors impacting gross margin like FX, portfolio mix, cost reduction programs, etc.? How should we think about getting back to 2019 levels of 59%?

3. **Opex and operating margin in 2024:** Expecting SG&A to be between $11.3-$11.4bn and R&D $2.6-$2.7bn, an increase vs recent years seen flattish spend, what is driving this? Street modeling 50bps of op margin expansion for the year with softer op margins in Q1 (190bps below full year 2024 op margins). Looking historically, Q1'17 op margin was 300bps below full year 2017 op margins; Q1'18 op margin was 270bps below full year 2018 op margins; Q1'19 op margin was 340bps below full year 2019 op margins. Is this the right way to think about Q1 - below full year op margins in line with what seen historically and then a step up over course of the year? Is the Street too high on Q1 op margin?

4. **Medicare CGM pricing:** In December 2023 the Officer of Inspector General put out a notice that it is looking at Medicare payments for CGM and how they compare to acquisition costs. Talk through the potential implications to the Libre business - what the price reductions could be, what part of business is impacted (is it just Medicare which we estimate is 1/3 of the US patients/12% WW) and timing of when any change could be implemented. Do you think this would hit more of the distributor vs CGM? Would you expect offsets to lower pricing from increased adoption?

5. **Fab 5 products (TriClip, Aveir, Navitor, CardioMEMS and Amulet):** Overall how thinking about growth contribution from these products, any that are expected to be a bigger driver than others? Have some catalysts coming up in 2024 with

TriClip US approval in 1H24E, Aveir CE Mark in 2H24E, CardioMEMS NCD in 2H24E. **TriClip:** With TriClip coming to market, how are you thinking about the ramp potential? Is looking to MitraClip as a precedent a good benchmark (MitraClip launch went 2013: $3m; 2014: $34m; 2015: $96m, 2016: $156m)? **Aveir:** How has the Aveir launch been in the US following FDA approval in July 2023 and do you expect it to be similar post CE Mark approval? **CardioMEMS:** How do you expect uptake of CardioMEMS to change post NCD? **Amulet:** Been on the market for a couple years and share has been consistent around low double digits. Where do you see share potential from here? Growth for Amulet been stepping down through 2023 (43% organic growth in Q1'23, 23% in Q2, and 10% in Q3), why has this been the case and what is the growth outlook or 2024? **Navtior:** Has been capturing 1-2pts of share, do you expect this to continue and where do you ultimately see your share with another name entering the US market end of 2024?

6. **Electrophysiology outlook:** Have you been seeing any impact to the Electrophysiology business in Europe where Farapulse and Affera PFA catheters have launched? In accounts that have adopted PFA, what kind of share shift have you seen? With Medtronic's PulseSelect getting FDA approval earlier than expected in December 2023 and Boston Scientific's Farapulse timing moving up to Q1'24 from 2H24, do your expectations for your EP business change in 2024/2025? Expected EP growth of 9% in 2024, what is assumed for share loss within this and what portion of the business is exposed? Latest on ABT's PFA development timeline, was planning to start first in human trials in 2023, did that track as expected?

7. **Libre growth:** Libre expected to grow high teens in 2024, what are the different drivers of growth especially with pump integration coming and basal gaining momentum post CMS coverage in 2023. How are you thinking about the pump integration opportunity with Tandem and Insulet and where are you in those processes of integration and launch? Do you expect a quick uptake or more moderated since first AID offering? On basal, in October mentioned had added 150k new basal users in the prior 12 months with acceleration in the second half of those 12 months. How does that compare to the ramp in insulin intensive market following coverage? Looking forward do you expect acceleration to continue and ramp to be faster or in line with insulin intensive market?

8. **GLP-1s:** View on GLP-1s and potential impact to diabetes and cardio markets? Put out data on how GLP-1s and CGMs are complimentary, are there any other studies or data looking into to further support this? When you think about the longer term outlook for Libre and cardio markets, what do you assume for GLP-1 uptake, compliance, coverage etc.?

9. **Other sensor developments: Glucose-ketone sensor:** What is the latest on the glucose-ketone sensor - had targeted starting the US trial in Q4'23, is that on track? Have talked about the dual sensor being strong for a specific diabetes population but also strong for a non-diabetes population, so who do you see as most likely to adopt the dual sensor / what are the use cases in the different populations? **Lingo:** What seeing post the UK launch in July for glucose? And in the US had intended to file by 2023 year end, what's the latest timeline and expectations there?

10. **China VBP in diagnostics:** A VBP on diagnostics was announced, what areas are expected to be impacted, how long is it expected to take to implement, how do you quantify it, and what is impact to growth outlook in 2024/2025?

11. **Pillar 2:** What's assumed in guidance for potential pressure on taxes from Pillar 2. Is this more of a 2025 concern than 2024? Some medtech peers that have been calling out the pressure have quantified it as 100-200bps of a headwind, is this appropriate for ABT as week?

Exhibit 3: ABT catalysts table
ABT's key upcoming catalysts include TriClip US approval in 1H24E, Aveir CE Mark in 2H24E, CardioMEMS NCD in 2H24E.

Company	Device/ Catalyst	Timing	End Market
ABT			
ABT	Pump integration	Approval in Q1'23; integration with TNDM in US before 2023 year end and broad availability in early 2024, TNDM OUS integration and PODD US/OUS likely in 2024	Diabetes
ABT	Libre 2	Streaming capability US launch in 2024	Diabetes
ABT	Glucose/ketone sensor	Trial to start in Q4'23 as of July '23. 2025+ US approval	Diabetes
ABT	Basal reimbursement	CMS coverage of basal as of mid-April '23. CMS coverage of Libre 3 in August 2023 post reader approval. France coverage for basal patients for Libre in June 2023.	Diabetes
ABT	Lingo	UK controlled launch began in July 2023 for glucose, full launch in UK in 2024; Intend to file with US by 2023 year end. Potential US launch in 2024	Consumer biowearables
ABT	Libre 15-day	Rollout in 2H'23 in US	Diabetes
ABT	Aveir DR Leadless Pacemaker (Dual Chamber)	FDA approval in July 2023. CE Mark 2H24E	Cardiology
ABT	TactiFlex Ablation Catheter	FDA approval in May 2023	Cardiology
ABT	Assert-IQ ICM	FDA approval in May 2023	Cardiology
ABT	Navitor (next-gen TAVR system)	FDA approval in Jan 2023. Label expansion for low/intermediate risk a few years out	Structural Heart
ABT	CardioMems	CMS NCD 2H'24	Structural Heart
ABT	MitraClip Moderate Risk DMR	REPAIR MR trial estimated completion in 2026	Structural Heart
ABT	TriClip	Filed with the FDA in January 2023, CMS reviewing simultaneously. FDA panel likely in January 2024. US approval in 1H'24	Structural Heart
ABT	Tendyne	US approval 2025+	Structural Heart
ABT	Amulet	CATALYST Trial est completion in Dec 2024. Label expansion in 2025+	LAAC
ABT	ESPRIT BTK resorbable stent	US approval 2H24E	Peripheral Interventions
ABT	DCB Peripheral - Surmodics Partnership	US launch 1H'24	Peripheral Interventions
ABT	Eterna (rechargeable SCS)	Approved in Dec'22 for chronic pain and in May 2023 for non-surgical back pain	Neuromodulation
ABT	Painful Diabetic Peripheral Neuropathy (DPN)	Proclaim XR spinal cord stimulation approved for DPN in May 2023	Neuromodulation
ABT	Volt	As of May 2023 planned to start first in human trial in 2023. CE Mark / US approval 2025+	Electrophysiology
ABT	Laboratory traumatic brain injury blood test	Whole blood label expansion CE Mark / US Approval 2H24	Diagnostics
ABT	Test menu expansions - sexual health	CE Mark / US approval 2025+	Diagnostics

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Baxter (BAX)

1. **New CFO:** Mr. (Joel) Grade, you joined BAX in Oct 2023 from Sysco. What attracted you to BAX and what changes can we expect in the metrics that you focus on?

2. **Revenue in 2024:** You have guided for ~2% CC growth for 2023. On the Q3 call, you talked about stable top-line growth into 2024 and growth in all 3 businesses, ex Kidney Care, higher in 2024 vs 2023. The Street is modeling 2.6% y/y CC growth in 2024. What are the puts and takes to higher growth in 2024 … what gets better and what gets worse? Is 2.6% y/y CC growth for 2024 the right place to be?

3. **Hospital capex:** You noted a bit of softness in capital spending in the Q3. As of the Q3 call, you saw a relatively stable capex environment with continued expectations for hospitals to exercise some degree of caution and said that two of three group purchasing organization (GPO) contracts for 2025 were being negotiated. How did negotiations go? What is your current outlook on customer capital spending?

4. **China:** China is ~6% of BAX total sales, and ~70% of BAX's business in China is Renal. You have talked about your expectations for Kidney Care to decline y/y in 2024. Can you review the factors (region-specific or otherwise) that drive Kidney Care to decline y/y and the expected cadence of impact through 2024? Comment on how China (with VBP, anti-corruption, macro concerns) is trending?

5. **Infusion pump market:** On the Q3 call, you said really good demand for Spectrum with hardware growth in the mid-teens. You expected hardware sales for 2023 to be up >20%, and demand for 2024 to be pretty solid. A competitor recently announced a multiyear agreement with Mayo Clinic for its infusion pump. How to think about the infusion pump market in 2024 as some contracts come up for renewal?

6. **Novum:** You have said that you plan to submit two hardware fixes, identified in Canada, to the FDA by year-end. As of the Q3 call, you had submitted a package to the FDA and provided all information required. Any updates on pump approval?

7. **Spinoff (Vantive) 1:** On the Q3 call, you shared your perspective on GLP-1s incl. Novo's announcement in Oct on FLOW. You maintained expectations to spin off Kidney Care by July 2024 and noted continued pressure testing, incl. as a result of evolving market conditions. Has your sense of opportunity for a successful spinoff of Kidney Care changed since the Q3 call? Is July 2024 still the right timeframe?

8. **Spinoff (Vantive) 2:** Thinking back to the Baxalta spin, BAX transferred its 19.5% stake ($4.2b) to creditors to cancel debt, Baxalta levered up to send a cash dividend of roughly equal size ($4b) back to BAX, and Baxalta assumed $0 debt from BAX. How might the playbook for Kidney Care (Vantive) differ from Baxalta? How quickly would the portfolio changes allow BAX and get back to buying back shares/M&A?

9. **Margins in 2024:** On the Q3 call, you talked about easing supply chain constraints, partially offsetting cost increases with pricing, cost favorability as BAX sold through a lot of higher cost inventory in 1H23, and cost savings offsetting rising oil/diesel prices and beginning to outpace inflation beginning in Q4. Your latest expectations for inflation, pricing, cost-savings programs … margin expansion in 2024?

10. **Pricing:** On the Q3 call, you talked about there being pricing opportunities in a couple of your businesses; as well as pricing initiatives, new product launches, and price being a focus as contracts come up for negotiation. How have contract renewal conversations gone in terms of price? Talk about BAX's ability to take positive pricing actions across its portfolio in 2024 and beyond?

11. **Other P&L:** You have talked about $80m interest expense benefit in 2024 over 2023, and double-digit EPS growth in 2024. What are your expectations for FX and tax in 2024 … is FX still a slight headwind to EPS in 2024? The Street is modeling 21% tax for 2024, relatively flat vs guide for 20.5-21% tax for Q4'23 … how to think about the impact of Pillar Two, or any other tax considerations, on 2024?

Exhibit 4: BAX catalysts table
BAX key upcoming catalysts include the spinoff of the Kidney Care business (Vantive) in July 2024 and approval of Novum IQ which we anticipate sometime in 2024

Company	Device/ Catalyst	Timing	End Market
BAX			
BAX	Novum IQ	Resubmitted 510(k) to FDA April '23. Plan to submit 2 fixes identified in Canada to FDA by end of 2023. Expected launch timing not provided but we estimate sometime in 2024.	Infusion Pump
BAX	BPS Divestiture	Sep '23, divestiture completed	BPS
BAX	Kidney Care Spin	Spin expected to occur July 2024, contingent on stress-testing market conditions	Renal

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Becton Dickinson (BDX)

1. **Margin ramp in 2024:** Guiding to 50bps of margin improvement in FY2024 vs the 23.5% op margin in 2023. FQ1'24 is expected to be down 350bps y/y (Q1'23 op margin was 22.9%) driven by 1) almost all of the 200bps headwind for the year from inventory related FX dynamics happening in Q1 and 2) ~100% of the inventory reduction happening in Q1 which is another 200bps headwind for the year. FQ2'24

is expected to be flat y/y (FQ2'23 op margin was 22.7%) which suggests F2H'24 is up 200-250bps. FY2023 also saw a steep 2H margin ramp which ended up coming in a little short of the at least 100bps of expansion y/y guidance (FY2022 op margin was 22.6% and FY2023 op margin was 23.5%). What gives you confidence in hitting this margin ramp in FY2024?

2. **Flu in 2024:** Called out in FY23 the flu season spiked higher and earlier than what is currently expected for FY24. FQ1 organic growth is expected to under-index the full year by over 200bps (full year organic rev growth guide 5.25-6.25%). Did this guidance for FQ1 factor in this flu dynamic?

3. **$500m share repurchase:** In November 2023 executed accelerated share repurchase agreements to repurchase $500 million of common stock. Why decided to execute this now? Does this change how thinking about the full year eps guide of $12.70-$13.00?

4. **FY2024 guidance:** Organic revenue guidance set at 5.25-6.25%, high end above the historical 5.5%+ typically have talked about. Have some tailwinds to growth from the Alaris ramp (+50bps) and prior M&A deals (+50bps) and headwinds from decline in covid only testing (>25bps) and China (75bps). Talk through some of the puts and takes on the guide, what can push performance to the higher end/over achieve the guide?

5. **Alaris revenue ramp:** Received FDA approval in July 2023 for Alaris and said remediation of replacement devices in the field is first priority. Where are you at in the remediation process and have you started to focus more on new customers? If not, when do you expect to be more on the offensive side with Alaris? For organic revenue growth for the year expecting 2H to be above full-year guidance of 5.25-6.25% as Alaris revenues ramp over the course of the year. Also have said expected $200m in Alaris revenue in FY24 which includes $100m of medical necessity a year have been getting for past few years. Talk through the different puts and takes of what is assumed in this Alaris ramp? What factors could cause the ramp to be faster or slower than expected?

6. **Alaris margin ramp and impact on margin goals:** How does the Alaris ramp impact margins – is it initially dilutive to margins but as comes back and ramps back to historical revenue level ($400-$450m) will be accretive? Have talked about Alaris giving 80bps of margin that comes back over next couple of years, when do we see that come back? Have said tracking ahead of FY2025 margin goal of 25%, how does Alaris approval impact that goal?

7. **Pharm systems business and GLP1s:** Pharm systems achieved 13 consecutive qtrs of double-digit growth and seems like that is sustainable with GLP1s and other biologics. Also capacity has increased 6x or so in last few years. When you think about durability of that business how do you frame GLP1 vs other biologics? And your peers talk about the high value solutions in that business that carry 10x ASPs and higher margins, what percent of that pharm systems business is high value segment today and where can go over time?

8. **Pricing:** Pricing pre-covid had been a headwind to revenue growth but in FY22 saw price tailwind of 220bps and in FY23 tailwind of 380bps. How do you think about the sustainability of pricing tailwinds even if inflation moderates? How much is structural vs translational since seems you've also been getting price from increased value of new products to market?

9. **Pillar 2:** How thinking about the Pillar 2 Global Minimum Tax headwind and any impact to FY24?

10. **M&A:** Have talked about ability to execute against larger tuck-in size deals and would be interested in a chunkier tuck-in in the $2-4bn size range. Are there any areas of focus in the business where would look to fill a gap through M&A?

Boston Scientific (BSX)

1. **Long range plan:** 2024-2026 LRP set at 8-10% with faster growth in 2025 than 2024. Should we think of that as a range that can be achieved every year or can some years be outside of that? Historically set a LRP range of 6-8%, is the 200bps acceleration to 8-10% a result of new products?

2. **2024 growth drivers:** Been experiencing higher growth than what saw pre-covid in recent years, how much of that is catch up from covid or markets now growing at a higher rate? Any areas you see moderating in growth or being able to sustain higher level? Have new products launching in 2024 but more back half weighted approvals and launches, how do you think about the contribution to growth in 2024 from those?

3. **Margin improvement:** What are the puts and takes on gross margin heading into 2024? Had talked about $375m macro headwinds on gross margin in 2022 and 2023 from freight, labor, materials etc, how does it compare in 2024? Longer term how does mix play a role in margin improvement as new products are launched? Set goal of 150bps op margin improvement over the 2024-2026 LRP from 2023 expected 26.4% op margin. How should we think about the 150bps being spread over the LRP, not necessarily 50bps a year?

4. **Watchman competition:** Saw two medtech names make acquisitions in the LAA space in 2H'23 (Medtronic acquisition of Penditure and JNJ acquisition of Laminar). How do you view competition entering the space and implications for market growth and Watchman share? How do you maintain your competitive position and further build a moat around the Watchman business in terms of product innovation and clinical data generation?

5. **Farapulse timing in US and ramp:** Now expect Farapulse approval in Q1'24 vs previous 2H24 expectation. What was the reason for moving up the expectation and what is the expected launch timing and process post approval? Since expected approval timing is earlier, will you still be able to have the supply constraint issue sorted before then? Does PulseSelect being first to market in the US change your view of being able to have a leadership position in the PFA market? What is the latest update on the roll out through Europe of the new supply from Minnesota?

6. **Accurate TAVR valve:** Expect to get approval for Acurate in Q4'24. What is your view of the TAVR market growth and penetration? Where do you see Accurate fitting in to the current market landscape and what kind of share do you think you'll be able to achieve? If BSX is able to increase its WW TAVR share by 5pts in 2025, this could add ~2pts of growth to total BSX – is this right way to think about the growth potential? How do you expect the launch in the US to compare to experience in Europe where product is available?

7. **Agent DCB:** Have the potential to be first and only coronary DCB in the US with expected approval in mid-2024. How do you think of this market opportunity in terms of current size and ability to expand the market? Why is this an attractive option for doctors over the existing methods of stents or plain old balloon angioplasty (POBA)? Can we think about this being a price uplift to stents and POBA?

8. **Tax:** What are you assuming for Pillar 2 tax in 2024 – does Europe go through but not other countries? When other countries implement will you give total impact for 2024 / 2025?

9. **M&A:** Have a long history of tuck-ins as the main focus of M&A activity. How do you identify which areas of medtech you want to invest in? Is there more focus in cardiovascular vs medsurg? Would you ever look to a medium or larger sized deal? What would be the criteria for looking at something like that? How thinking about continued M&A activity given FCF goals set at the Analyst Day in 2023?

10. **FCF:** At Analyst Day in 2023, set a goal of ~70% FCF conversion by 2026. What are the drivers of being able to reach this target?

Exhibit 5: BSX catalysts table
BSX's key upcoming catalysts include Farapulse US approval in 2H'24, Agent DCB US approval mid-2024, Acurate TAVR valve US approval Q4'24.

Company	Device/ Catalyst	Timing	End Market
BSX			
BSX	Watchman FLX Trial Data	OPTION trial data in early 2025; CHAMPION-AF data in 1H 2026	LAAC
BSX	Watchman TruSteer Access System	2024E	LAAC
BSX	Watchman FLX Pro	Approved in Sept 2023. Full launch early in 2024	LAAC
BSX	Acurate (all risk indications and sizes) TAVR valve	US approval in Q4'24E. EU full access & expansion in 1H'25. Japan approval in 2025	Structural Heart
BSX	Farapulse (Pulsed Field Ablation)	As of Oct 26, Farapulse filed with FDA. US approval expected in Q1'24	Electrophysiology
BSX	FARAWAVE Nav & FARAVIEW	US 2024E year end	Electrophysiology
BSX	Farapoint	Part of second phase of ADVANTAGE trial, expect to complete enrollment in Q1'24. US 2025E	Electrophysiology
BSX	AVANT GUARD trial (Persistent AF, front line therapy)	Starting trial in 1H'24	Electrophysiology
BSX	POLARx (Cryo Single Shot)	FDA approval in August 2023	Electrophysiology
BSX	Wolf Thrombectomy	Completing early access as of Sept 2023 for DVT. May choose to release products in 2024. TBD on PE.	Vascular Thrombectomy
BSX	Agent DCB	2H24E US expected launch. 2025E expected launch in China	Cardiology
BSX	Next gen LUX Dx	Approved in 2023	Cardiology
BSX	BodyGuardian UL	2024E expected approval	Cardiology
BSX	Leadless Pacer Empower / Modular CRM	MODULAR ATP trial results in 2024. US launch 2025E	Cardiology
BSX	LUX HF	2024+	Cardiology
BSX	Next Gen CRM Platform	Submit the first family of these devices from the platform to regulators in 2025	Cardiology
BSX	Embold	Launched in early 2023. Line extensions to launch in 2024 globally	Peripheral Interventions
BSX	Obsidio	US launch in 2023. Global launch expected in 2024+	Peripheral Interventions

Source: Company materials, BofA Global Research

BofA GLOBAL RESEARCH

Cooper Companies (COO)

1. **Fiscal Q1:** On the Q4 call, you said that short-term manufacturing supply issues on MyDay might limit growth in fiscal Q1. The Street is around 6% organic growth in Q1 which is much lower than the comment "not double-digit". Have those manufacturing issues gone as you had expected? Do the supply constraints pose a threat to current street Q1 numbers?

2. **2024 revenue growth guide:** The initial fiscal 2024 organic revenue growth guide was 6-8%, the same as last year's initial guide despite some indication that the fundamentals were strong enough to support a higher initial guide. What were the factors that kept you from starting with a higher initial revenue growth guide? In each of the last two years you exceeded the high end of the initial guide by 200-300bps. Is that how we should be thinking about growth in fiscal 2014 if everything hits? Or are there specific concerns whether macro or specific businesses that kept you from a higher guide?

3. **2024 EPS guide (1)**. The initial EPS guide of $13.60-14.00 assumes only 8% y/y which seems conservative given that you expect double digit operating income growth. What are the key headwinds to EPS? Fx, interest expense, tax? Where could there be upside to the headwinds?

4. **2024 EPS guide (2) – Fx impact.** The 2024 EPS guidance includes about a $0.65 or 5% headwind from Fx which seems conservative given the recent weakening of the USD since COO reported in early December. What is the Fx headwind today based on current rates? If you benefit from Fx, still committed to letting any Fx benefit fall through to the bottom line? Are there any circumstances when you would not let that benefit fall through?

5. **Contact lens market demand:** Comment on the current state of supply and demand in the contact lens market. What is COO doing to expand capacity to meet demand? How much capacity needs to be added? How quickly can it be added? Can COO do it better than others in industry?

6. **Fertility:** The fertility business is now a $480m business and 13% of overall COO. It has grown double digits for 12 straight quarters, contributing 100-150bps to overall growth. Given favorable market dynamics, is double digit growth sustainable? Is the overall fertility market growing double digits? Are you expanding the market or taking share?

7. **Debt paydown.** At the end of you fiscal 2023, you had ~$2.5bn in debt. How should we think about debt paydown in 2024? Is any debt paydown contemplated in interest expense guidance?

8. **Economic slowdown:** If there were to be a recession, what impact would that have on the contact lens industry? The contact lens market has traditionally been recession resistant, so growth may not drop dramatically, but is there a scenario where the market slows by a couple of pct points?

9. **Capex spend**: Capex spend was $393m in 2023 and it is expected to be at a similar level in 2024. Where is that investment going? Manufacturing? When do you start to see benefits from the investment? Will there be moderation of capex in 2025?

10. **Pillar 2:** COO tax rate has been ~13% for the last two years. You expect 15% tax in fiscal 2024 before discrete items. Does your 2024 tax rate assumption include any impact from Pillar 2? Do you expect your tax rate to increase once Pillar 2 is fully implemented by all countries?

Edwards Lifesciences (EW)

1. **2024 cadence and 2025 acceleration:** How should we think about the 8-10% 2024 TAVR growth through the year, Street is modeling 7.3% TAVR growth in Q1, is that the right spot to be given the 11% comp in Q1'23? Does TAVR growth start to get into full year guide range of 8-10% by Q2 or 2H'24? Expect TAVR growth of 8-10% in 2024 to accelerate to 10%+ in 2025. What are the drivers of this acceleration? What's assumed for TAVR market growth and market share given new entrants in the market by then and potential indication label expansion. What's assumed for new products in TMTT like Evoque and Sapien?

2. **Critical care spin-off:** Why evaluating the spin now? How should we think about the margin profile of the business and what that may mean for Edwards RemainCo? Is 20% operating margin for critical care in the right ballpark, similar to when Edwards was pre-TAVR? What is the outlook for Critical Care as a separate entity?

3. **TAVR market growth outlook:** Seen high growth in the TAVR market historically as the market switched from SAVR to TAVR. Now that a lot of those patients have been captured, how are new patients being identified and moved through the funnel for TAVR treatment?

4. **Capital allocation:** In 2023 will have about $1bn in cash flow – what are the priorities for capital allocation. At analyst day talked about the 10%+ growth including contributions from valvular and additional structural heart initiatives.

Edwards has 2 or 3 external options in heart failure in the near term. Where do those fall in priorities for capital allocation and how do we think about them in terms of contributing to the 10%+ growth longer term?

5. **EARLY TAVR for asymptomatic AS:** Will be presenting data at TCT in 2024. What are expectations for the trial data / what do you think it needs to show to get approval for label expansion in asymptomatic? How think about the asymptomatic patient opportunity? How think about the potential impact on TAVR market growth and the mix of TAVR procedures being done over time? Would you expect adoption to be similar to what we've seen historically or slower if will still take time to identify patients and bring them through the funnel?

6. **PROGRESS for moderate AS:** Trial enrolled quicker than expected, 2 years earlier. How was this achieved – was enrolling patients easier than expected, was there a change to the trial design or criteria? Does this put data from the trial in the 2026 timeframe? How do you think about moderate AS contribution in the $10bn TAVR market size in 2028?

7. **Competition:** How think about competition between your valve which is balloon expandable vs others are self-expanding? What has feedback been from physicians/what is seen in clinical data on if there is a valve type that is easier to use or more durable? Another self-expanding valve, Boston Scientific's Acurate Prime, expected to be approved in the US end of 2024. How thinking about the entrant of another name given it's a self-expanding valve?

8. **Longer term TAVR data:** Seen 5-yr data from PARTNER 3 and 4-yr data from Medtronic's Evolut low risk trial. How are using this data in the field and what seeing from Medtronic in their marketing of the data? How do physicians use this data to make decisions on which valve to use for patients? Are you seeing any changes in practice as a result?

9. **TMTT $5bn target by 2028:** At analyst day in 2023 didn't reiterate the previous $5bn market size for TMTT by 2028. What was the reason for this? Do you think it is still achievable to reach this market size and timing is pushed out by a year or 2 or has there been a change in confidence of getting to this market size in near term?

10. **TMTT inflection point:** At analyst day talked about being at an inflection point in TMTT with PASCAL global expansion, launching tricuspid replacement with Evoque, and launching SAPIEN M3 in 2025 for mitral replacement. How do you think about the replacement vs repair opportunity in mitral and tricuspid? Which opportunity are you most excited about? How should we think about contribution to growth potential and is there anyway you quantify the inflection point?

Exhibit 6: EW catalysts table

EW's key upcoming catalysts include EARLY TAVR data for asymptomatic AS at TCT 2024, Evoque tricuspid US approval expected mid-2024, and PROGRESS trial for moderate AS completing enrollment in early 2024.

Company	Device/ Catalyst	Timing	End Market
EW			
EW	Sapien X4	ALLIANCE enrollment restart in Q3'23. Continuing enrollment in 2024. Likely launch in 2025+	Structural Heart
EW	Sapien 3 Ultra Resilia	Japan launch in Q2'23. CE Mark expected in early 2024.	Structural Heart
EW	Asymptomatic	EARLY TAVR trial data expected to be presented at TCT in 2024	Structural Heart
EW	Moderate AS	PROGRESS trial data expected to complete enrollment early 2024. 2yr follow up, data in 2026 (our estimate)	Structural Heart
EW	US Pascal Precision Degenerative MR	Full CLASP IID Cohort Data at TCT in October 2023	Structural Heart
EW	US Pascal Precision Functional MR	Enrolling CLASP IIF pivotal trial through 2023	Structural Heart

Exhibit 6: EW catalysts table
EW's key upcoming catalysts include EARLY TAVR data for asymptomatic AS at TCT 2024, Evoque tricuspid US approval expected mid-2024, and PROGRESS trial for moderate AS completing enrollment in early 2024.

Company	Device/ Catalyst	Timing	End Market
EW	Sapien M3	ENCIRCLE trial enrollment completed in Oct '23. CE Mark expected by end of 2025. US approval to follow	Structural Heart
EW	Evoque Eos	Completed enrollment in MISCEND early feasibility study in early 2023	Structural Heart
EW	Pascal Precision for tricuspid	CLASP II TR 2024 year-end expected completion	Structural Heart
EW	Evoque Tricuspid	Europe commercialization in 2024. Expect US approval mid-2024. TRISCEND II full cohort data presentation at TCT 2024. 56m valve launch in 2025	Structural Heart
EW	MITRIS RESILIA valve.	Global commercialization in 2024	Structural Heart
EW	Critical care spin-off	Intends to complete tax-free spin-off at end of 2024. Mid-2024 SEC Form 10 submission	Critical Care

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

GE Healthcare (GEHC)

1. **Revenue in 2024:** Street is expecting revenue growth of 4.5% in 2024. Order growth was 1% in Q3. In Q4 the comp is tougher (called out China stimulus in 2022). If order growth is again LSD in Q4, how should we think about the ability to hit MSD revenue growth?

2. **China – anticorruption**: Have there been any new developments with the anti-corruption campaign in China? Why have you only seen a limited impact when other competitors have seen a significant impact on orders and revenue? Is the impact from anti-corruption in Q4 still expected to be similar to Q3?

3. **China – tough comp in Q4/Q1 & macro trends:** China is 15% of GEHC sales. On Q3 call you said that the stimulus in China at the end of 2022, creates a tough China comp for you in Q4 and Q1. How should we think about the impact of the tougher comp on overall order and/or revenue growth? Comment on how macro environment trends that could impact orders/revenue in 2024?

4. **Hospital capital equipment environment:** Comments from the Q3 call suggest a stable hospital capex environment globally. Have there been any changes in trends at the end of the year that would change your view for a stable environment in 2024?

5. **Margin expansion (1):** Are you still tracking to your medium-term margin growth targets to expand EBIT margin to the high-teens to 20% over the medium term? The Street is modeling similar margin expansion of 70bps in 2024 and 2025. Should we expect linear margin expansion, or will it be weighted more towards later years?

6. **Margin expansion (2):** What areas of the P&L do you expect to see the most savings – COGS, selling, G&A? Exiting the TSAs are a key driver of cost savings. Are you still on track to exit the bigger ones in 2024? And should we expect accelerating EBIT margin expansion in 2025 vs 2024 because of the TSAs?

7. **Pricing**: Are you on track to get the 2-3% pricing you expected? Much of that pricing was baked into orders already – what level of price have you seen in the most recent orders? What gives you the confidence that you can maintain 1-2% of positive price going forward when the industry has traditionally seen negative price?

8. **Artificial Intelligence:** GEHC has announced a number of deals/acquisitions focused on AI and digital. In addition, GEHC has also announced partnerships with hospitals focused on AI & digital. Talk about what GEHC is doing in AI/digital with its EDISON platform. How does GEHC win in AI/digital? What parts of your business stand to benefit the most from AI? Are you better positioned in certain businesses more than others? How can you monetize it? You mentioned that it could add 3-5 pct pts of margin expansion to a product – how should we think about the percentage of products that could see that 3-5 pct pt margin benefit?

9. **Capital allocation/M&A:** You have talked both about desire to pay down but also add technology via licensing or M&A. How do you prioritize these? Should we expect smaller tuck-in types deals or would you be open to a larger acquisition?

Intuitive Surgical (ISRG)

1. **2024 procedure growth:** Initial procedure growth guide has been low double digits to mid-teens (in 2022 was 11-15% and 12-16% in 2023). When looking historically you usually finish the year 2-4 points higher than the high-end of the initial guide. Is this the right way to think about setting an initial guide for the year that's more conservative and where potential upside may end up? What are the puts and takes on procedure growth in 2024? In 2023 saw a number of headwinds (China anti-corruption campaign, bariatrics growth moderating from GLP-1s) and tailwinds ("catch-up" in Q1), how do you see these playing out in 2024?

2. **New system potential ramp:** When thinking about a new robot launch today vs historical launches, we are thinking a new robot launch would be different than historical when didn't have leases and today 25% of the installed base is leased. Would having this base of 2k leased systems help the ramp of the new system move faster? We estimate many of the leased systems could upgrade in 1-2 yrs so the ramp would be 3-4x faster than historically. How should we think about the value of a new system and those lease payments and impact to revenue? Also have the systems that are not leased, which we estimate there are 4,245 non-leased systems that are 7+ yrs old and ripe for trade-ins. Historically during a product cycle annual trade-ins go to 8% of the installed base vs 4% during non-product cycle years. Would you expect the same increased rated of trade-ins during the next product cycle?

3. **Gross margin in 2024:** Have talked about getting back to 70%+ gross margins over the medium term of 3-5yrs but there could be some variability in margin over that time. What factors are influencing gross margin in 2024 that would cause variability back to that level and are there enough positive offsets to the headwinds where could see gross margin expansion y/y or would it be pressured to down y/y?

4. **Utilization:** Utilization broadly coming in higher than historically has been the last couple of quarters and was 9% in Q2'23 and 6% in Q3'23. Historically, it's been a 5% CAGR. Could you give a little color on what's driving that higher utilization, and how sustainable are some of these above normal utilization trends?

5. **Appendectomy opportunity:** In May 2023 received FDA approval for robotic appendectomy on X and Xi which we estimate is a 300k+ procedure opportunity. How do you think about uptake of robotics in this procedure category given it has historically been predominantly laparoscopic? Do you see potential for appendectomy to be like hernia and chole where there's been more of a push to switch to robotics? What has been driving conversion in these procedure categories and does that apply to appendectomy as well?

6. **Impact of GLP-1s:** Saw bariatrics growth moderate in 2023 as patients evaluated GLP-1s but expect will find a new normal in the next few qtrs. as of the Q3 eps call. The rate of deceleration from Q2 to Q3 was slower than it was from Q1 to Q2 - in Q2 US bariatrics slowed to roughly 19% growth and in Q3 US bariatrics still grew double digits. Any updates on what seeing with bariatric surgery and if you still think new normal will be found in next few qtrs. and at what rate that will be? Also SELECT data came out in November 2023 and showed gallbladder disorders are a side effect of GLP-1s (1.2x higher rate). How can we think about the opportunity here given your cholecystectomy procedures are 2x bariatric?

7. **Indication expansion opportunities:** In November 2023 there were positive cost data published on robotic CABG (coronary artery bypass graft). ISRG has also done a lot of work on breast mastectomies. We also estimate Ion to be a $7bn opportunity that is still in early innings. How thinking about these different opportunities and any others you would call out that you're doing work on or plan to near term?

8. **Smoke evacuation:** How do you think about adding value and capabilities to the existing ecosystem in terms of instruments & accessories? Is smoke evacuation an area where you see market value?

9. **Pillar Two:** How are you thinking about timing and implications of the Pillar Two Global Minimum Tax? Have a larger portion of your business in the US than some other medtech names so do you think you would be more insulated than others that are expecting a 100-200bps tax increase?

10. **China:** What is the latest on the anti-corruption campaign and the effects of it? New China quota came out in June 2023 for 559 systems which is double the prior quota. How are you thinking about the latest quota and share potential?

Exhibit 7: ISRG catalysts table
ISRG's key upcoming catalysts include smoke evacuation partnership with Novanta and potential new system in 2024 or 2025.

Company	Device/ Catalyst	Timing	End Market
ISRG			
ISRG	SP Expanded Indications	Completed IDE in US for thoracic and colorectal, as of Sept'23 not yet submitted in US.	General Surgery (Robotics)
ISRG	SP Expanded geographies	SP submitted in Europe. Japan clearance in 2023.	General Surgery (Robotics)
ISRG	Da Vinci expanded indications	FDA approval for appendectomy in May 2023	General Surgery (Robotics)
ISRG	Ion	First ion installs in UK and first cases in Q2'23	General Surgery (Robotics)
ISRG	New system	Late 2024?	General Surgery (Robotics)
ISRG	Novanta smoke evacuation	Novanta second-generation smoke evacuation platform launch in 2H24. Novanta quote on Q323 EPS call: "We continue to see active engagement and urgency with our customers to ensure their new product launches are a success. As a result, we're seeing a broad new product super-cycle entering late in 2024 and in 2025 and beyond, with key drivers including smoke evacuation insufflation, robotic surgery..."	General Surgery (Robotics)

Source: Company materials, BofA Global Research

BofA GLOBAL RESEARCH

Medtronic (MDT)

1. **FY2025 puts and takes:** Have talked about FX being a headwind in FY25 but that it's dynamic. Tax is also an incremental headwind in FY25 vs FY24 from Pillar Two. Inflation is stabilizing but also still a headwind. On the positive side have talked about feeling good about product launches, pricing, and plans in place to drive improvement in global operations and supply chain but still in early to mid-innings there. So how should we think about all of these different puts and takes? On FY25 EPS we assume 600-700bps of incremental headwinds (-200bps tax, -200-300bps FX, and –200bps inflation). But we also see 500-600bps of offsets mostly coming from gross margin productivity with some help on SG&A leverage. Net/net it's a slight headwind suggesting EPS likely grows somewhere in line with revenue growth. Is that the right way to think about it?

2. **PulseSelect and PFA outlook:** Received FDA approval for PulseSelect, first PFA catheter approved in US, in December 2023 and expect to start commercialization in early 2024. Have said expect PFA to first pressure cryo but that the opportunity in focal to more than offset pressure in cryo single shot. Do you expect the launch of PulseSelect to mostly cannibalize the cryo business initially and you need Affera to really drive growth? What have you been seeing in Europe where have Farapulse,

PulseSelect as of November 2023, and Affera in terms of PFA adoption and if that's coming from cryo or RF or both? Estimate that Affera timing in US is 2H'24 if the trial was finishing patient follow up at the end of December 2023?

3. **Patient monitoring & respiratory interventions (PMRI) separation:** Have said expect the separation to complete in 1H'FY25 and that a spin sets a high bar and will be the likely way the businesses will separate. Is this still how thinking about the separation? How thinking about the potential dilution from the separation and ways to offset or partially offset that through share buyback for example?

4. **Patch pump:** Recently announced termination of agreement to acquire EOFlow, which would have allowed you to have a patch pump offering in the market in the not too distant future. So now what is the latest timeline expectation for your internal patch pump development?

5. **Diabetes outlook:** Expect growth for diabetes to be above Medtronic average in FY25. What is assumed in this growth expectation and how much above is possible? On the pump side, how much growth is coming from upgrade of existing customer base vs new customers. On the CGM side, have also mentioned better attachment rates from the Guardian 4 Sensor. Any way to think about how much better attachment rates are now and potential once Simplera is available with the 780G pump? Given the recurring revenue associated with the sensor how much visibility do you have into the diabetes growth outlook for FY25?

6. **Hugo:** Started the urology US IDE trial in Dec 2022 and haven't provided much of an update. Is the trial tracking in line or behind expectations? Is US approval in 1H 2024 possible? In FQ2'24 received FDA approval to move forward with an IDE for hernia, is it reasonable to expect that would move at a similar pace as the urology trial so far? How has Europe uptake been? What is the high-level strategy for Hugo in terms of which markets and indications you're pursuing?

7. **TAVR data and competition:** In 2023 put out new TAVR data including 4-yr Evolut low risk trial data which showed continued favorable outcomes for Evolut vs SAVR at four years for the primary endpoint of all-cause mortality or disabling stroke and 10-yr NOTION trial data which showed good durability out to 10-years for the first-gen CoreValve. How do you plan to use this data in 2024 and how big of a driver can it be in gaining more share and/or expanding the market. What is your view of the market and your share position with another player expected to receive US approval in Q4'2024 that is also a self-expanding valve such as Evolut?

8. **R&D:** How think about prioritizing investment to drive top line vs margin expansion? Historically when looking at the combined R&D investment from pure play medtech names in key markets such as diabetes, stimulation, structural heart and robotics, Medtronic has under-invested relatively in R&D. R&D has been around 8% of sales, do you think this is the right place to be or should it be higher? What are areas of prioritization for R&D investment?

9. **Margin opportunity:** Talk about steps have taken and programs put in place around supply chain to make it more resilient and identify cost savings? Have started to see COGS productivity 2-3x better than historically but it has been masked by inflation. When does this start to show up in the P&L and when could you get back to high 60% gross margin?

10. **Artificial intelligence:** Currently use AI in GI Genius for colonoscopies, in LINQ for atrial fibrillation, and in surgical spine and surgery. How do you think about artificial intelligence becoming a bigger part of the business and integrated into additional business units? Where else could it go and what is the significance of the opportunity?

Exhibit 8: MDT catalysts table
MDT's key upcoming catalysts include PulseSelect commercialization in early 2024 in the US, potential Affera approval in the US in 2H'24, Aurora EV-ICD full launch in 2024, possible RDN coverage decisions in 2024, and Hugo progress with the approval in FQ2'24 to move forward with an IDE for hernia indication.

Company	Device/ Catalyst	Timing	End Market
MDT			
MDT	PulseSelect	CE Mark in Nov 2023 and will be commercially available early in 2024. US approval Dec 2023, commercialization early 2024.	Electrophysiology
MDT	Sphere-9 Mapping and Ablation Catheter (Pulse Field Ablation)	CE Mark in March 2023 and in LMR. US pivotal trial 12-mo follow up to be completed end of '23 and FDA submission will follow. Potential US approval in 2024.	Electrophysiology
MDT	Evolut FX	CE Mark in Nov 2023	Structural Heart
MDT	Aurora EV-ICD	CE Mark in Feb 2023. FDA approval in October 2023 followed by limited launch. Full launch in 2024E	Cardiology
MDT	Micra AV2 and VR2	FDA approval in May 2023	Cardiology
MDT	Micra AR (sinus node disfunction)	FY2024+	Cardiology
MDT	Symplicity Spyral Renal Denervation	FDA approval and immediate commercialization in Nov'23	Cardiology
MDT	Percept PC & RC with adaptive therapy (closed loop)	FY24+ Launch	Neuroscience
MDT	Inceptiv ECAPS	CE Mark approval in FQ1'24 (Aug 2023), with availability in the following months. Submitted for FDA approval	Neuroscience
MDT	SCS Expanded Indication	Upper limb and neck CY2024?	Neuroscience
MDT	Hugo	Activated new sites for Expand URO U.S. pivotal trial, progressing to plan as of Sept 2023. In FQ2 received FDA approval to move forward with an IDE for Hernia indication	General Surgery (Robotics)
MDT	780G	US approval in April 2023, started shipping in June 2023	Diabetes
MDT	Simplera (standalone)	CE Mark approval, first commercial patients started in October with expanded rollout in FY2H'24	Diabetes
MDT	780G + Simplera	Filed for CE Mark; Fully enrolled U.S. pivotal (ages 7-80) with final study completion expected in FY24Q4; followed by 780G+Simplera FDA submission expected in H1 CY24	Diabetes
MDT	InPen + Simplera	As of June 2023 under FDA/CE Mark review	Diabetes
MDT	8-Series Pump ACHL + Next Gen CGM	In development as of June 2023	Diabetes
MDT	Patch Pump + Next Gen CGM	FY2024+	Diabetes
MDT	Extended infusion set	Global rollout of 7-day wear continues as of Sept 2023	Diabetes
MDT	PM/RI Separation	1H FY25	Corporate

Source: Company materials, BofA Global Research

BofA GLOBAL RESEARCH

Teleflex (TFX)

1. **Revenue in 2024:** The Street is modeling 4% revenue growth in 2024 which is a meaningful deceleration compared to the 6.4-6.6% guidance for 2023 You talked about a 50bps headwind to growth from the $70m of MSA rolling off and $55+m of Palette contribution. Even factoring that 50bps headwind, the Street's growth seems like a meaningful step down. Is the Street factoring all the puts and takes for 2024 revenue correctly?

2. **2024 EPS:** The Street 2024 EPS came down following the Q3 call and is now down to $13.87 which ~4% y/y growth but implies ~10% growth backing out the headwinds - Palette ($0.35), MSA roll off ($0.25) and higher tax rate ($0.30). You said that you can still grow EPS in 2024, so is the Street number now in the right ballpark?

3. **Urolift:** The Street is expecting ~$40m of incremental revenue for Interventional Urology in 2024. If we assume ~$50m of inorganic revenue from Palette which implies LSD declines for UroLift. If we assume Japan/China contribute some revenue, implied US UroLift is down MSD. Is that right way to think about US UroLift growth? Can it return to growth in 2024?

4. **Inflation / supply chain:** You're expecting inflation of $60m in 2023, the same amount as 2022 and above the normal $20m. How should we think about inflation in 2024? What do you expect to get better or worse?

5. **Pricing:** What pricing did you get in 2023? How confident are you that you can get at least 50 bps of price in 2024? Do you think you can sustain positive price for next several years? At 50bps level?

6. **Revenue LRP of 6%:** Your revenue LRP is 6% which implies ~$3.32bn in revenue in 2025 which is 7% y/y growth over 2024. How should we think about the growth drivers that will drive that level of growth in 2025?

7. **Segment growth:** In 2023, the segments have a wide range of growth – Interventional (up mid-teens), Anesthesia (down LSD), Interventional Urology (down LSD), OEM (up high teens), Surgical (up DD), vascular access (up LSD). How should we think about the growth trajectory of these businesses in 2024 and beyond?

8. **M&A:** Talk about your appetite for M&A. The Standard Bariatrics ($0.10-0.15) and Palette ($0.35) acquisitions were both dilutive to EPS in first full year. Has your appetite to do dilutive M&A deals changed? Do you still see a valuation gap between buyers and sellers? You're 2x levered and said you have lots of firepower – what is your maximum level or debt when you think about acquisitions?

9. **Palette/Standard bariatrics.** What gives you the confidence that Palette can grow high teens to low 20s? What would have to happen for Palette to grow at a higher rate? How dependent is the 20% growth on cross-selling to your UroLift urologists? How much of Standard Bariatrics guidance reduction was due to GLP-1 impact? How should we think about incremental growth contribution from Standard Bariatrics?

10. **Tax rate.** You are expecting a higher tax rate in 2024. The tax rate used in your LRP was 12%. Is that the right tax rate for 2024? Is the increased tax in 2024 vs 2023 only related to Pillar 2? What Pillar 2 assumptions are included in your tax rate? Does it only consider countries that have implemented Pillar 2? The 12% tax rate is still considerably lower than the global minimum tax of 15% - what is the risk that your take rate ends up moving closer to 15%?

Zimmer Biomet (ZBH)

1. **2024 MSD growth rate:** What is driving the elevated MSD growth rate vs historical levels and how sustainable is the MSD growth? How do you think about contribution from backlog? ZBH typically sets guidance it can beat and raise, still setting up for that and where are potential areas for upside?

2. **Gross margin in 2024:** Have noted that underlying gross margins will be flat y/y and reported will be down y/y (expecting 2023 gross margin higher than 2022 of 71%, Street modeling 72% in 2023). What are the moving parts assumed in this regarding portfolio mix, inflation, and fx?

3. **Operating margin in 2024:** What levers do you have to still reach OM expansion in 2024? Have said will expand margins but less than the 100bps of expansion getting in 2023. Street modeling 40bps of expansion (operating margin of 28.7%), is that the right way to think about it?

4. **M&A:** Have said capital allocation strategy is M&A-centric primarily. How think about willingness to do a dilutive deal? Is $300m revenue right deal size based on your balance sheet? What other criteria do you look for such as ROIC targets and growth in strategic areas? What are areas of strategic focus?

5. **Debt issuance:** Have $850m of 1.45% fixed debt maturing in 2024. On December 1, 2023, ZBH issued $500m of 5.35% fixed debt (2028 maturity). We assume, all else equal, this $500m at a 390bps higher rate is a $0.08 (or 1%) headwind on 2024 EPS that needs offsetting. How should we think about offsets to this headwind? We estimate if ZBH just pays down the $350m remaining, it could offset half of this $0.08. Is this the right way to think about it? What about interest income on cash as an offset?

6. **Pillar 2 tax:** Have said would see 150bps headwind to tax rate in 2024 (vs 2023 estimated tax rate of 16.5%). What's assumed in this headwind regarding Pillar 2 - is it just the EU countries that have adopted Pillar Two so far in 2024? If these countries delay the implementation until 2025 do you still expect a headwind?

7. **Rosa shoulder:** Seem confident will be the first to market with a shoulder robotic platform, have said sooner rather than later. Could we see something within the next 6 months? Will the robot be the same as what is being used today and interchangeable? How do you think about the shoulder opportunity and potential contribution to growth?

8. **GLP1s:** Have talked about working with some of the largest societies and running research with a third party. What kind of data is being gathered and what do you expect to show with the data? When can we see this data?

9. **Pricing:** Historically have had 200-300bps pricing erosion and in 2023 expecting it to be 100-200bps. Where do you think pricing can go in 2024 and beyond, is the better pricing than historical sustainable? How much of it is environmental vs structural?

10. **Change in WAMGR:** Talk about the change in ZBH WAMGR historically to expectations for the future. Have said 80% of new products are going to be in areas growing north of 4%. What areas are you focusing on for new product development and what is the WAMGR in these areas?

Exhibit 9: ZBH catalysts table
ZBH's key upcoming catalyst is launch of Rosa shoulder in 2024.

Company	Device/ Catalyst	Timing	End Market
ZBH			
ZBH	Persona IQ Smart Implant	Full Launch by YE23 or early 2024	Orthopedics
ZBH	Persona OsseoTi Keel Tibia	1Q23, limited launched; 2024 US full launch	Orthopedics
ZBH	Rosa shoulder	First company to launch shoulder robotic platform, sooner rather than later (as of Nov 2023)	Orthopedics
ZBH	Rosa expanded indication	Launching sometime in 2024 the posterior application for hip	Orthopedics
ZBH	Next-gen Rosa for knees	2024E (our estimate)	Orthopedics
ZBH	Hip Hammer	Expect to launch in 3Q23	Orthopedics
ZBH	Analyst day	2024	

Source: Company materials, BofA Global Research

BofA GLOBAL RESEARCH

Key questions/catalysts – SMID cap medtech

Axonics (AXNX)

1. **Revenue in 2024:** You achieved Consensus at $442m (22% y/y) for 2024. Your revenue has historically been ~45%/55% 1H/2H weighted. You have F15 launching in Australia and Europe in 2024, commercial availability of Radian mid-2024, and new external trialing system on the market by YE24. What are the puts /takes to 22% y/y growth? How to think about revenue ramp through 2024 vs history?

2. **SNM growth**: AXNX SNM grew 30% y/y in Q3, and we estimate the SNM market grew 10%. On the Q3 call, you talked about AXNX SNM revenue growth of 25% y/y in 2024. What are the puts and takes to 25%? What does 25% assume in terms of AXNX share gain vs SNM market growth, growth from new accounts vs same-store sales? How big is the SNM market today and what is the US /OUS split?

3. **Competition:** In 2H23, ITNS got CMS hospital outpatient coverage equal to SNM and BlueWInd got FDA approval. Since your Q3 call, MDT announced expectations to complete its ITNS FDA submission in 2024 and in Dec'23, Neuspera announced completion of implant procedures for its SNM pivotal trial to support a submission to the FDA. How do you envision the SNM market evolving in 2024 and beyond?

4. **Pricing**: You have said that you contract prices based on annual implant volume; you have said that AXNX maybe has 35% share of the US SNM market. ITNS recently got CMS hospital outpatient coverage equal to SNM; an ITNS developer (BlueWind) has talked about pricing at a premium to current market. How do you see AXNX's pricing /pricing strategy evolving with time?

5. **Radian technology:** On the Q3 call, you talked about getting the foramen finder tech you acquired from Radian in Apr'23 in the hands of docs for usability testing later in 2023. You have talked about the tech having potential to reduce procedure time and facilitate more accurate placement. How is usability testing going /what has initial feedback been? Is mid-2024 commercial launch still the right timing?

6. **MDT SNM patent dispute:** In Aug'23, on appeal, the Federal Circuit court held that the Patent Trial & Review Board (PTAB) need consider AXNX's arguments under the new /most recent claim construction. You said that you expect a response within 6mos of the ruling and litigation expense in 2024 should be relatively consistent vs 2023 ($6m-$7m). Has the PTAB responded? Is $6m-$7m still the right ballpark?

7. **Bulkamid 1:** In Mar'23, you said that ~1/2 of Bulkamid customers are doing SNM. Of those doing SNM, on the Q3 call, you said that ~1/2 of Bulkamid customers are doing SNM with AXNX (vs MDT SNM or Botox). Did we interpret that correctly? What % of total and new Bulkamid customers are doing SNM today? Where can the % of Bulkamid customers that are doing SNM with AXNX go with time?

8. **Bulkamid 2**: In Nov'23, you said Bulkamid can safely exit Q4'24 at $100m run rate. Your initial estimate for Bulkamid was $50m/yr. What gives you confidence in that $100m estimate? In Dec'23, CMS released 2024 DME rates, and reimbursement for the Bulkamid material (code L8606) increased by 3% at the midpt, down from a 9% increase in 2023. How did the 3% increase compare to your expectations?

9. **Profitability:** You have talked about mid-70s % GM at scale; Q3'23 GM was 74.2% and guidance is 74-75% GM for Q4'23. You recently talked about mid-teens EBITDA margin in 2024 and up to high teens in 2025. What are your latest thoughts on margin trajectory in 2024 and beyond? What are the levers /drivers? How should we think about opex cadence over the next couple of qtrs?

10. **M&A:** Most recently, you acquired tech from Radian in Apr'23. You have since said that AXNX is focused on incontinence and biased toward women's health, and you do not want to go into adjacent markets and pick up other products. You have said that you would consider tuck-ins and would not be afraid to pull the trigger on a bigger idea if it makes sense. What are your latest thoughts on M&A?

Exhibit 10: AXNX catalysts table

AXNX key upcoming catalysts are commercial launch of F15 in Australia and Europe in 2024 and launch of Radian technology mid-2024

Company	Device/ Catalyst	Timing	End Market
AXNX			
AXNX	F15 Non-rechargeable	Commercial launch in Australia and Europe in 2024	Stimulation
AXNX	Radian technology	Expect commercial availability in mid-2024	Stimulation

Exhibit 10: AXNX catalysts table
AXNX key upcoming catalysts are commercial launch of F15 in Australia and Europe in 2024 and launch of Radian technology mid-2024

Company	Device/ Catalyst	Timing	End Market
AXNX	Indication expansion	Expect a study in 2024 for chronic constipation	Stimulation
AXNX	External trialing system	File with FDA mid-2024; On market by end of 2024	Stimulation
AXNX	Implantable Tibial reimbursement (competitor)	July '23, tibial gained HOPD coverage equivalent to SNM	Stimulation
AXNX	MDT ITNS development (competitor)	Oct '23, TITAN 2 (tibial pivotal trial) completed primary (6mos) endpoint. MDT has submitted a couple of modules so far, but the final submission is likely a calendar 2024 event.	Stimulation
AXNX	Neuspera SNM development (competitor)	Apr '24, expect study completion per ct.gov	Stimulation
AXNX	BlueWind (competitor)	FDA approval in Aug 2023 for urge urinary incontinence. US launch 2024E	Stimulation
AXNX	Valencia (competitor)	FDA approval in Mar 2022 for urge urinary incontinence. US launch 2024E	Stimulation

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Bausch & Lomb (BLCO)

1. **BHC spin:** Is there any information you can provide on the timing of the spin? What is the likelihood that the spin happens in 2024? Are there any milestones or events that we should be looking for?

2. **2024 revenue**: The Street is expecting $4.5bn revenue in 2024 which implies 11% y/y growth. If we assume Xiidra adds $260m of non-organic revenue and use the $100m Fx headwind you provided on Q3 call, organic growth looks to be around 6% in 2024 which would be a deceleration from 2023. Is that the right way to think about growth? What growth headwinds may be causing the slowdown?

3. **2024/2025 Margins**: On Q3 call, you said that you were committed to margin improvement, but that you also wanted to make the right level of investment to grow the business. The Street is modeling EBITDA margin at 19.4% in 2024 which is 130 bps higher than 2023. Is this level of y/y improvement achievable given some of the headwinds (Fx, Lynchburg) and investments (miebo) you plan to make and the Xiidra benefit? The Street is currently modeling 100bps of margin improvement in 2025, slightly less than what is expected for 2024. Should we expect more expansion in 2025 given you'll lap some investment headwinds and pick up operating leverage?

4. **2024 EPS:** The Street is expecting flat y/y EPS growth in 2024 despite 150bps of margin improvement. What gets worse in 2024 compared to 2023 that negatively impacts EPS growth? Interest expense? Tax rate?

5. **Daily SiHy contact lenses:** Daily SiHy growth accelerated from 42% in Q2 to 79% in Q3? What drove that growth? What are your daily sihy sales? Growing faster than competitors – how are you winning business? How much of growth is cannibalizing existing users vs wining new starts? Are you seeing more success in certain countries or US regions? What is your confidence that you can continue to manufacture enough to meet end market demand?

6. **Xiidra:** Are Xiidra sales tracking to the $80-90m you guided to for Q4? Are Xiidra scripts still running below 2023 on monthly/weekly basis? Has there been a sequential improvement in scripts? What gives you confidence that Xiidra can grow MSD in 2H24 and beyond?

7. **Xiidra margin impact:** Guidance implies Xiidra EBITDA margin of 35% in Q4 2023. Should we assume that is a starting point and that as Xiidra sales grow EBITDA margin can move closer to 40%? Do you still expect to drop through the incremental benefit from Xiidra to the bottom line?

8. **Miebo:** Weekly scripts were strong for the first several weeks post launch. Have scripts continued to accelerate through the end of the year? How should we think about the Miebo sales ramp and can Miebo sales be over $50m in 2024? Is $350m

peak Miebo sales still the right way to think about the opportunity or have you learned something that would suggest a higher peak level?

9. **Pricing:** Can you give us a sense of what level of price increases you were able to implement in 2023 and on which products? What magnitude of price increases do you anticipate in 2024?

10. **China:** China was down 1% in Q3 on a tough y/y comp. What is a normalized level of growth we can expect from China going forward? Most of your China sales come from the Vision Care business. Which products are the key drivers in China? Do you have IOL sales in China? Have they been impacted by the IOL VBP?

Exhibit 11: BLCO catalyst table
BLCO has several key upcoming premium intra ocular lens (IOL) launches coming in 2024

Company	Device/ Catalyst	Timing	End Market
BLCO			
BLCO	SiHy daily disposable toric contact lens	2024	Ophthalmology
BLCO	enVista Envy (trifocal IOL)	US, EU, Canada launch in 2024 (submissions in process)	Ophthalmology
BLCO	enVista Aspire (extended range monofocal IOL)	US launch in process; Canada launch 4Q23 (submitted 1Q23); EU launch in 2024 (submitted 2Q23)	Ophthalmology
BLCO	enVista Beyond (extended depth of focus IOL)	Expect 2025/2026 launch	Ophthalmology

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Conmed (CNMD)

1. **Supply issues:** In Q3, you had supply constraints in legacy Ortho and your allograft tissue partner experienced disruption. You said that you expected supply to continue to improve, remediate in Q4'23, and be back to normal by the Q1'24; and that Q4 revenue and GM would be impacted. You expect <100bps of GM expansion in Q4 (from 100-150bps prior). How are supply issues resolving vs your expectations?

2. **Seasonality:** In Q1'23, you benefitted from 1 more selling day (1% tailwind), work-through of backlog from a warehouse issue, and recent acquisitions (6% tailwind); aside, you estimated that CNMD likely grew HSDs y/y in Q1'23. Given this, how to think about q/q seasonality in Q1'24 and through the year? How many more /fewer selling days will 2024 have vs 2023, and how do those days fall qtr to qtr?

3. **Revenue in 2024:** You had double-digit organic revenue growth in Q3 (with 2 fewer selling days). You said that, given healthy medtech markets, double-digit growth should continue for the foreseeable future. You also said that if you dipped down to 9% growth, you would not be disappointed. How are CNMD's markets trending? Can CNMD achieve double-digit revenue growth in 2024?

4. **Margins:** You have said that you are targeting 150bps of GM expansion in 2024 and GM approaching 60% by end of 2025. On the Q3 call, you reiterated commitment to that 60% level. You have said that the logic is, if costs stabilize, then higher growth and higher margin product mix should show through the P&L; and in Q3, you saw costs stabilizing. What are your latest thoughts on costs /mix /margins' trajectory?

5. **Competition:** Novanta has talked about integrating with a leading robotic surgery company for a smoke evac + insufflation technology, and Novanta expects rev ramp in 2024; you have said that a big clinical difference is that AirSeal performs smoke evac + insufflation simultaneously, constantly and delivers stable, low pressure; vs Novanta's product does not and delivers variable, high pressure. How do you see market evolving next 2-3 years?

6. **Pricing:** In March 2023, you said that pricing had not yet proven to be a challenge. You have also said, in 2020, that AirSeal had low-70s GM % and Buffalo Filter had GM % in the 60s. How has pricing trended over the last couple of years and what are your expectations for pricing in 2024 and beyond? Do AirSeal and Buffalo Filter still enjoy similar margins today?

7. **Hospital capex:** Capital equipment (smaller capital, priced $2.5k-$50k) represents about 17% of CNMD sales. On the Q3 call, you viewed the capital markets that you serve as pretty steady. What is your current outlook on customer capital spending?

8. **M&A:** You acquired Biorez and In2Bones in 2022 and are focused on debt paydown /getting leverage in the 3x's, which you have said you will do soon. You have said that you are more interested in platforms (vs single product lines), and call points that CNMD is an expert in; and that an asset growing from $10m to $20m, or $30m to $40m, would 'move the needle' for CNMD. Latest thoughts on M&A?

9. **Other P&L:** You have said that you were nervous about FX into 2023 and, as of the Q3 call, FX still looked to be a headwind for 2024 but not as bad as 12 months ago. Latest thoughts on FX into 2024? On the Q3 call, you said that you expect your tax rate to remain around 25% going forward. How to think about impact of Pillar 2?

10. **Medtech markets:** Other companies have talked about markets overcoming the staffing crisis now and ortho backlog continuing well into 2024. You too have talked about staffing levels continuing to improve and healthy underlying surgical markets. Your current view on staffing /backlog /market health? You have said that GLP-1s' hypothesized impact on medtech markets is overblown. Any change to that view?

Exhibit 12: CNMD catalysts table
CNMD key upcoming catalysts include Biorez data expected in late 2024 or in 1H25

Company	Device/ Catalyst	Timing	End Market
CNMD	Biorez Data	Late '24/1H25, expect data from RCT	Orthopedics

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Dexcom (DXCM)

1. **2024 guidance:** Could you outline assumptions and disclose more on Dexcom ONE / basal / intensive / non insulin etc? Seems like have more positive growth contributors from these newer areas, what would cause you to keep 15-20% guide vs baking in a little extra initially? What is the thought process on setting guide?

2. **Margins and opex leverage:** Q3'23 represented the 7th straight qtr DXCM has generated at least 250bps of y/y opex leverage. CEO Kevin Sayer talking a lot more about profitability and cash flow "Our ability to generate consistent and growing free cash flow has become more apparent every quarter, and we delivered the highest free cash flow quarter in our company's history in Q3." Does DXCM have an increased focus on free cash flow? How thinking about operating leverage in 2024? Guided to 31% EBITDA margins longer term, why can't it be higher?

3. **Medicare CGM pricing:** In December 2023 the Officer of Inspector General put out a notice that it is looking at Medicare payments for CGM and how they compare to acquisition costs. Talk us through the potential implications to your business - what the price reductions could be, what part of business is impacted (is it just Medicare which we estimate is 25% of the US patients/16% WW) and timing of when could be implemented. Do you think this would hit more of the distributor vs CGM? Would you expect offsets to lower pricing from increased adoption?

4. **Basal opportunity:** Could basal revenue be $200m in 2024? Talked about an exit rate of $150m for 2023 that could be higher in 2024. How has the basal ramp compared to expectations? At the Analyst Day laid out basal penetration today of 10% is expected to 25-30% in 2025. Do you see a linear ramp in penetration to get

there in 2025? Can share be roughly split even between Libre and DXCM? How have you been competing with ABT since they have had a head start in primary care offices? Is there a potential for CMS to move down to $4-5 pharmacy pricing vs the $6.50 it's at today with basal?

5. **Non-insulin sensor opportunity:** Launching a new sensor for non-insulin population summer 2024. This population of people represents 25m+ people. How do you plan on going after this market? What have you seen in the field regarding demand for a cgm in this population? What are your expectations for uptake once the new sensor is available? How should the Street think about modeling this opportunity in terms of ASP and utilization?

6. **Reimbursement for non-insulin product:** In Q3'23 Kevin said on reimbursement in this population "I don't think it's going to take five years. I think this is more of two to three-year journey, but you know what, that's the gospel according to me. I don't have anything else to base that on, but you'll see data continue to pile up in this segment particularly as we launch a cash-pay product to start and then get some basic reimbursement from that from others for making our case." What does reimbursement look like for this population? What kind of data will you focus on collecting to help build the case for reimbursement?

7. **15-day sensor impact on margins:** Talked about the non-insulin sensor coming in summer 2024 being a 15-day sensor. A 15-day sensor seems like could be a 1/3 reduction in cogs when considering the 1 less sensor per month and the associated shipping, warranty and freight costs. Why isn't this hugely expansive on gross margin line?

8. **Clinical data:** Have put out some clinical data to show how CGM is complimentary to GLP1, do you plan on putting out more data or running any studies on this? What other data do you think needs to be shown? What about additional data in other patient populations you're going after like in non-intensive to support reimbursement?

9. **Competition in pump integration:** How do you think the payer / patient / doctor conversations change when ABT is broadly available with pump connectivity? Is pricing / payer contracts at risk of changing if payers see them as equal (will they cover both CGMs or go exclusive?)

10. **OUS and Dexcom ONE:** With Dexcom ONE going after 19m population OUS does that total addressable market keep growing in 2024 or is it more about penetrating the countries you are in? How long does it take DXCM to catch up with ABT in terms of number of patients OUS? How have you been able to gain share in international markets? What is the expected mix in 3-5 years OUS of G series vs Dexcom ONE? What is the impact on margins between the two?

11. **Pregnancy and hospital opportunities:** Had the contra-indication in pregnancy removed with the G7 approval. How do you think about the size of this opportunity? When could this be a more significant opportunity and what is needed to get there? What are next steps taking from clinical trials and produce development perspectives that working on or toward? When do we learn more about hospital? When could hospital be a $100m business, 2 years or 5? What is the pricing potential in the hospital? Have talked about being more in line with hospital diagnostic test ASP maybe hundreds of dollars/sensor, is that right way should be thinking about it?

Exhibit 13: DXCM catalysts table
DXCM's key upcoming catalysts are the 15-day non insulin sensor in summer 2024 and continued adoption of cgm in basal with OUS expansion.

Company	Device/ Catalyst	Timing	End Market
DXCM			
DXCM	G7 OUS	Expand European geographies in 2023. APAC in 2024.	Diabetes

Exhibit 13: DXCM catalysts table
DXCM's key upcoming catalysts are the 15-day non insulin sensor in summer 2024 and continued adoption of cgm in basal with OUS expansion.

Company	Device/ Catalyst	Timing	End Market
DXCM	Pump integration	Integration with TNDM's tslim X2: US commercial launch in Dec 2023, OUS launches expected in early 2024. Integration with PODD's Omnipod 5: LMR in early 2024	Diabetes
DXCM	Basal reimbursement	US: CMS covering basal patients as of mid-April. OUS: Approval for everyone in Japan. France likely to approve for everyone in 2024. Other countries likely to follow including Germany, Nordics, and UK.	Diabetes
DXCM	DexcomOne	Rollout on G7 in Q1'24	Diabetes
DXCM	Non-insulin, not at risk for severe hypoglycemia sensor	Oct 2023 finished the clinical trial required for submission before the end of the year. US launch summer of 2024. Reimbursement likely a 2-3 yr journey.	Diabetes
DXCM	15-day Sensor	Summer 2024 for non-insulin, not at risk for severe hypoglycemia population; G7 and other products to 15 day to follow	Diabetes
DXCM	Malaysia facility	Online in June 2023	Diabetes
DXCM	Direct to Apple Watch	By end of 2023	Diabetes
DXCM	Next-gen extended wear	2025+	Diabetes
DXCM	$10 sensor standard cost	2025	Diabetes
DXCM	Roche CGM (competitor)	Roche tech day talking about CGM on May 22, 2024	Diabetes

Source: Company materials, BofA Global Research

BofA GLOBAL RESEARCH

Embecta (EMBC)

1. **2024 guide:** For FY24, you expect rev $1,085m-$1,105m (incl. -1% FX headwind) and 0% to -2% org rev decline; GM 63-64%, OM 23.75-24.75%, tax 22%, and EPS $1.90-$2.10. You also talked about R&D at 7% as a floor and ~$116m in interest expense. Puts /takes to guide? Cadence qtr to qtr (incl. contract mfg. headwinds)? What would bring R&D to >7%? Impact of Pillar 2 in 22%? Latest view on FX?

2. **Revenue growth:** You have guided for 0% to -2% organic revenue decline in FY24. You had previously said that your US business is stable, emerging markets (EMs) are growing, and non-US developed markets (DMs) fall in-between. Talk about the puts /takes to growth in the US, EMs, non-US DMs in FY24 and beyond? What gives you confidence that EMs can continue to be a source of growth for EMBC?

3. **Pricing:** You have said that pricing has historically been a 50bps benefit annually, except covid years. In FQ4'23, you said that pricing exceeded your expectations in the qtr. You guided to pricing flattish for FY24 as compared to FY23. What was impact of pricing on FY23 revenue? Talk about puts /takes to guide for flat price in FY24? Your outlook on EMBC's ability to take price in US and OUS thereafter?

4. **Patch pump timing:** In May 2023 you announced a partnership with Tidepool to develop an AID algo for a closed loop T2 patch pump. You have said that you expect to launch an open loop patch pump before closed loop and are working to achieve critical milestones in FY24. You expect no patch pump revenue in FY24. Any early wins you can share in partnering with Tidepool? Any updates on pump timing?

5. **R&D:** You have highlighted that EMBC rebuilt its R&D org post-spin, and you have improved ability to attract R&D talent as a standalone company (vs under-invested division of BD). In Nov'23, you hired a new CMO who is a practicing physician and endocrinologist. You invested 7.6% of sales in R&D in FY23. How you see your R&D org evolving /where does R&D % sales go with time?

6. **GLP-1s, 1:** You have said that T1 insulin users avg 3-4 needles/day and T2 MDI avg 5-6 needles/day, and discount ~50% given US reuse rates. You estimate your biz is roughly 50% T1, 25% T2 MDI and 25% T2 basal. You have talked about piloting refill prompts at pharmacies and digital marketing to reduce reuse. Early feedback on these programs? What impact could a 10% reduction in reuse have on your biz?

7. **GLP-1s, 2:** Pen injector GLP-1s sometimes come packaged with disposable needles; other times, needles are bought separately. E.g., older GLP-1 LLY VICTOZA is a pen

injector with needles sold separately, vs OZEMPIC is packaged with EMBC pens and NVO needles. You have said that NVO has talked about OUS launch in a different format. Puts /takes to EMBC contracting with NVO to supply needles in US /OUS?

8. **GLP-1s, 3:** You have said that <1.5% of your pen needle business comes from LLY VICTOZA and it is a declining business. You have said that you are in discussion with *branded* GLP-1 companies (incl. NVO, LLY, and other branded mfg.), but discussions have also included EMBC looking to package its needles with LLY VICTOZA when it goes *generic* in 2024. How to think about this potential opportunity for EMBC?

9. **GLP-1s, 4:** LLY WEGOVY & MOUNJARO are autoinjectors (come with 1x-use needle attached). LLY has talked about launching in different formats. EMBC does not do anything with autoinjectors today, but you have said this could be an inorganic oppy given that autoinjectors (plastic & steel) match nicely with EMBC's mfg capabilities. How might EMBC get into autoinjector biz? Puts /takes to vol /growth if you do?

10. **Capital allocation:** You have talked about seeking additional partnerships or M&A opportunities that leverage the strengths that EMBC already has. You exited FY23 3.2x levered. You have said that debt covenants on your secured notes allow you to take leverage up to 4.75x. What are your latest interests in /thoughts on M&A? Talk about your capital allocation priorities, incl. your dividend philosophy?

Exhibit 14: EMBC catalysts table

EMBC key upcoming catalysts include milestone updates in 2024 on open loop patch pump (to launch before closed loop), which we expect will launch in 2025+

Company	Device/ Catalyst	Timing	End Market
EMBC	Patch pump - T2 Closed loop	2025+ Expect to launch (BofA estimate)	Diabetes
EMBC	Patch pump - T2 Open loop	"Working to achieve critical milestones in FY24". 2025+ Expect to launch (BofA estimate).	Diabetes
EMBC	Next-gen safety pen needle	2025, launch	Diabetes

Source: Company filing, BofA Global Research

BofA GLOBAL RESEARCH

Inari Medical (NARI)

1. **2024 Guidance:** Have said the mechanical thrombectomy segment of the VTE market is growing ~20% and that NARI is the market leader in this area which implies growth at or above the market. Street modeling 19% growth in 2024, is this the right place to be?

2. **LimFlow acquisition:** Why is Inari doing M&A at this stage in growth trajectory? Why was this the right time to acquire LimFlow? How do you see LimFlow fitting into Inari and how can Inari further develop this product/market? What is the market opportunity here and how does it compare to core VTE in terms of ramp potential, expected penetration, etc?

3. **Capital position:** Talk about how paying for the acquisition including the total deal consideration, what is upfront vs milestones, and your sources of capital. Do you have enough capital to cover the payments without additional fundraising? The milestones are more back-end weighted, so how should we think about the size of those payments vs where Limflow is expected to be in its ramp?

4. **Sustained profitability target:** With the LimFlow acquisition, pushed out timing of sustained profitability to 2H'25 from previous 1H'24 due to $25-$35m in dilution from supporting LimFlow commercial launch. Do you view the timing of sustained profitability as conservative? Is it possible to reach profitability sooner than 2H'25 but maybe not on a consistent qtr to qtr basis?

5. **Pricing and stocking:** When talk about the 20% growth of the market, is that procedure growth or is there price factored in? Has there been a change in the difference between procedure and revenue growth? How do you establish pricing for the new products with customers since some of are outside of the DVT and PE

toolkits? In 2023 launched 6 new products and stocking revenue was lower than historically, around low single digits as a % of total revenue. How do new product launches effect stocking revenue and what proportion of stocking revenue can we expect going forward?

6. **New product contribution reporting:** In 2023 launched 6 new products, some of which are related to core DVT and PE market but have also launched others outside of the core such as RevCore for in-stent restenosis and InThrill for small vein thrombosis. Also plan on launching Artix in 2024 for arterial and other new products. As the business gets more diversified from core DVT and PE how will you think to provide color on contribution from new products and from LimFlow?

7. **Artix in 2024:** Received approval for Artix in 2022 and was in limited market release through early 2023 when made the decision to pause and re-enter in 2024. What was the reason for this, what did you focus on changing with Artix since then, and what can we expect to see that is differentiated from the standard of care for arterial treatment and other arterial thrombectomy devices? Any more clarity on when in 2024?

8. **New products in 2024:** Launched 6 new products in 2023, is 2024 more about continued roll out of these or how should we think about the cadence of new launches in 2024? Will they be more complimentary to what have already launched or any focused on the other new TAM areas outlined at the analyst day?

9. **Competition:** Had your main competitor launch a new product for DVT and PE, but based on performance and revenue growth through 2023 it doesn't seem like competition has had much of an impact on your business, why is that? Do you think the other product is helping to expand the market vs taking share from Inari or being used more by its existing user base? Any other competing devices on your radar coming to market in the near to mid-term?

10. **Clinical data:** Have three RCTs ongoing, DEFIANCE looking at ClotTriever vs anticoagulation only in DVT, PEERLESS looking at FlowTriever vs catheter directed thrombosis, and PEERLESS II looking at FlowTriever vs anticoagulation alone. Data from PEERLESS will be out in 2024. What do you expect to show or how do you plan to use the data you're generating in clinical trials? How important of a factor have you seen clinical data be to date in doc/hospital decision making to use Inari products and how might it change, if at all, with new trials?

Exhibit 15: NARI catalysts table
NARI key upcoming catalysts include Artix re-entering LMR in 2024, PEERLESS trial data readout in 2024, new product launches.

Company	Device/ Catalyst	Timing	End Market
NARI			
NARI	Artix System	Re-enter LMR in 2024	Vascular Thrombectomy
NARI	PEERLESS trial	Data readout in 2024	Vascular Thrombectomy
NARI	PEERLESS II trial	First patient enrolled in Nov 2023. Primary completion estimated in 2026	Vascular Thrombectomy
NARI	New products	RevCore, InThrill, ProTrieve, T16 Curve, CT XL, next gen CT Bold in full market release in 2H'23. In 2024 to a large extent, new products will be within or under the umbrella of the existing toolkits alongside refinements to the existing toolkit as opposed to new additions.	Vascular Thrombectomy
NARI	Geographic expansion	Anticipate beginning to treat patients in China and Japan in 2024	Vascular Thrombectomy
NARI	LimFlow acquisition and milestone payments	Close expected in Q4'23. ~$250M cash outlay upon deal close. Q1 2025: NARI agreed to pay 1.5x 2024 revenue which is expected to be modest given it is just now launching. Q2 2025: NARI agreed to pay two reimbursement milestones totaling $25m max ($12.5m for NTAP; $12.5m for new tech APC). With the OPPS 2024 final rule LimFlow was reassigned to a new tech APC which is expected to pay $27.5k, a ~$10k increase. Q1 2026: The 2025 revenue milestone is expected to pay out at 0.85x 2025 revenue. This milestone is likely self-funded given LimFlow's gross margin. Q1 2027: The 2026 revenue milestone is expected to at 0.5x 2026 revenue. This milestone is likely self-funded given LimFlow's current gross margin.	Chronic limb-threatening ischemia

Exhibit 15: NARI catalysts table
NARI key upcoming catalysts include Artix re-entering LMR in 2024, PEERLESS trial data readout in 2024, new product launches.

Company	Device/ Catalyst	Timing	End Market
NARI	Profitability	Anticipate initial operating support for LimFlow's commercial launch of approximately $2 million to $3 million per month. As LimFlow's revenue begins to ramp throughout 2024 and into 2025, NARI believes it will increasingly cover its expenses, reducing the impact on NARI operating income. Now expects to reach sustained operating profitability in the second half of 2025.	Financial performance

Source: Company materials, clinicaltrials.gov, BofA Global Research

BofA GLOBAL RESEARCH

Inspire (INSP)

1. **Q3, payor mix:** Q3'23 sales were in-line vs Street due to two issues. (1) In Q1'23, you changed rep comp to incentivize utilization. As a result, Medicare mix (due to faster, easier pre-auth /approval process as compared to Commercial) increased; in Q1 and Q2, Medicare approached 50% of mix (from normal 25-30%). INSP did not disclose Medicare mix in Q3. (2) You temporarily tried to enable centers to be more independent in managing pre-auths, which disrupted /slowed pre-auth volumes.

   To correct these two issues, in July 2023, you changed rep comp to also incentivize shepherding patients through the funnel. You also began to triage simple and complex pre-auth cases to a third-party or in-house team, respectively. In Q3'23, you said that you saw pre-auth volume start to normalize. How are these dynamics trending? Given the corrections, and that Q4 is seasonally strong for Commercial, how quickly can payor mix normalize? Will there be a 'new normal' payor mix?

2. **Q3, derogation progress:** In Q3'23, you had inventory supply issues for poly-urethane leads. You are targeting *formal* EU MDR approval for silicone leads in early 2024, and pursuing a *temporary* pathway by-country to allow for shipping of leads in the interim. Any update on timing? Most of your EU revenue is from Germany and the Netherlands. In which countries do you have temporary-path approval today?

3. **Moving parts in Q3'23**: So in Q3'23, you had negative impacts from 1) the change in prior-auth process /support and 2) the lead supply /EU MDR bottleneck. You grew 1% q/q in Q3'23 vs historically 10-15% q/q in Q3. Is the gap (1% vs 10-15% q/q) what we can think of as the hit from these two dynamics in Q3? How to think about the % contribution from one dynamic vs the other?

4. **Q1'24 seasonality:** In Q1'23, you benefitted from patient backlog plus maybe 400-500bps of inventory rebuilding (84% y/y growth, vs ~80% y/y growth ex-inventory rebuilding). Consensus is modeling -6.8% sequential decline in Q1'24. How big was the patient backlog benefit in Q1'23? How should we think about Q4'23 to Q1'24 seasonality, and seasonality through 2024, given these dynamics?

5. **Revenue in 2024:** You got FDA approval in May 2014 and your device has an 11-yr battery life. You had treated ~2.7k patients by Q1'17 and >50k by Q3'23. Patients are beginning to be up for replacement. You expect 80% conversion to new battery. Why 80%? How material of a tailwind can the replacement cycle be in 2024, 2025? Once available, what % of replacements do you think would go to Inspire V (5)?

6. **Inspire V, 1:** Inspire V features an internal sensor and lead removal. You submitted a PMA supplement end of Q2'23 and the FDA returned questions on the product and its bio- and electro-magnetic compatibility. You expect full launch in 2025 following submission of a package to the FDA in early 2024. Any update on timing? Were FDA questions standard ... or nuanced to any data /patient experiences in particular?

7. **Inspire V, 2:** You introduced the 2-incision procedure (down from 3 incisions), which brought procedure time down to 90min (from 120min), in June 2021. By the beginning of Q4'21, you had 100% conversion. Inspire V is expected to reduce

procedure time to 60min (from 90min). How quickly can you achieve 100% conversion of procedures from the 4th to the 5th (Inspire V) generation device?

8. **Profitability:** You have said that you are focused on top-line growth with strong GMs, and profitability will follow. Your net loss in Q3'23 was $8.5m vs $16.8m in Q3'22. You have been EBITDA-positive for two consecutive qtrs and have talked about being more targeted in your approach to direct-to-consumer (DTC). What does the path to higher /more consistent profitability look like through 2024?

9. **GLP-1s:** LLY is expected to announce SURMOUNT-OSA trial results in 1H24. You have said that GLP-1s could bring high-BMI patients into your funnel, and low-BMI patients predominantly have tongue-based OSA (vs lateral wall collapse), so majority of the funnel will remain intact. Has your view of potential impact of the LLY trial and /or GLP-1s changed? Are your conversations with docs evolving at all?

10. **Competition:** A direct competitor expects FDA approval for its device before the end of 2024. You have said that you know you are going to have competition, but the market is extremely large. As the competition likely draws nearer, how are you thinking about competition /your competitive strategy? What are you hearing, if anything, in the field regarding interest in the competitor's device?

11. **UNH policy:** UNH recently updated its coverage to 1) require that patients fail oral appliance therapy (in addition to CPAP), a potential negative; and 2) include INSP's higher BMI and AHI label, a potential positive. The policy also removed language around what's defined as CPAP failure. What is the net impact to INSP of UNH's policy change? How great is the potential for other payors to adopt similar policies?

Exhibit 16: INSP catalysts table
INSP key upcoming catalysts include FDA approval of Inspire V in 2024 and full commercial launch of Inspire V in 2025.

Company	Device/ Catalyst	Timing	End Market
INSP			
INSP	Inspire V (fifth gen device)	Will send response to FDA questions in early 2024. Expect Q3'2024 approval and will do limited launch, 2025 full commercial launch.	Stimulation
INSP	Remote patient programming	2024 (our estimate)	Stimulation
INSP	Nyxoah DREAM US pivotal trial	Expect data readout in March 2024	
INSP	Inspire VI & VII	2025+	Stimulation
INSP	Initial commercial units replacements	2025+	Stimulation

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Insulet (PODD)

1. **US 2024 growth:** Provided color of US Omnipod growth for 2024 in the mid-20% range which was higher than expected. What gives you confidence in setting this as a starting point for the year? What is assumed in this guidance? Can new starts be higher in 2024 than in 2023?

2. **Margins in 2024:** Historically had a goal of 200bps per year of op margin improvement but have been pointing more toward 100bps for 2024 vs 2023 op margin of 9-10%. Why can't it be closer to the historical 200bps?

3. **2024 growth and margin cadence:** Saw really strong US Omnipod growth in Q1 and Q2'2023 of 50% and 48% respectively when adjusting for stocking revenue. How should we think about 1H vs 2H in 2024 given the strong comp? Street modeling 27% US growth ex-stocking in Q1, above the full year mid-20%. Is the Street thinking about it in the right way? What are the puts and takes to consider with the tough comp but also annuity model and recent qtrs. of record patient starts? How should we think about the margin cadence in 2024?

4. **OUS ramp:** Gave some color for OUS growth in 2024 of high single digits for the year with 2H'24 accelerating to high single digits to low double digits as Omnipod 5

ramps internationally. Launched OP5 in the UK in June 2023 and in Germany in August and by end of 2024 have a goal for OP5 to be in the majority of European markets. Once you have OP5 in most European markets, could we see OUS growth accelerate closer to the 25% growth that you expect in the US?

5. **GLP-1s:** With recent SELECT data saw a ~70% prevention of T2 diabetes. How do you think about the potential impact of GLP-1s on the T2 opportunity whether it be preventing T2 diabetes or slowing the progression of patients to T2 and needing a pump? Are you doing any additional work or studies on patients using GLP-1s and an Omnipod?

6. **G7 and Libre integration:** Plan to enter limited market release early 2024 for G7 integration. How long do you expect the LMR to last and at what point do you consider moving to a full launch? Are there patients waiting for OP5 + G7 and how do you expect integration to contribute to growth? For Libre 2 integration you have the RADIANT trial in Europe which began enrolling in Q3'23. Had previously mentioned don't need the trial for regulatory approval and the purpose of the trial is to build evidence for premium reimbursement. Is this still the case and what data are you expecting to show to make this case? Any updates on Libre 2 and 3 integration timing, are you working on both or first Libre 2?

7. **Share of new patients:** We estimate share of new patients converting from MDI shifted to 75% PODD / 25% TNDM in 2023 vs in 2022 estimate ended it was 60% PODD. Tandem has a new product coming to market in 2024 and Medtronic has had 780G in the US now since June 2023. Do you expect to be able to maintain this share capture of new patients from MDI or would you expect it to go back to levels seen in 2022?

8. **Long range plan:** Do you plan to set a long-range plan in 2024? What is your process for setting a long-range plan and what details might you give?

9. **CFO:** Any updates on the search for a CFO and when expect to have one on board? Anything can share about looking internally vs externally?

10. **Other opportunities:** With the introduction of the basal pod and trying to move upstream in the patient's progression, would PODD ever try to develop a CGM or move outside of core insulin? What kinds of developments could we expect to see on the data capability side?

Exhibit 17: PODD catalysts table
PODD key upcoming catalysts include G7 integration LMR in early 2024 and continued OUS rollout of OP5.

Company	Device/ Catalyst	Timing	End Market
PODD			
PODD	Omnipod 5	Continued US rollout of OP5 in 2023. OP5 UK launch in June 2023 and Germany launch in August 2023. By end of 2024 goal to have OP5 in majority of European markets	Diabetes
PODD	iOS	Approval in October 2023, will launch with G6. LMR for G7 in early 2024	Diabetes
PODD	Pump integration with Dexcom	Integration with G7 LMR in early 2024	Diabetes
PODD	RADIANT study (Libre 2 integration)	Began enrollment in Sept 2023	Diabetes
PODD	EVOLUTION study (next-gen AID algo)	Recruitment began in July 2023 in New Zealand	Diabetes
PODD	SECURE study (T2 pivotal)	Reached enrollment goal of 400 participants in early Nov 2023. 13 week study	Diabetes
PODD	Omnipod GO	Launched US commercial pilot program in 2023. Commercialization in 2024	Diabetes
PODD	EOFlow injunction	Court granted request for a preliminary injunction against EOFlow in Oct 2023	Diabetes
PODD	Malaysia facility	Operational by mid-2024	Diabetes

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Integer Holdings (ITGR)

1. **Implied Q4 guidance:** FY23 revenue guidance of $1,575-1595m implies Q4 revenue is flat sequentially (despite $5m contribution from the InNeuroCo acquisition) and up only 8% y/y (vs 18% YTD). What is the reason for the conservatism?

2. **Operating income growth.** Q3 was the first quarter where operating income growth (+39%) grew 2x revenue growth (18%) in line with your long-term target. Guidance for 2023 still calls for operating income (+25% at midpt) to grow 1.6x revenue growth (15% at midpt) which implies a similar 1.6x ratio in Q4. What will it take to sustain the 2x ratio and how soon can that happen? Do you expect to see the 2x ration in certain quarters in 2024 or potentially the full year? Would a more normalized revenue growth make it easier or more difficult to reach 2x operating income growth?

3. **Customer inventory comments:** Over the past several months, your biggest customers have talked about either reducing elevated inventory levels or the number of suppliers. Would that be a headwind to your growth? If not, why wouldn't it be? Have you seen reduced activity with any of your larger customers? What type of visibility do you have into any changes in customer ordering patterns?

4. **Margin expansion:** Gross Margins (27% in Q3) and EBITDA (20% in Q3) have been improving over the last several quarters but are still below pre-covid levels (GM - 31% and EBITDA -23% in 2019). Can margins return to pre-covid levels? What are the key drivers to improve margins?

5. **Emerging company pipeline**. Talk about the strategy and the benefits of your emerging customer business. Why do the PMA products make the business much stickier? Emerging company revenue was $50m in 2022 and you said that you expected that to grow to $80-100m in 2024. Are you above tracking ahead of that guidance? How should we think about emerging growth from 2024 to 2026? Can it double again?

6. **Strong revenue growth/market outperformance**: Your guidance implies 15% revenue growth at the midpoint which is more than your goal of growing 200 bps above the market. What do you attribute that outperformance to and how sustainable do you think that outperformance is? Should we think that you may be able to outperform your end markets by more than the 200bps goal?

7. **M&A:** Part of your strategy is to expand capacity and technology expertise through M&A. Talk about your acquisition strategy. What does the acquisition landscape look like for you? Are there many targets to look at? What financial parameters do you evaluate when looking at new deals? Your current leverage (3.1x) is within your target leverage range (2.5-3.5x) but would you go outside of the range for a deal?

8. **Backlog:** ITGR has close to $1bn in backlog versus only $300m before the pandemic. What caused the backlog to grow to that level during the pandemic? Was it excess customer demand or supply chain constraints that slowed delivery? What is a normalized backlog level going forward?

Integra LifeSciences (IART)

1. **2024 revenue:** Street is modeling $1.629bn revenue which we believe is slightly lower than $1.640bn 2024 revenue implied by IART's framework – midpt of 2023 revenue guide at the analyst day ($1.611bn) multiply by low end of revenue growth LRP (5%) less $50m expected 2024 Boston revenue impact ($50m). Is the original framework still the best way to think about 2024 revenue? Is the Street's 2024 estimate reasonable? Are there other moving pieces that the Street should be considering?

2. **2024 EPS:** The Street is expecting 2024 EPS of $3.44 which implies 6% after excluding the Boston EPS impact from both 2023 (42c) and 2024 (30c). Is the Street thinking about 2024 EPS the right way? Are there expenses that were deferred/delayed in 2023 following the Boston shutdown that may be weigh on 2024 EPS?

3. **LRP revenue targets:** How should we think about IART tracking to LRP revenue targets – Codman +3-5% and Tissue +7-9% (excluding the impact from Boston)? Are you still tracking towards reaching low end of LRP targets – 70-72% GM and 28-30% OM – by 2025? What impact/delay will Boston have on those targets?

4. **Boston reopening:** You turned the Boston facility back on in early December – did everything go smoothly? Are you still on track for a "dress rehearsal" audit at the end of January/early Feb? Is plan to still have final audit report done by end of Q1? On track to start shipping mid to late Q2? Have you had any additional discussion with the FDA?

5. **Margins at Boston facility:** With the remediation work that you have done on the facility, will there be any incremental sustained manufacturing or operational costs?

6. **Share recapture from Boston recall:** Is a $50m revenue impact from Boston in 2024 still the right way to think about it? What gives you the confidence that you can recapture that quickly? Have you talked to customers that indicated they will go back to you immediately or are not coming back? How does that share recapture look between private label, surgimend and primatrix? Do you still expect 100% within 12 months?

7. **Cerelink recall:** Did you receive FDA approval for Cerelink yet? Do you still expect it to be in January? If not, what is the reason for the delay? Should we assume $12m of Cerelink sales in 2024 once its back on the market similar to what you generated with the initial launch? How will Cerelink units in the field be upgraded? Will you be able to sell to new customers immediately upon getting back on the market?

8. **Acclarent acquisition:** Why was now the right time to complete the acquisition? Talk about how you are going to leverage your ENT call points (which we believe are slightly different than Acclarent ENT call points? Why didn't Acclarent grow much in the 10+ years under JNJ? Why is JNJ selling?

9. **M&A:** You have been active in M&A for many years. How are you thinking about further M&A over the next year? Are you more likely to tuck-in deals versus larger acquisitions? Do you expect more in Tissue Tech or Codman?

10. **Surgimend breast indication timing:** you said that you expect PMA audits to happen in late 2024 or early 2025 and that you could get PMA approval in 2025. Have you submitted all modules of the approval that you can at this point and you only need the approval of the facility to get final PMA approval? Has the FDA asked follow up questions or have you had any new conversations with the FDA about the submissions?

Exhibit 18: IART catalysts table

IART has several tissue product catalysts, but most important catalyst is the reopening of its Boston manufacturing facility which is expected in mid to late Q2 2024

Company	Device/ Catalyst	Timing	End Market
IART			
IART	Boston facility distribution restart	mid to late 2Q24	Wound Reconstruction
IART	Cerelink on market in all OUS countries	all by end of 2023	Wound Reconstruction
IART	Cerelink relaunch in US (needs 510k approval)	1Q24 (submitted 510k at end of 3Q23)	Neurosurgery
IART	DuraSorb for breast reconstruction	Expected 2025/2026	Wound Reconstruction
IART	Surgimend for breast reconstruction	1H25 - FDA inspection of Boston facility in 4Q24 / 1Q25	Wound Reconstruction

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Nevro (NVRO)

1. **SCS market growth:** Your US SCS business ex-PDN declined -5% y/y in Q3. ABT US SCS grew 26% y/y org (our est.), BSX US SCS grew 2% y/y org (our est.), and MDT US SCS grew HSDs. You said that you continued to expect non-linear recovery in the core SCS market in 2023 and 2024. How has your market share trended last 4 qtrs? Latest outlook on core SCS market for 2024 and beyond ... drags /drivers?

2. **iQ, 1:** On the Q3 call, you raised 2023 revenue guide by the Q3 beat, offset by price pressure and lower volume due to regulatory delays from selling iQ into Europe. You said that timing of iQ approval in Europe was uncertain (announced submission of application in Nov'22) but expected. Any update on timing? What back-and-forth with Europe regulators have you had /what's been the biggest hold up?

3. **iQ, 2:** You launched iQ in the US in 1Q'23. You aspired for iQ to achieve 75-80% of mix 6-9mos post launch. As of Q3, iQ accounted for 43% of your permanent implant procedures, up from 30% in Q2 and 11% in Q1. You have said that you expect the positive trend to continue. Why the qtr-to-qtr lumpiness in iQ adoption? What is US /OUS split of your SCS implants (i.e., ex-Europe iQ approval, what's the cap)?

4. **Margins:** Q3'23 GM was 90bps soft vs Street. On the Q3 call, you did not comment on 2024 and said that you continued to expect a path to mid-70s % GM over time, driven by 1) lower cost as mfg volume transitions from contract mfg to your Costa Rica plant and 2) pricing uplift from iQ (launched in US in 1Q'23), assuming pricing holds. What is your latest outlook on pricing, margin expansion?

5. **PDN:** US PDN sales grew 56% y/y, 10% q/q in Q3. There were new entrants to the PDN market in 2023, and BSX expects PDN indication for SCS in Q1'24. You have said that you are confident in NVRO's leadership position in PDN, and new entrants will only help educate the market. What are you hearing from /seeing in the field on competitor devices? Your latest outlook on the PDN market for 2024 and beyond?

6. **Vyrsa:** You announced acquisition of Vyrsa, focused on minimally invasive SI joint technology, in Nov'23 and expect it to be accretive to revenue and adj EBITDA in 2024. Speak to Vyrsa's product portfolio, call points, and integration with NVRO's current offering? Your current view on and outlook for SI joint market? Given the acquisition /financing, your latest thoughts on M&A /capital allocation priorities?

7. **Salesforce reorg:** You realigned your sales force in Q2'23 which included a change in incentive comp. With the changes complete in Q2'23, you anticipated 6-9mos for the teams to become fully comfortable and effective. Any early wins you can share as the realignment has had time to marinate? Is 6-9mos still the right time to maturity? How do you anticipate the changes contributing to growth in 2024?

8. **Reimbursement:** In Jan'23 BCBS NJ updated its policy to incl. PDN (+4m lives), In June'23 FL Blue did the same (+5m lives), and in July'23 Novitas and First Coast MACs retired their SCS LCDs (+19m) lives. These positive developments followed UNH denying coverage in Oct'22. What is your payor mix for permanent implant procedures? Outlook on reimbursement environment /expected developments?

Exhibit 19: NVRO catalysts table
NVRO key upcoming catalysts includeiQ approval in Europe and incremental growth from Nov'23 Vyrsa deal

Company	Device/ Catalyst	Timing	End Market
NVRO			
NVRO	New iQ platform launch	Limited launch in US underway (since Oct); iQ approval in Europe expected but timing uncertain	Stimulation
NVRO	Vyrsa Tech Deal	Deal closed Nov 30th 2023; likely adds incremental growth to NVRO over time	Pain / SI Joint

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Outset Medical (OM)

1. **2024 revenue guidance:** On Q3 eps call gave 2024 revenue guidance of mid-teens revenue growth. What assumptions are baked into guidance that make this a conservative starting point and where are potential areas for outperformance? In 2023 called out headwinds from TabloCart delaying orders, competitive noise, and elongated sales decisions for capital purchasing. Do you expect these headwinds to carry into 2024?

2. **2024 revenue cadence:** In 2023 had talked about capital equipment purchasing seasonality impacting Q1 growth. Do you expect to see similar seasonality in 2024 or more pronounced this year given the elongated sales cycle have already called out? Guidance also assumes TabloCart with pre-filtration comes back in 2H'24. What are expectations once TabloCart with pre-filtration gets FDA approval? Are there a number of orders you know of already that have been delayed that will immediately come through or do you need to go through the ordering process again with customers and will take more time to see it come through?

3. **New long-range plan:** Gave 2025-2027 guidance of high teens annual revenue growth and ~50% gross margin as revenues reach $250m exiting 2027. Talk through the assumptions that are factored into the high teens annual growth rate? What's assumed from a macro perspective and company specific?

4. **Gross margin:** Expect gross margin in 2024 to be in low-30% range for full yr, exiting Q4 in mid-30% range. Also expect to reach 50% goal in 2027 and a linear ramp to get there. Talk about the gross margin drivers and levers you have to reach this goal.

5. **Cash position:** Have said expect to consume $100m of cash in 2024 which is about 25% less than in 2023 and you continue to consume less cash in each year than the year before. What are some things you're doing on the opex side to control your level of cash burn. In December 2023 received $33.5m under your term loan agreement with SLR Investment and in early January received another $66.5m so maybe go over what your current cash position/access to capital and if you expect to need additional capital to get you to your cash flow breakeven goal in 2027.

6. **Home revenue ramp:** Expect 25% of total revenue to be from home in 2027 vs 20% of total revenue in 2023. We estimate that suggests only adding $30-$40m in home revenue from 2023 to 2027. What are the gating items to home adoption and why can't we see a faster pace of growth in home?

7. **Home programs:** What is the strategy for home and the different pathways for sending patients home? Where has growth in home been coming so far and do you expect that to change over time? What trends have you seen in capacity for programs to send patients home?

8. **GLP-1s:** In October Novo announced the FLOW trial was stopped based on positive interim analysis and full data is expected in 1H'24. Do you have any expectations on what the data will show? What is your view on GLP-1s and potential implications for the population of people needing dialysis?

9. **Retention:** Have talked about controllable attrition holding sub 10% at 12 mos. How are you able to have better retention vs incumbent device? How do you plan to control this as home scales further?

10. **Competition:** What are your thoughts on the competitive landscape following the launch of competitor Quanta's product at American Society of Nephrology conference in October 2023?

Paragon 28 (FNA)

1. **2024 revenue.** The Street is modeling 2024 revenue of $256 which implies ~19% growth over 2023, essentially the same growth as 2023. How likely do you think it is that the business can return to 20% growth?

2. **Supply constraint.** You said that the supply chain headwinds peaked in Q2 2024 and said the impact on certain products got better in Q3 but didn't quantify the impact. How much of a negative impact do you expect the supply constraint to have on sales in 2023? Have those supply constraint issues been resolved? Will you see some impact in Q4 but lower than the past quarters? Will there be a lingering impact in 2024? What is your confidence level that these supply constraints will not resurface?

3. **Foot and ankle market:** What are the key subsegments that are driving foot and ankle market growth? How is Paragon positioned relative to competition in these markets? Total Ankle? Bunions? Where is Paragon underindexed? Soft Tissue?

4. **Competition.** Henry Schein acquired a small extremity company seemingly to leverage its existing relationships with ASCs to sell extremity implants (most surgeries done in ASC) and potentially try a rep-less model. What do you think of this acquisition? And how do you view the broader competitive landscape? How do you compare the pureplay (or relatively pure play) foot and ankle companies to some of the larger ortho companies?

5. **2024 EBITDA.** The Street consensus for 2024 EBITDA is ~$6m but there is a wide range from $0 EBITDA to $13m. You said you expect positive EBITDA in 2024, but will it be positive in each quarter? Marginally positive for the year? What factors could help/hinder getting to positive EBITDA?

6. **US growth.** US growth was 15% in Q2 and Q3 (adj for days) on tough comps and the sterile packaging supply constraint. On a stacked 2yr average, growth was high teens in Q2 and Q3. Can US growth reaccelerate to get back above 20%? What are the key drivers for growth in the US?

7. **International.** International has grown 40% YTD. What is driving that growth? International only represents ~15% of your sales today but is growing faster than the US. How important is international expansion to the future growth of the company? What are some of the markets that you are doing well in today? How are you thinking about expanding into other markets?

8. **Smart 28.** You received FDA approval for the software foundation for Smart 28 in December. What is the plan and timing of the launch for the different Smart 28 modules? How can you monetize Smart 28? Is Smart 28 more about incremental revenue per procedure or taking share?

9. **Cash.** With the new credit facility, you have $100m in cash on the balance sheet and the option to draw another $50m down. Talk about your cash needs in 2024 and why they will be meaningfully lower than 2023. Do you have enough cash to get to breakeven? What revenue level do you need to get to cash flow breakeven and profitability?

RxSight (RXST)

1. **Systems.** The Street models only 3% in system placement growth in 2024 and then little growth in 2025. Is there a reason to think that the system placements will peak around 260 per year? How would you frame the current addressable opportunity? How many doctors' offices in the US? How many surgeons performing cataract surgeries that would purchase a system?

2. **New reconfigured LDD ASP:** You said that ASP on the new system is ~$130k which is roughly a 10% premium over the prior version. How sustainable is that ASP?

3. **Premium IOL market.** What is the growth of the premium IOL market? Is the market expanding (shifting people from monofocal? What % of the IOL market is currently premium? Are LALs expanding the premium IOL market?

4. **Utilization (1):** Utilization in the first three quarters has been around 9 LALs per system per month which is 24% above last year. The Street is modeling ~10% for utilization growth in 2024. Is that the right way to think about utilization growth given the trends you are seeing with recently placed systems?

5. **Utilization (2):** How does utilization trend amongst docs that got a system a 1 yr ago or 2 yrs ago vs ones that purchased this year? Is there a limit to how many cases a system can do per month? How many LALs are your biggest users doing per month? Are any of your docs decrease utilization?

6. **International expansion.** What is your international strategy? Which countries do you plan to target? How long before you intend to enter these international markets?

7. **Gross Margin.** Your GM is expected to be 17 pct points higher in 2023 than it was in 2022. How much of that is better GM on the LDDs (including the reconfigured LDD) vs a higher proportion of revenue from the higher margin LALs? What is the GM for the reconfigured LDD? High 30s/low 40s? What is peak GM for the entire company? Can GM reach 80%?

8. **Opex spend.** Operating expense growth is expected to be 1/3 of revenue growth driving significant operating leverage. How do you balance investing to maintain the very high growth vs delivering leverage to get closer to profitability? Should we expect a different approach to opex spend in 2024?

9. **Cash balance.** Does your $132m in cash a/o Q3 get you to breakeven? Do you have a target revenue where you think you will be breakeven?

10. **Recession:** Do you see a potential recession as a risk to your business model? Have you heard any feedback from customers that they may delay or defer any purchases in a more challenging macro environment?

Exhibit 20: RXST catalyst table
RXST will launch a new LDD and LAL at the end of 2023/early 2024

Company	Device/ Catalyst	Timing	End Market
RXST			
RXST	Full launch of reconfigured LDD	Started in Sept 23, full launch in 4Q23	Ophthalmology
RXST	LAL+ launch	1H24	Ophthalmology

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Shockwave (SWAV)

1. **US peripheral prior auth:** Q3'23 was impacted by tougher peripheral prior pre auth approvals after recent news articles discussed overtreating peripheral artery disease broadly. Aetna put out a new policy on Aug 30th which was seen in the Q3 US peripheral revenue which was -6% q/q ($6m below the Street) vs US coronary revenue which was +5% q/q ($2m above the Street). What is the latest you are seeing on the prior authorizations with Aetna? How are you helping to address the issue? Have you seen any other payers adopt a similar policy or do you expect them to? What types of cases does it apply to relative to your total business?

2. **2024 guidance:** Have said remain comfortable with the $920m Street number for 2024 despite the prior authorization noise. What makes you still comfortable with that number? How long do you expect the prior authorization headwind to last and what is factored into 2024 guidance (gave color of 10-20% US peripheral rev growth in 2024 which should accelerate over the course of the year)? What other puts and takes are factored into how thinking about 2024?

3. **Coronary reimbursement:** How are you thinking about any potential impact to your business in the back half of '24 after the TPT sunsets in the middle of next year? Since you did not get IVL mapped to the higher APC5194 code in the latest CMS ruling it is expected to come in 2025. Do you think this 6-month gap will have an impact on the business? How confident are you it will make it into the next ruling for 2025? What are the next steps you're taking here?

4. **Operating margin:** At the analyst day in October gave a LRP of 500bps OM expansion in '24-'26 and said most of the expansion would be in 2025/2026. Street modeling 25% operating margin for 2024 would be 300bps of expansion from 2023 guidance of high end of 20-22%. Is the Street modeling too aggressive op margin expansion?

5. **China:** In Q3 saw an impact to the business from the anti-corruption campaign, called out a $10m hit to revenue in 2023. Where is the impact coming from, is it opening new accounts or issues with existing accounts? What is the latest you're seeing in China and the impacts of the campaign? Do you still expect to see this headwind over the next few qtrs.? Can you give any color on how big your China business is now and what impact you're expecting in 2024?

6. **E8 in 2024:** Outlined a number of new products at the analyst day in October 2023. One of them E8 for mid-size and long BTK lesions is expected to be in the US in 2024. Can you update us on the latest development timeline there, when in 2024 do you expect to have the product in the US and when should it start contributing to growth?

7. **Competition:** Anything new on the competition front? When do you expect another IVL name to come into the market? How do you feel about your competitive positioning if/when another player does come to market?

8. **M&A:** In August 2023 raised a $650m converting note offering and have talked about how it gives you strategic optionality if you found the right opportunity. What is your latest thinking on willingness to do M&A and what size deal would you be interested in pursuing? What areas in your portfolio may you look to add to inorganically vs what you have in development organically?

9. **OUS business:** What are your expectations for Europe and Japan in 2024? Had an improvement in reimbursement in Germany in 2023, what has the uptake been like since then? Where are you in terms of the launch there? How big is that market opportunity? Similar question for Japan, how do you size that opportunity and where are you now in terms of penetration?

10. **Other new products:** Other products talked about at the analyst day include Javelin peripheral in 2025 in the US, C2 Aero in 2025 in the US, and Javelin coronary in 2026 in the US. Also talked about products for other TAM areas such as RX System for Carotid in 2027 in the US and Crescendo for aortic stenosis in 2028 in the US. Which opportunity are you most excited about, where do you see the easiest and most difficult paths for getting these products to market and widely adopted?

Exhibit 21: SWAV catalysts table
SWAV's key upcoming catalysts include E8 for Peripheral BTK in the US in 2024.

Company	Device/ Catalyst	Timing	End Market
SWAV			
SWAV	C2+	C2+ (next gen coronary IVL) US launch in 2H23	Coronary
SWAV	Germany	German reimbursement improvement went live Jan 2023	Coronary
SWAV	E8 (BTK)	US market entry in 2024E	Peripheral
SWAV	Javelin Peripheral IVL Catheter (BTK)	US market 2025E	Peripheral
SWAV	C2 Aero (coronary)	US market 2025E	Coronary
SWAV	Javelin Coronary IVL Catheter	US market 2026E	Coronary
SWAV	Reducer	US Approval 2027E	Reducer
SWAV	RX System - Carotid IVL	US market 2027E	Carotid
SWAV	Crescendo (Aortic Stenosis)	US market 2028E	TAVR
SWAV	Mitral VTL System (Mitral)	US market entry 2029E	Mitral

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Silk Road Medical (SILK)

1. **New CEO:** Mr. (Chas) McKhann, you joined SILK as CEO in Nov'23 from Apollo Endosurgery. What attracted you to SILK? What will be your priorities? SILK has talked about minimizing cultural disruption and continuing to execute against LRP. It is early, but do you feel those comments are consistent with your intentions /plans? How do your prior experiences inform your views /enable a smooth transition?

2. **NCD:** In Oct'23, CMS finalized an NCD to open CAS coverage to the same, broad group of patients as TCAR, putting CAS on a much more even playing field moving forward (potential negative for SILK). You have said that the NCD is favorable for TCAR and CAS as the market will rise and CEA, which has the greatest market share, has the most to lose. Your latest thoughts on NCD /feedback from the field?

3. **Q3 dynamics, 1:** On the Q3 call, you said that July was a strong month and Aug and Sep were softer than expected, which is the reverse of typical seasonality pattern you see in Q3. At the time, you attributed this to stronger summer /vacation dynamics. What is your latest view on what happened in Q3? Did the same trend – stronger to start and softer to end the qtr – continue through Q4?

4. **Sales infrastructure:** In Q1'23, you reorganized your sales force to increase sales reps' touchpoints with docs, to drive docs more effectively up the adoption curve. On the Q3 call, you attributed TCAR procedure growth weakness to reorg disruption and expected this to cont. through 1H24. Hurdles the transition from broadening to deepening adoption has faced? Still see reorg contributing /delivering in 2H24?

5. **Q3 dynamics, 2:** On the Q3 call, you said that you had plans to dig into trends and drivers of docs' behavior /adoption in coming months. Early findings you can share?

6. **Competition:** In Nov'23, a competitor (InspireMD, NSPR) announced positive 30-day results from its US IDE trial including a 30-day MAE rate (incl stroke) at 0.95% … Vs in ROADSTER 2, TCAR 30-day MAE rate (incl stroke) was 1.7%. The standalone stroke rate for NSPR C-Guard was not disclosed. NSPR expects US approval of C-Guard in 1H25. Your outlook on the market /perspective on NSPR's early results?

7. **Pipeline, 1:** In the US, you began full launch of ENFLATE balloon catheter in Q2'23 and were evaluating US launch of NPS Plus protection system by YE'23. You are focused on approval of ENROUTE stent and NPS Plus in China; and reimbursement submission for NPS in Japan. Any update(s) on timing? What is your latest outlook on your product pipeline and expansion efforts in China /Japan?

8. **Pipeline, 2:** In Q2'23, you received approval for a US IDE trial for acute ischemic stroke, and your ROADSTER 3 trial - to assess real-world treatment of standard surgical risk patients with your ENROUTE stent - is ongoing. Out of the latter, you

expect to submit a PMA and as of Sep'23, you said that the study was tracking to your expectations. Any updates on progress /timing?

9. **Breakeven:** You exited Q3 with $193m in cash and your annual cash burn is $30m-$40m. On the Q3 call, you said that you are confident that you can accomplish your current growth and organizational objectives, including executing on your path to profitability, with your current capital. Consistent with current view /any updates?

10. **Metrics in 2024:** Exiting Q3, you had 85 active territories; and by our estimates., rev per procedure was ~$7k, you had ~2.7k trained surgeons, and procedures per doc was at ~2.4 ... are our ests. in the right ballpark? Growth expectations for these metrics in 2024 and beyond? In 2023, you launched ENFLATE balloon with a premium price strategy; recent SILK ASP trends and expectations for ASP trajectory given pipeline?

Exhibit 22: SILK catalysts table
SILK's key upcoming catalysts include launch of the tapered ENROUTE stent in 1H24 and expansion into China/Japan

Company	Device/ Catalyst	Timing	End Market
SILK			
SILK	Tapered ENROUTE stent	1H24, expect to launch	TCAR
SILK	NPS Plus protection system	2H23, expect limited market release	TCAR
SILK	Japan/China expansion	2024+ (Early '23, received China NPS approval)	TCAR
SILK	ROADSTER 3	2024+	TCAR
SILK	Stroke treatment	2024+	TCAR
SILK	NSPR C-Guard (InspireMD)	Nov '23, positive 30-day CT results at VIVA. 1H24, expect to initiate TCAR study. 1H25, expect US C-Guard approval.	TCAR
SILK	Contego stent trial completion	New stent with embolic protection. Enrollment completed as of Nov 2023 - will support PMA application.	TCAR

Source: Company filings, BofA Global Research

BofA GLOBAL RESEARCH

Special Disclosures

BofA Securities is currently acting as financial advisor to Inari Medical Inc in connection with its proposed acquisition of LimFlow SA, which was announced on Nov 1, 2023.

Disclosures

Important Disclosures

BofA Global Research personnel (including the analyst(s) responsible for this report) receive compensation based upon, among other factors, the overall profitability of Bank of America Corporation, including profits derived from investment banking. The analyst(s) responsible for this report may also receive compensation based upon, among other factors, the overall profitability of the Bank's sales and trading businesses relating to the class of securities or financial instruments for which such analyst is responsible.

Other Important Disclosures

From time to time research analysts conduct site visits of covered issuers. BofA Global Research policies prohibit research analysts from accepting payment or reimbursement for travel expenses from the issuer for such visits.
Prices are indicative and for information purposes only. Except as otherwise stated in the report, for any recommendation in relation to an equity security, the price referenced is the publicly traded price of the security as of close of business on the day prior to the date of the report or, if the report is published during intraday trading, the price referenced is indicative of the traded price as of the date and time of the report and in relation to a debt security (including equity preferred and CDS), prices are indicative as of the date and time of the report and are from various sources including BofA Securities trading desks.
The date and time of completion of the production of any recommendation in this report shall be the date and time of dissemination of this report as recorded in the report timestamp.

Recipients who are not institutional investors or market professionals should seek the advice of their independent financial advisor before considering information in this report in connection with any investment decision, or for a necessary explanation of its contents.
Officers of BofAS or one or more of its affiliates (other than research analysts) may have a financial interest in securities of the issuer(s) or in related investments.
Refer to BofA Global Research policies relating to conflicts of interest.
"BofA Securities" includes BofA Securities, Inc. ("BofAS") and its affiliates. Investors should contact their BofA Securities representative or Merrill Global Wealth Management financial advisor if they have questions concerning this report or concerning the appropriateness of any investment idea described herein for such investor. "BofA Securities" is a global brand for BofA Global Research.
Information relating to Non-US affiliates of BofA Securities and Distribution of Affiliate Research Reports:
BofAS and/or Merrill Lynch, Pierce, Fenner & Smith Incorporated ("MLPF&S") may in the future distribute, information of the following non-US affiliates in the US (short name: legal name, regulator): Merrill Lynch (South Africa): Merrill Lynch South Africa (Pty) Ltd., regulated by The Financial Service Board; MLI (UK): Merrill Lynch International, regulated by the Financial Conduct Authority (FCA) and the Prudential Regulation Authority (PRA); BofASE (France): BofA Securities Europe SA is authorized by the Autorité de Contrôle Prudentiel et de Résolution (ACPR) and regulated by the ACPR and the Autorité des Marchés Financiers (AMF). BofA Securities Europe SA ("BofASE") with registered address at 51, rue La Boétie, 75008 Paris is registered under no 842 602 690 RCS Paris. In accordance with the provisions of French Code Monétaire et Financier (Monetary and Financial Code), BofASE is an établissement de crédit et d'investissement (credit and investment institution) that is authorised and supervised by the European Central Bank and the Autorité de Contrôle Prudentiel et de Résolution (ACPR) and regulated by the ACPR and the Autorité des Marchés Financiers. BofASE's share capital can be found at www.bofaml.com/BofASEdisclaimer; BofA Europe (Milan): Bank of America Europe Designated Activity Company, Milan Branch, regulated by the Bank of Italy, the European Central Bank (ECB) and the Central Bank of Ireland (CBI); BofA Europe (Frankfurt): Bank of America Europe Designated Activity Company, Frankfurt Branch regulated by BaFin, the ECB and the CBI; BofA Europe (Madrid): Bank of America Europe Designated Activity Company, Sucursal en España, regulated by the Bank of Spain, the ECB and the CBI; Merrill Lynch (Australia): Merrill Lynch Equities (Australia) Limited, regulated by the Australian Securities and Investments Commission; Merrill Lynch (Hong Kong): Merrill Lynch (Asia Pacific) Limited, regulated by the Hong Kong Securities and Futures Commission (HKSFC); Merrill Lynch (Singapore): Merrill Lynch (Singapore) Pte Ltd, regulated by the Monetary Authority of Singapore (MAS); Merrill Lynch (Canada): Merrill Lynch Canada Inc, regulated by the Canadian Investment Regulatory Organization; Merrill Lynch (Mexico): Merrill Lynch Mexico, SA de CV, Casa de Bolsa, regulated by the Comisión Nacional Bancaria y de Valores; Merrill Lynch (Argentina): Merrill Lynch Argentina SA, regulated by Comisión Nacional de Valores; BofAS Japan: BofA Securities Japan Co., Ltd., regulated by the Financial Services Agency; Merrill Lynch (Seoul): Merrill Lynch International, LLC Seoul Branch, regulated by the Financial Supervisory Service; Merrill Lynch (Taiwan): Merrill Lynch Securities (Taiwan) Ltd., regulated by the Securities and Futures Bureau; BofAS India: BofA Securities India Limited, regulated by the Securities and Exchange Board of India (SEBI); Merrill Lynch (Israel): Merrill Lynch Israel Limited, regulated by Israel Securities Authority; Merrill Lynch (DIFC): Merrill Lynch International (DIFC Branch), regulated by the Dubai Financial Services Authority (DFSA); Merrill Lynch (Brazil): Merrill Lynch S.A. Corretora de Títulos e Valores Mobiliários, regulated by Comissão de Valores Mobiliários; Merrill Lynch KSA Company: Merrill Lynch Kingdom of Saudi Arabia Company, regulated by the Capital Market Authority.
This information: has been approved for publication and is distributed in the United Kingdom (UK) to professional clients and eligible counterparties (as each is defined in the rules of the FCA and the PRA) by MLI (UK), which is authorized by the PRA and regulated by the FCA and the PRA - details about the extent of our regulation by the FCA and PRA are available from us on request; has been approved for publication and is distributed in the European Economic Area (EEA) by BofASE (France), which is authorized by the ACPR and regulated by the ACPR and the AMF; has been considered and distributed in Japan by BofAS Japan, a registered securities dealer under the Financial Instruments and Exchange Act in Japan, or its permitted affiliates; is issued and distributed in Hong Kong by Merrill Lynch (Hong Kong) which is regulated by HKSFC; is issued and distributed in Taiwan by Merrill Lynch (Taiwan); is issued and distributed in India by BofAS India; and is issued and distributed in Singapore to institutional investors and/or accredited investors (each as defined under the Financial Advisers Regulations) by Merrill Lynch (Singapore) (Company Registration No 198602883D). Merrill Lynch (Singapore) is regulated by MAS. Merrill Lynch Equities (Australia) Limited (ABN 65 006 276 795), AFS License 235132 (MLEA) distributes this information in Australia only to 'Wholesale' clients as defined by s.761G of the Corporations Act 2001. With the exception of Bank of America N.A., Australia Branch, neither MLEA nor any of its affiliates involved in preparing this information is an Authorised Deposit-Taking Institution under the Banking Act 1959 nor regulated by the Australian Prudential Regulation Authority. No approval is required for publication or distribution of this information in Brazil and its local distribution is by Merrill Lynch (Brazil) in accordance with applicable regulations. Merrill Lynch (DIFC) is authorized and regulated by the DFSA. Information prepared and issued by Merrill Lynch (DIFC) is done so in accordance with the requirements of the DFSA conduct of business rules. BofA Europe (Frankfurt) distributes this information in Germany and is regulated by BaFin, the ECB and the CBI. BofA Securities entities, including BofA Europe and BofASE (France), may outsource/delegate the marketing and/or provision of certain research services or aspects of research services to other branches or members of the BofA Securities group. You may be contacted by a different BofA Securities entity acting for and on behalf of your service provider where permitted by applicable law. This does not change your service provider. Please refer to the Electronic Communications Disclaimers for further information.
This information has been prepared and issued by BofAS and/or one or more of its non-US affiliates. The author(s) of this information may not be licensed to carry on regulated activities in your jurisdiction and, if not licensed, do not hold themselves out as being able to do so. BofAS and/or MLPF&S is the distributor of this information in the US and accepts full responsibility for information distributed to BofAS and/or MLPF&S clients in the US by its non-US affiliates. Any US person receiving this information and wishing to effect any transaction in any security discussed herein should do so through BofAS and/or MLPF&S and not such foreign affiliates. Hong Kong recipients of this information should contact Merrill Lynch (Asia Pacific) Limited in respect of any matters relating to dealing in securities or provision of specific advice on securities or any other matters arising from, or in connection with, this information. Singapore recipients of this information should contact Merrill Lynch (Singapore) Pte Ltd in respect of any matters arising from, or in connection with, this information. For clients that are not accredited investors, expert investors or institutional investors Merrill Lynch (Singapore) Pte Ltd accepts full responsibility for the contents of this information distributed to such clients in Singapore.
General Investment Related Disclosures:
Taiwan Readers: Neither the information nor any opinion expressed herein constitutes an offer or a solicitation of an offer to transact in any securities or other financial instrument. No part of this report may be used or reproduced or quoted in any manner whatsoever in Taiwan by the press or any other person without the express written consent of BofA Securities.
This document provides general information only, and has been prepared for, and is intended for general distribution to, BofA Securities clients. Neither the information nor any opinion expressed constitutes an offer or an invitation to make an offer, to buy or sell any securities or other financial instrument or any derivative related to such securities or instruments (e.g., options, futures, warrants, and contracts for differences). This document is not intended to provide personal investment advice and it does not take into account the specific investment objectives,

financial situation and the particular needs of, and is not directed to, any specific person(s). This document and its content do not constitute, and should not be considered to constitute, investment advice for purposes of ERISA, the US tax code, the Investment Advisers Act or otherwise. Investors should seek financial advice regarding the appropriateness of investing in financial instruments and implementing investment strategies discussed or recommended in this document and should understand that statements regarding future prospects may not be realized. Any decision to purchase or subscribe for securities in any offering must be based solely on existing public information on such security or the information in the prospectus or other offering document issued in connection with such offering, and not on this document.

Securities and other financial instruments referred to herein, or recommended, offered or sold by BofA Securities, are not insured by the Federal Deposit Insurance Corporation and are not deposits or other obligations of any insured depository institution (including, Bank of America, N.A.). Investments in general and, derivatives, in particular, involve numerous risks, including, among others, market risk, counterparty default risk and liquidity risk. No security, financial instrument or derivative is suitable for all investors. Digital assets are extremely speculative, volatile and are largely unregulated. In some cases, securities and other financial instruments may be difficult to value or sell and reliable information about the value or risks related to the security or financial instrument may be difficult to obtain. Investors should note that income from such securities and other financial instruments, if any, may fluctuate and that price or value of such securities and instruments may rise or fall and, in some cases, investors may lose their entire principal investment. Past performance is not necessarily a guide to future performance. Levels and basis for taxation may change.

This report may contain a short-term trading idea or recommendation, which highlights a specific near-term catalyst or event impacting the issuer or the market that is anticipated to have a short-term price impact on the equity securities of the issuer. Short-term trading ideas and recommendations are different from and do not affect a stock's fundamental equity rating, which reflects both a longer term total return expectation and attractiveness for investment relative to other stocks within its Coverage Cluster. Short-term trading ideas and recommendations may be more or less positive than a stock's fundamental equity rating.

BofA Securities is aware that the implementation of the ideas expressed in this report may depend upon an investor's ability to "short" securities or other financial instruments and that such action may be limited by regulations prohibiting or restricting "shortselling" in many jurisdictions. Investors are urged to seek advice regarding the applicability of such regulations prior to executing any short idea contained in this report.

Foreign currency rates of exchange may adversely affect the value, price or income of any security or financial instrument mentioned herein. Investors in such securities and instruments, including ADRs, effectively assume currency risk.

BofAS or one of its affiliates is a regular issuer of traded financial instruments linked to securities that may have been recommended in this report. BofAS or one of its affiliates may, at any time, hold a trading position (long or short) in the securities and financial instruments discussed in this report.

BofA Securities, through business units other than BofA Global Research, may have issued and may in the future issue trading ideas or recommendations that are inconsistent with, and reach different conclusions from, the information presented herein. Such ideas or recommendations may reflect different time frames, assumptions, views and analytical methods of the persons who prepared them, and BofA Securities is under no obligation to ensure that such other trading ideas or recommendations are brought to the attention of any recipient of this information.

In the event that the recipient received this information pursuant to a contract between the recipient and BofAS for the provision of research services for a separate fee, and in connection therewith BofAS may be deemed to be acting as an investment adviser, such status relates, if at all, solely to the person with whom BofAS has contracted directly and does not extend beyond the delivery of this report (unless otherwise agreed specifically in writing by BofAS). If such recipient uses the services of BofAS in connection with the sale or purchase of a security referred to herein, BofAS may act as principal for its own account or as agent for another person. BofAS is and continues to act solely as a broker-dealer in connection with the execution of any transactions, including transactions in any securities referred to herein.

Copyright and General Information:

Materials prepared by BofA Global Research personnel are based on public information. Facts and views presented in this material have not been reviewed by, and may not reflect information known to, professionals in other business areas of BofA Securities, including investment banking personnel. BofA Securities has established information barriers between BofA Global Research and certain business groups. As a result, BofA Securities does not disclose certain client relationships with, or compensation received from, such issuers. To the extent this material discusses any legal proceeding or issues, it has not been prepared as nor is it intended to express any legal conclusion, opinion or advice. Investors should consult their own legal advisers as to issues of law relating to the subject matter of this material. BofA Global Research personnel's knowledge of legal proceedings in which any BofA Securities entity and/or its directors, officers and employees may be plaintiffs, defendants, co-defendants or co-plaintiffs with or involving issuers mentioned in this material is based on public information. Facts and views presented in this material that relate to any such proceedings have not been reviewed by, discussed with, and may not reflect information known to, professionals in other business areas of BofA Securities in connection with the legal proceedings or matters relevant to such proceedings.

This information has been prepared independently of any issuer of securities mentioned herein and not in connection with any proposed offering of securities or as agent of any issuer of any securities. None of BofAS any of its affiliates or their research analysts has any authority whatsoever to make any representation or warranty on behalf of the issuer(s). BofA Global Research policy prohibits research personnel from disclosing a recommendation, investment rating, or investment thesis for review by an issuer prior to the publication of a research report containing such rating, recommendation or investment thesis.

Any information relating to the tax status of financial instruments discussed herein is not intended to provide tax advice or to be used by anyone to provide tax advice. Investors are urged to seek tax advice based on their particular circumstances from an independent tax professional.

The information herein (other than disclosure information relating to BofA Securities and its affiliates) was obtained from various sources and we do not guarantee its accuracy. This information may contain links to third-party websites. BofA Securities is not responsible for the content of any third-party website or any linked content contained in a third-party website. Content contained on such third-party websites is not part of this information and is not incorporated by reference. The inclusion of a link does not imply any endorsement by or any affiliation with BofA Securities. Access to any third-party website is at your own risk, and you should always review the terms and privacy policies at third-party websites before submitting any personal information to them. BofA Securities is not responsible for such terms and privacy policies and expressly disclaims any liability for them.

All opinions, projections and estimates constitute the judgment of the author as of the date of publication and are subject to change without notice. Prices also are subject to change without notice. BofA Securities is under no obligation to update this information and BofA Securities ability to publish information on the subject issuer(s) in the future is subject to applicable quiet periods. You should therefore assume that BofA Securities will not update any fact, circumstance or opinion contained herein.

Certain outstanding reports or investment opinions relating to securities, financial instruments and/or issuers may no longer be current. Always refer to the most recent research report relating to an issuer prior to making an investment decision.

In some cases, an issuer may be classified as Restricted or may be Under Review or Extended Review. In each case, investors should consider any investment opinion relating to such issuer (or its security and/or financial instruments) to be suspended or withdrawn and should not rely on the analyses and investment opinion(s) pertaining to such issuer (or its securities and/or financial instruments) nor should the analyses or opinion(s) be considered a solicitation of any kind. Sales persons and financial advisors affiliated with BofAS or any of its affiliates may not solicit purchases of securities or financial instruments that are Restricted or Under Review and may only solicit securities under Extended Review in accordance with firm policies.

Neither BofA Securities nor any officer or employee of BofA Securities accepts any liability whatsoever for any direct, indirect or consequential damages or losses arising from any use of this information.