

1 *Counsel for Plaintiff*

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8 **UNITED STATES DISTRICT COURT**
9 **CENTRAL DISTRICT OF CALIFORNIA**

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11 DHIMANT PATEL, Individually and on
12 Behalf of All Others Similarly Situated,

13 Plaintiff,

14 v.

15
16 EDWARDS LIFESCIENCES
17 CORPORATION, BERNARD J.
18 ZOVIGHIAN, LARRY L. WOOD,
and SCOTT B. ULLEM

19 Defendants.
20
21

Case No. 8:24-cv-02221

CLASS ACTION

**COMPLAINT FOR VIOLATIONS
OF THE FEDERAL SECURITIES
LAWS**

DEMAND FOR JURY TRIAL

1 Plaintiff Dhimant Patel (“Plaintiff”), individually and on behalf of all other
2 persons similarly situated, by his undersigned attorneys, alleges in this Complaint
3 for violations of the federal securities laws (the “Complaint”) the following based
4 upon knowledge with respect to his own acts, and upon facts obtained through an
5 investigation conducted by his counsel, which included, *inter alia*: (a) review and
6 analysis of relevant filings made by Edwards Lifesciences Corporation (“Edwards”
7 or the “Company”) with the United States Securities and Exchange Commission (the
8 “SEC”); (b) review and analysis of Edwards’ public documents, conference calls,
9 press releases, and stock chart; (c) review and analysis of securities analysts’ reports
10 and advisories concerning the Company; and (d) information readily obtainable on
11 the internet.

12 Plaintiff believes that further substantial evidentiary support will exist for the
13 allegations set forth herein after a reasonable opportunity for discovery. Most of the
14 facts supporting the allegations contained herein are known only to the defendants
15 or are exclusively within their control.

16 NATURE OF THE ACTION

17 1. This is a federal securities class action on behalf of all investors who
18 purchased or otherwise acquired Edwards securities between February 6, 2024 to
19 July 24, 2024, inclusive (the “Class Period”), seeking to recover damages caused by
20 Defendants’ violations of the federal securities laws (the “Class”).

21 2. Defendants provided investors with material information concerning
22 Edwards’ expected revenue for the fiscal year 2024, particularly as it related to the
23 growth of the Company’s core product, Transcatheter Aortic Valve Replacement
24 (“TAVR”). Defendants’ statements included, among other things, strong
25 commitment to the TAVR platform, confidence in the Company’s ability to
26 capitalize on a subset of untreated patients through scaling of its various patient
27

1 activation activities, and continued claims of significant demand in allegedly lower-
2 penetrated markets.

3 3. Defendants provided these overwhelmingly positive statements to
4 investors while, at the same time, disseminating materially false and misleading
5 statements and/or concealing material adverse facts concerning the true state of
6 Edwards' TAVR platform; notably, that the Company's claims and confidence
7 relied far too heavily on their perceived ability to engage the claimed low-treatment-
8 rate population of patients and an overestimation of the desire for hospitals and other
9 care facilities to continue to utilize and otherwise commit resources to the TAVR
10 procedures over newer, innovative treatment alternatives.

11 4. On July 24, 2024, Edwards unveiled below-expectation financial
12 results for the second quarter of fiscal 2024 and, in particular, slashed its revenue
13 guidance for the TAVR platform for the full fiscal year 2024. The Company
14 attributed the TAVR setback on the "continued growth and expansion of structural
15 heart therapies ... [which] put pressure on hospital workflows." Investors
16 understood this to mean that developments in new procedures, including
17 Defendant's own Transcatheter Mitral and Tricuspid Therapies ("TMTT"), put
18 significant strain on hospital structural heart teams such that they were under-
19 utilizing TAVR, despite the Company's continued claim of a significantly under-
20 treated patient population. Moreover, the Company announced three acquisitions
21 during the second quarter designed to embolden their treatments alternative to
22 TAVR, suggesting further that the company was aware of the potential for the TAVR
23 platform's decelerated growth.

24 5. Investors and analysts reacted immediately to Edwards' revelations.
25 The price of Edwards' common stock declined dramatically. From a closing market
26 price of \$86.95 per share on July 24, 2024, Edwards' stock price fell to \$59.70 per
27 share on July 25, 2024, a decline of about 31.34% in the span of just a single day.
28

JURISDICTION AND VENUE

6. Plaintiff brings this action, on behalf of himself and other similarly situated investors, to recover losses sustained in connection with Defendants’ fraud.

7. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

9. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Edwards is headquartered in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

10. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

11. Plaintiff purchased Edwards common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants’ fraud. Plaintiff’s certification evidencing his transaction(s) in Edwards is attached hereto.

12. Edwards Lifesciences Corporation is a California corporation with its principal executive offices located at 1 Edwards Way, Irvine, CA 92614. During the Class Period, the Company’s common stock traded on the New York Stock Exchange (the “NYSE”) under the symbol “EW.”

13. Defendant Bernard J. Zovighian (“Zovighian”) was, at all relevant times, the Chief Executive Officer and Director of Edwards.

1 14. Defendant Larry L. Wood (“Wood”) was, at all relevant times, the
2 Corporate Vice President and the Group President of TAVR and Surgical Structural
3 Heart Therapies of Edwards.

4 15. Defendant Scott B. Ullem (“Ullem”) was, at all relevant times, the
5 Corporate Vice President and Chief Financial Officer of Edwards.

6 16. Defendants Zovighian, Wood, and Ullem are sometimes referred to
7 herein as the “Individual Defendants.” Edwards together with the Individual
8 Defendants are referred to herein as the “Defendants.”

9 17. The Individual Defendants, because of their positions with the
10 Company, possessed the power and authority to control the contents of Edwards’
11 reports to the SEC, press releases, and presentations to securities analysts, money
12 and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual
13 Defendant was provided with copies of the Company’s reports and press releases
14 alleged herein to be misleading prior to, or shortly after, their issuance and had the
15 ability and opportunity to prevent their issuance or cause them to be corrected.
16 Because of their positions and access to material non-public information n available
17 to them, each of these Individual Defendants knew that the adverse facts specified
18 herein had not been disclosed to, and were being concealed from, the public, and
19 that the positive representations which were being made were then materially false
20 and/or misleading. The Individual Defendants are liable for the false statements
21 pleaded herein, as those statements were each “group-published” information, the
22 result of the collective actions of the Individual Defendants.

23 18. Edwards is liable for the acts of the Individual Defendants, and its
24 employees under the doctrine of respondeat superior and common law principles of
25 agency as all the wrongful acts complained of herein were carried out within the
26 scope of their employment with authorization.

1 19. The scienter of the Individual Defendants, and other employees and
2 agents of the Company are similarly imputed to Edwards under respondeat superior
3 and agency principles.

4 **SUBSTANTIVE ALLEGATIONS**

5 **A. Company Background**

6 20. Edwards is an international company that researches, develops,
7 provides products and technologies for heart valve repair and replacement therapies,
8 as well as critical care monitoring solutions.

9 21. Edwards categorizes its therapies and technologies into four categories:
10 Transcatheter Aortic Valve Replacement (“TAVR”), Transcatheter Mitral and
11 Tricuspid Therapies (“TMTT”), Surgical Structural Heart therapies, and Critical
12 Care therapies.

13 **B. The Defendants Materially Misled Investors Concerning the**
14 **Growth of Edwards’ Flagship TAVR Therapies**

15 *February 6, 2024*

16 22. On February 6, 2024, Edwards Lifesciences issued a press release
17 publishing their fourth quarter results, highlighting, in pertinent part, that “Q4 TAVR
18 sales grew 13 percent; constant currency sales grew 12 percent.” Speaking on the
19 results, CEO Bernard Zovighian was quoted stating, in relevant part:

20 In 2023, our team made significant progress advancing
21 transformational therapies for patients while delivering strong financial
22 performance. Full year sales increased 12 percent, including impressive
23 growth across each of our four product groups. We exited the year with
24 strong momentum driven by our broad portfolio of innovative
25 therapies. In 2024, we anticipate launching multiple breakthrough
26 technologies globally and advancing important clinical trials as we
27 embark on a new era of structural heart innovation. These
28 breakthroughs, along with significant unmet patient needs, give us
confidence in our ability to accelerate growth in 2025 and beyond.

1 23. The press release further detailed the Company's TAVR results, in
2 pertinent part:

3 For the quarter, the company reported global TAVR sales of \$979
4 million, an increase of 13 percent versus the prior year, or 12 percent
5 on a constant currency basis. Performance was driven by double-digit
6 constant currency growth in the U.S., Europe and Japan. ***The***
7 ***company's competitive position was stable globally and local selling***
8 ***prices were also stable.***

9 In the U.S., the company remains pleased with the continued expansion
10 and adoption of the SAPIEN 3 Ultra RESILIA platform. This
11 technology builds on Edwards' leadership in tissue technology and
12 durability by combining advancements in tissue science with the
13 industry leading SAPIEN 3 Ultra valve to offer the only dry storage
14 transcatheter heart valve for U.S. patients today. ***The company remains***
15 ***confident that the future of TAVR remains strong driven by an***
16 ***increased focus on patient activation, a platform that delivers lifetime***
17 ***management for aortic stenosis patients, advances in new***
18 ***technologies such as RESILIA tissue, as well as indication expansion***
19 ***and increased global adoption.***

20 Looking ahead, the company is pleased with the recently announced
21 CE Mark approval for the SAPIEN 3 Ultra RESILIA platform and plans
22 a disciplined launch in Europe. Long-term, the company continues to
23 anticipate excellent opportunities for growth, as international adoption
24 of TAVR therapy remains quite low.

25 (Emphasis added).

26 24. During the same-day Earnings Call, CEO Bernard Zovighian
27 elaborated on TAVR's performance and confidently spoke about the Company's
28 expectations for TAVR in 2024, stating, in relevant part,

We are pleased with our strong 2023 financial performance with full
year sales up 12% to \$6 billion, including strong growth across each of
our 4 product groups. We invested more than \$1 billion in research and
development, and we achieved key strategic milestones, including the
introduction of new technologies and indication expansion to ensure
sustainable healthy growth in the near, mid and long term. We exited
the year with strong momentum with Q4 growth of 13% and TAVR

1 growth of 12%. These results were better than expected, driven by our
2 broad portfolio of innovative therapies.

3 In 2024, we are well positioned to enter a new era of structural heart
4 innovation. In TAVR, we are strengthening our leadership. We are
5 experiencing strong adoption of our flagship SAPIEN 3 Ultra RESILIA
6 and continuing enrollment in our ALLIANCE pivotal trial for our next-
7 gen TAVR technology, SAPIEN X4.

8 ...

9 Now I will provide some additional detail by product group. ***In TAVR,***
10 ***our full year 2023 global sales of \$3.9 billion increased 10.6% year-***
11 ***over-year. Our U.S. and OUS sales growth rates were similar. In the***
12 ***fourth quarter, our global TAVR sales of 979 million increased 12%***
13 ***year-over-year. Performance was driven by double-digit growth in the***
14 ***U.S., Europe and Japan.***

15 The company's competitive position was stable globally and local
16 selling price were also stable. In the U.S., we remain pleased with the
17 continued expansion and adoption of a SAPIEN 3 Ultra RESILIA
18 platform. This technology builds on Edwards' long-standing leadership
19 in tissue technology and durability by combining advancements in
20 tissue science with the industry-leading SAPIEN 3 Ultra valve.

21 Developing safe, effective and durable heart valve requires significant
22 long-term commitment, and we are proud to be on 65 years on valve
23 innovation while leveraging the expertise and know-how of more than
24 2,000 engineers and R&D specialists across the company. We are proud
25 of uninterrupted leadership in structural heart and will continue to
26 invest vigorously in these platforms. ***In addition, our scaling of patient***
27 ***activation initiatives, along with next-gen TAVR and additional***
28 ***evidence on asymptomatic and moderate AS patients position us for***
healthy, sustainable TAVR growth well into the future.

Outside of the U.S., in the fourth quarter, our double-digit growth was
comparable with our global TAVR growth, driven by Europe and
Japan. Long term, we continue to anticipate excellent opportunities
for growth. The international adoption of TAVR therapy remained
quite low in many regions. In Europe, Edwards sales growth was driven
by the broad-based adoption of our SAPIEN platform. ***It is***

1 ***encouraging that the growth in Q4 was widespread across all major***
2 ***countries.***

3 Looking ahead, we are pleased with the recently announced CE Mark
4 approval for SAPIEN 3 Ultra RESILIA, and we are planning for a
5 disciplined launch. We were pleased with our sales growth in Japan,
6 and as expected, we grew faster than overall procedural growth. After
7 more than 20 years of rigorous clinical experience and over 1 million
8 patients treated with SAPIEN around the world, ***our TAVR platform is***
positioned for continued global leadership and strong sustainable
growth.

9 ***Given the undertreatment rates, we are confident in the future of***
10 ***TAVR, driven by greater awareness, patient activation, a platform***
11 ***that delivers lifetime management for AS patients, advances in new***
12 ***technologies such as RESILIA as well as indication expansion and***
increased global adoption.

13 In TAVR, we will continue to drive global adoption of SAPIEN 3 Ultra
14 RESILIA, present pivotal trial data from early TAVR, studying
15 asymptomatic AS patients and enrolling ALLIANCE a pivotal trial
16 studying the next-generation SAPIEN X4.

17 (Emphasis added).

18 25. During the question-and-answer segment of the earnings call,
19 Defendants fielded multiple questions concerning TAVR and continued to display
20 confidence in TAVR's market and growth potential in their answers during the
21 following pertinent exchanges:

22 <Q: Robert Justin Marcus – JPMorgan Chase & Co – Analyst> . . .
23 Maybe one on the TAVR market. We have the exciting data from early
24 TAVR coming later this year at TCT. How do you think about what
25 that does to the TAVR market growth going forward? Do you put up
26 double-digit growth in the fourth quarter, that's what guidance includes
27 the next few years for the most part. How do you think about what's
28 coming from low, intermediate and high risk and severe? And then how
do you think about what asymptomatic adds? Is that just what helps
keep you with double digit? Or can that help accelerate growth?

1 <A: Larry L. Wood> Yes. This is Larry. That's a great question. I think
2 the first thing is we're just going to learn a lot from this trial. There's a
3 lot of unknown questions out there in terms of what percentage of
4 patients are truly asymptomatic when subjected to a stress test?

5 I think how fast do people progress and what happens to people why
6 they're waiting. I think the biggest thing about it is, as we've talked
7 about, and I spent a lot of time at the investor conference, the time from
8 a patient to get diagnosed to treated is just really long. And a lot of that
9 is the interpretation, the guidelines and this overlay of symptoms. And
10 it's all really stand in the gears preventing the patients from moving
11 through. And unfortunately, given the deadliness of the disease, a lot of
12 people never actually make it to therapy.

13 I think with the early TAVR trial, assuming that it's successful, it will
14 just streamline that process where we can just apply guideline criteria
15 to aortic stenosis, and it won't require this additional evaluation of
16 symptoms and people can just move through. ***But remember, only
17 about 13% of patients right now with severe aortic stenosis actually
18 get treated. So there's a huge undertreatment right now. We think
19 asymptomatic just adds to that.***

20 <A: Bernard J. Zovighian> In addition, Robbie, what I like is our
21 commitment to -- after 20 years of TAVR, we are still in a super
22 committed to bring big evidence. Look at these 2 trials, progress and
23 early TAVR. This is a potential for sure not to learn more, but also to
24 expand indication. To change the guidelines. So as a leader in the space,
25 for sure, we like it, we are committed. ***But I believe that in the next 10
26 years, here in TAVR, we are going to see some very exciting things
27 happening.***

28 ...

<Q: Patrick Andrew Robert Wood - Morgan Stanley – Former Research
Analyst> Amazing. I guess maybe for the first one on TAVR and Japan
in general. Do you think you've been taking back some share post
trialing. It sounded like you feel very good about the market, and you
were taking back some share on that side. Just any color you could give
there would be great.

1 <A: Larry L. Wood> Sure. I think what happens when new technology
2 comes into Japan just because of the way the certification process works
3 and people having to move through that process, that certainly had an
4 impact for us. ***I think in Q4, we grew faster than the market.*** And I
5 think that really relates to some of the trialing ending and people kind of
6 moving back to our platform. But this is sort of something that goes on,
7 ***but we're very pleased with how we grew in Japan in Q4 and continue
to look forward to that market growing because it's a very -- it's a much
lower penetrated market than places like the U.S. and Europe. So we
continue to see that as a long-term growth driver for us.***

8 ...

9
10 <Q: Vijay Muniyappa Kumar – Evercore ISI Institutional Equities –
11 Senior MD and Head of Medical Supplies & Devices and Life Science
12 Tools & Diagnostics Team> Congratulations on a nice sprint here.
13 Maybe one last question on EVOQUE . . . Like, there's a reason this
14 valve was a forgotten valve. So I'm curious what wakes up physicians
15 to take the valve seriously, maybe compare in contrast on how this
16 adoption curve could look like versus I don't know if TAVR is a good
17 example, but I would love your comments.

18 ...

19 <A: Bernard J. Zovighian> . . . And we are very excited. Think about
20 TAVR. 20 years later, we are still generating evidence. We are still
21 innovating with Ultra RESILIA X4. ***We still believe that there is a way
for TAVR to grow healthy double digit in the many years to come
globally.***

22 ...

23 <Q: Matthew Stephan Miksic – Barclays Bank PLC – Research
24 Analyst> Okay. And then the TAVR side, did you see any results you
25 feel from these field activations and patient activation efforts in Q4? Or
26 is that something that's still to come?

27 <A: Scott B. Ullem> Matt, I think we saw some benefit from the patient
28 activation initiatives that we have in place. It's tough to isolate those
from the other efforts that we have underway to continue to support the

1 growth of TAVR. ***But no, that's certainly helping drive growth in the***
2 ***fourth quarter and beyond.***

3 <A: Larry L. Wood> ***Just to add on to this, I mean, I think it'd be***
4 ***incorrect to say our patient activation efforts are just starting to pay***
5 ***dividends now.*** We've been doing patient activation for the last, I don't
6 know, 5 or 6 years through our digital campaigns, through some of our
7 website stuff, some of our patient resources, some of the general
8 cardiology awareness events we do and a number of other things that
9 have been driving this. ***So I think patient activation has been***
10 ***contributing all the way along the way.***

11 ***I think what we're talking about now, though, is a much more***
12 ***sophisticated approach and program to really tapping in to these***
13 ***untreated patients that are in the system, but hospitals don't really***
14 ***realize that they're there. And how do we bridge those gaps. And that's***
15 ***really where our activation now is because we know the patients are***
16 ***there. We know they're diagnosed with an echo, but they're not***
17 ***moving. And so it's just a matter of tapping into those patients in the***
18 ***right way and getting the accelerated through the system.***

19 <A: Bernard J. Zovighian> What's fair to say though is, in the past few
20 years, we have done many pilots, many initiatives. We have extracted
21 so many learnings. ***What we are doing right now is scaling. We are***
22 ***scaling and spending. We are spending resources in Q4 last year, this***
23 ***year and the next few years. So you are going to see more and more***
24 ***because we believe there are so many patients in need not receiving a***
25 ***treatment.***

26 (Emphasis added).

27 April 25, 2024

28 26. On April 25, 2024, Defendants published their first quarter fiscal year
2024 results, announcing that “Q1 TAVR sales grew 6%; constant currency sales
grew 8% adjusted for billing days.”

27 27. During the corresponding earnings call discussing the results,
28 Defendants provided some clarity to TAVR’s slow growth in the first quarter. In
pertinent part, CEO Zovighian stated,

1 Now I will provide some additional detail on Q1 results by product
2 group. In TAVR, first quarter global sales of \$1 billion increased 8%
3 year-over-year when adjusted for billing days. Q1 marked the first
4 quarter that Edwards TAVR sales exceeded \$1 billion, an exciting
5 milestone for our team and a testament to clinician confidence in our
6 leading technology. Performance was driven by growth in the U.S. and
7 Japan, Edwards' global competitive position and selling prices were
8 both stable. In the U.S., our year-over-year first quarter TAVR sales
9 growth rate was higher than our global constant currency growth rate.
10 We estimate total procedure growth was stable. Procedure volumes
11 increased as the quarter progressed.

12 We remain pleased with the continued performance of our best-in-class
13 TAVR platform. SAPIEN 3 Ultra RESILIA, which build on Edwards'
14 long-standing leadership in tissue technology and durability. This
15 innovative technology now makes up the majority of our sales in the
16 U.S. This platform is supported by the robust real-world data for more
17 than 10,000 patients in the TVT Registry that demonstrated excellent
18 outcomes across hundreds of centers.

19 ...

20 Outside of the U.S., in the first quarter, our constant currency TAVR
21 sales growth was slightly below our global TAVR growth. Strong
22 growth in Japan and the rest of the world was partially offset by slower-
23 than-expected growth in Europe. In Europe, our results were softer than
24 expected in Q1. But we expect full year 2024 performance to normalize.
25 We are actively preparing for the launch of SAPIEN 3 Ultra RESILIA
26 in Europe, and we anticipate introducing the technology into the
27 European market in Q2.

28 In Japan, we continue to see strong TAVR adoption driven by SAPIEN
3 Ultra RESILIA. We believe AS remains a significantly undertreated
disease among the substantial elderly population and continue to focus
on expanding the ability of an evidence supporting this therapy.

In closing, we are confident that Edwards is positioned for healthy and
sustainable TAVR growth well into the future, driven by our
development of differentiated TAVR technology, our deep
commitment to advancing patient care through high-quality clinical
evidence and our investment in patient activation initiatives.

1
2 Importantly, we are proud of our groundbreaking research into the
3 treatment of AS through our early TAVR and PROGRESS trial, which
4 could fundamentally change how AS patients are treated. We remain
5 confident in our full year TAVR sales growth of 8% to 10%. We expect
6 higher year-over-year second half growth rate than in the first and
7 second quarter.

8 (Emphasis added).

9 28. The question-and-answer portion of the call followed, which again
10 heavily featured questions related to TAVR's growth and ongoing potential. In their
11 responses, Defendants again touted TAVR's success and displayed confidence in
12 continued growth for the product portfolio in relevant part during the following
13 exchanges:

14 <Q: Robert Justin Marcus - JPMorgan Chase & Co. – Analyst> Great.
15 Maybe a follow-up. I caught the comments that the U.S. TAVR grew
16 faster than the global organic TAVR growth rate and that procedure as
17 accelerated throughout the quarter. So how are you thinking about
18 TAVR growth for the rest of the year? And do you feel like the U.S.
19 has finally recovered after some of the setbacks you saw during the
20 disruptive years of COVID?

21 <A: Bernard J. Zovighian> Thanks, Robbie. Let me start, and again, I
22 will ask Larry to add some insights here. ***So when we put together a
23 guidance for the year, the guidance 8% to 10%, we knew that the
24 growth will ramp throughout the year and that Q1 will be our lowest
25 growth quarter. So we feel we are confident about our 8% to 10%. We
26 feel confident about what's happening in the U.S. Share and price are
27 stable. So we feel good about all of that.***

28 Larry, you want to add anything?

<A: Larry L. Wood> Yes. I don't have a lot to add. We saw good
progression throughout the quarter. It's always a little slow in January
as we come out of the break, but we are pleased with how the quarter
went overall. And we remain excited about the year. We have a lot of
activities on patient activation. We have a huge data set coming out of
TCT that I think all of us are going to be excited to see what that say,

1 what those data say and how they inform the field. *And so I continue*
2 *to believe we have a long runway long term with TAVR and it is good*
3 *to see the U.S. kind of out COVID, I think, finally in the rearview*
4 *mirror, and we can just focus on accelerating patient care.*

5 ...

6 <Q: Travis Lee Steed – BofA Securities – Managing Director>
7 Congrats on a good quarter. Maybe on TAVR again, curious why
8 European growth was slower than expected. And then on the billing
9 days, were those U.S. or OUS and those come back in any quarter?

10 <A: Larry L. Wood> Yes, thanks. *Yes, overall, we felt good about the*
11 *quarter, and we just talked about the U.S. We saw a lot of strength in*
12 *Japan, but Europe was -- it grew year-over-year and it grew*
13 *sequentially, and we lost a couple of billing days. But even with that,*
14 *we were a little bit disappointed with our overall growth in Europe.*
15 We saw some pretty aggressive pricing from competitors that I think
16 led to some trialing. But we're really excited that we're launching S3UR
17 that actually starts this month, and we're excited to bring that
18 technology to Europe, *and we expect these to normalize through the*
19 *course of the year.*

20 ...

21 <Q: Travis Lee Steed> All right. That's helpful. And then on TAVR
22 and some of that you've been doing with Egnite and kind of helping
23 drive center growth and diagnosis. Curious to see how that's going and
24 at what point do you start to kind of scale those programs out and an
25 impact on -- see the impact on TAVR growth?

26 <A: Larry L. Wood> Yes. *We have a lot of patient activation activities*
27 *where there's a lot of work that we do.* We have multiple fronts, and
28 Egnite is just one part of our strategy there. But we're excited about
what these technologies can do. *And there are so many patients, if you*
look at the [indiscernible] publication, and I know he's spoken to you
guys before, there's just a lot of patients upstream that aren't moving
through the system at the speed in which they should. And I think
there's a patient identification aspect, there's a referral aspect.

1 So we have multiple work streams working on this. But I think the
2 appreciation and understanding for the undertreatment of aortic stenosis
3 is growing. And I think as that grows and people start to understand the
4 magnitude of the problem, I think it gives more opportunity for our
patient activation strategy to take hold.

5 <A: Bernard J. Zovighian> And maybe in addition, Larry, I'm very
6 proud about what we are doing. We are the only one basically having a
7 deep commitment to advancing science for AS patients through the
8 progress and early TAVR trial. ***So this is truly our commitment, but***
9 ***we feel that there is a ton of potential. These patients are***
10 ***underdiagnosed [indiscernible], and we are committed to offer***
11 ***treatment for these patients. So as a company, very proud about how***
12 ***we do all of this.***

13 ...

14 <Q: Lawrence H. Biegelsen - Wells Fargo Securities, LLC – Senior
15 Medical Device Equity Research Analyst> I just wanted on TAVR, I
16 wanted to confirm, Bernard, that Q2 TAVR growth will be better than
17 Q1, in response to Robbie's question. And why do you expect TAVR
18 growth to accelerate in the second half? And how are you guys
19 factoring in the SMART trial results? And I have one follow-up.

20 <A: Larry L. Wood> Yes. Yes, we do expect to have procedures to
21 ramp. That's always been a part of our plan, and so we continue to
22 expect that to happen. And I think it's a lot of things, Larry, I think it's
23 a lot of our patient activation work. But it's also just the market
24 continues to improve, and ***we're very pleased where we finished Q4***
25 ***last year. We were happy with the ramp in Q1. So I think we do expect***
26 ***to see an increase in Q2 over Q1. But even with that, we expect the***
27 ***second half to have a higher growth rate than the first half. So I think***
28 ***that that's good.***

...

<Q: Matthew Stephan Miksic – Barclays Bank PLC – Research
Analyst> Just one question on sort of TAVR and transcatheter valve
growth, and I'll just keep it to one. If you could maybe talk a little bit
about the launch of EVOQUE and the activity that, that drives in some
of your major centers. And I guess how you're -- you and the team in

1 the field is kind of managing those activity levels [indiscernible] centers
2 versus the continuing volumes that they perform in TAVR. Just maybe
3 any color or thoughts on how that might play into the total transcatheter
4 business?

5 ...

6 <A: Bernard J. Zovighian> *It is fair to say that so far, we have not*
7 *faced a big challenge in terms of center, having a lack of capacity to*
8 *be able to treat the patients, whether TAVR patients or EVOQUE*
9 *patients.*

10 ...

11 <Q: Shagun Singh Chadha – RBC Capital Markets – Research
12 Analyst> Sorry about earlier. It just sounds like U.S. TAVR growth was
13 high single digits. Is that fair? Was it about 10%? And other drivers that
14 can get you to consistent double-digit growth in the foreseeable future?
15 Just what's your confidence there?

16 ...

17 <A: Scott B. Ullem> Yes. I'll take the first part of that about U.S. TAVR
18 growth. We try not to be too specific about breaking down every region.
19 But what we can say is that TAVR in the U.S. grew faster than our
20 global underlying growth rate for TAVR in the first quarter. Larry, do
21 you want to talk about the other pieces?

22 (Emphasis added).

23 29. In closing, CEO Zovighian pertinently noted on the call that “TAVR,
24 for sure, it is the largest business for us. It’s still our #1 focus. TAVR has a lot of
25 growth potential.”

26 June 5, 2024

27 30. On June 5, 2024, Defendant Ullem presented on behalf of the Company
28 at Jefferies 2024 Global Healthcare Conference. During the interview-structured
presentation, CFO Ullem pertinently discussed TAVR’s impact on Edwards’
guidance and outlook for FY 2024 and beyond. In relevant part:

1 <Q: Matthew Charles Taylor, Jefferies LLC, Senior Analyst> So let's
2 start with TAVR. Could you talk a little bit about the TAVR trends in
3 Q1? I guess you grew a little over 6%, about 7%. And talked about
4 some trialing in Europe and some pricing pressure there.

5 So I guess, could you give us an overview on what's happening, if
6 there's any update in Q2? And then overall, how do you expect the
7 TAVR market to grow and your growth to be within that?

8 <A: CFO Scott B. Ullem> Yes. So yes, ***TAVR, we started out in the***
9 ***first quarter with lower year-over-year growth rate than we expect for***
10 ***the full year.*** Our guidance for TAVR for the year is 8% to 10%. ***We***
11 ***always knew that the first half of the year was going to be a lower***
12 ***year-over-year growth environment than the second half of the year.***
13 ***That's been our plan, and we saw that in the first quarter again.***

14 Just breaking it down between the 4 areas of the world where we focus
15 our attention, U.S. grew faster than the OUS business in the first
16 quarter. Japan was our fastest big growing region in the first quarter. In
17 Japan, we saw some competitive pressure last year that abated in the
18 second half of last year, and we're back to more of a normalized growth
19 curve in Japan. ***In Europe, we were surprised a little bit in the first***
20 ***quarter by some of the competitive trialing that we saw. We expect the***
21 ***European environment though to normalize as we get later into 2024.***

22 ***And then the Rest of World where, today, we're in TAVR in over 60***
23 ***countries. And so there are big growth opportunities in other areas of***
24 ***the world, and that's been a pretty exciting area for us in 2024, and***
25 ***we think it will be in '25 and beyond.***

26 Overall, the business is performing well. There's still an environment
27 now where around 13% of patients who have aortic stenosis, severe
28 aortic stenosis get treated today. And it's a remarkably low treatment
rate, especially relative to other diseases with a high mortality rate like
severe aortic stenosis, and it ***gives us confidence that we should keep***
investing in this opportunity.

In fact, we just finished enrollment in an important clinical trial
studying aortic stenosis in patients who just have a moderate form of
the disease, where it has not progressed yet to severe. And we think
there's a real opportunity to help patients who need earlier intervention

1 to get their valve replaced and today are not on indication to do so with
2 TAVR.

3 There's another trial that's actually reading out later this year at the TCT
4 Conference, studying patients who have severe aortic stenosis without
5 symptoms. And if the trial shows what we think it will, it will be an
6 important opportunity to make this therapy available to patients who
7 have this deadly disease, but who did not get screened for care because
8 they don't have symptoms today.

9 So those are some of the factors that are underlying our current
10 performance and what we think are going to benefit our longer-term
11 growth trends as well.

12 (Emphasis added).

13 31. The above statements in Paragraphs 22 to 30 were false and/or
14 materially misleading. Defendants created the false impression that they possessed
15 reliable information pertaining to the Company's projected revenue outlook and
16 anticipated growth while also minimizing risk from seasonality and macroeconomic
17 fluctuations. In truth, TAVR's growth was at risk of decelerating. Edwards'
18 optimistic reports of TAVR's growth and anticipated ramp in the second quarter and
19 further ramp throughout the fiscal year fell short of reality as Defendants "patient
20 activation activities" failed to reach the perceived low-treatment-rate population
21 TAVR's growth relied upon obtaining and, further, Defendants relied far too heavily
22 or otherwise overstated hospital desire to continue to utilize the Company's TAVR
23 procedures over newer, innovative structural heart therapies.

24 **C. The Truth Emerges during Edwards' Second Quarter Earnings
25 Report**

26 July 24, 2024

27 32. On July 24, 2024, Defendants released their Q2FY24 TAVR results
28 below expectations and lowered FY24 projections for TAVR in pertinent part as
follows:

Highlights and Outlook

- Q2 sales grew 7%; constant currency sales grew 8%
- **Q2 TAVR sales grew 5%; constant currency sales grew 6%**
- Q2 TMTT sales grew 75%; increasing contribution to Edwards' growth
- Q2 EPS of \$0.61; adjusted¹ EPS of \$0.70
- Significant TAVR and TMTT clinical evidence to be presented at TCT in October 2024
- Positive EVOQUE introduction with excellent patient outcomes; NCD process on track
- Critical Care sale expected to close late Q3 2024
- Expect full-year 2024 Edwards sales growth of 8 to 10%; **lowering TAVR guidance to 5 to 7% from 8 to 10%**; increasing TMTT guidance to the higher end of \$320 to \$340 million

“Second quarter total company sales growth of 8 percent reflected strong contributions from our rapidly growing TMTT product group, **offset by lower-than-expected growth in TAVR**,” said Bernard Zovighian, CEO.

...

Transcatheter Aortic Valve Replacement (TAVR)

In the second quarter, **the company reported TAVR sales of \$1.0 billion, which grew 5%, or 6% on a constant currency basis**. Edwards' competitive position did not meaningfully change globally, **although the company experienced some regional pressures**, and pricing was maintained.

Edwards remains pleased with the performance of its SAPIEN 3 Ultra RESILIA platform, which is the leading platform in the U.S. and Japan. In the second quarter, Edwards began the introduction of the SAPIEN 3 Ultra RESILIA valve in Europe. The RESILIA tissue's anti-calcification technology is designed to address one of the primary causes of reintervention following heart valve replacement and provides the potential to extend the durability of the valve.

(Emphasis added).

1 33. During the same-day earnings call, CEO Zovighian elaborated on the
2 setbacks, highlighting that TAVR grew significantly more slowly than anticipated
3 and restated less than one month before the second quarter’s close. In pertinent part,
4 Defendant Zovighian stated:

5 *In the U.S., our year-over-year second quarter TAVR sales growth*
6 *was slightly below our global constant currency growth rate.* We
7 believe our U.S. competitive position was largely unchanged. *Second*
8 *quarter U.S. TAVR sales grew slower than expected.* The continued
9 growth and expansion of structural heart therapies, including newly
10 approved tricuspid therapies and other fast-growing structural heart
11 therapies put pressure on hospital workflows, which impacted TAVR.
12 These pressures were also observed in the recent spike in emergent
13 TAVR cases as reflected in claims data as centers adopt these new
14 therapies, and they become part of their standard processes, we expect
15 this will stabilize.

16 ...

17 In closing, *we now anticipate second half TAVR sales growth similar*
18 *to the first half year-over-year growth rate, 5% to 7% full year growth*
19 *rate versus previously guidance of 8% to 10%.* This equates to full year
20 global TAVR sales of \$4 billion to \$4.2 billion.

21 (Emphasis added).

22 34. During the call, Defendants also highlighted Edwards’ recent
23 acquisitions, stating in pertinent part:

24 Earlier this month, we announced the acquisition of Innovalve.
25 Innovalve early-stage technology will add to a growing pipeline of
26 innovative therapy in TMTT, and we expect to close the acquisition
27 later this year. We further expect that Innovalve technology, combined
28 with Edwards expertise in mitral disease will enhance the company
TMVR technologies to address large unmet structural heart patient
needs and support sustainable long-term growth.

...

1 Turning down to the strategic acquisition of JenaValve and Endotronix.
2 These acquisitions provide an expanded opportunity in new therapeutic
3 areas to address the unmet needs of AR and heart failure patients around
4 the world. Furthermore, the acquisition reflects our deep commitment
5 to advancing patient care through our unique strategy and reinforce our
6 confidence in Edwards sustainable long-term growth. Starting with
7 JenaValve, a pioneer in the transcatheter treatment of AR, a deadly
8 disease that impacts more than 100,000 patients in the U.S. alone and
9 is largely untreated today. Edwards anticipate U.S. FDA approval of
10 JenaValve Trilogy Heart Valve System in late 2025, which will
11 represent the first approved therapy for patients suffering from AR.
12 Edwards will invest to accelerate development of this novel technology
13 to enable earlier patient access. As the pioneers in valve innovation, we
14 believe we are best positioned to lead this next frontier of aortic valve
15 disease treatment. We expect this to be the beginning of a long-term
16 iterative strategy similar to TAVR.

17 Turning to Endotronix. Edwards made its first investment in the
18 company in 2016. So we are very familiar with the technology, the
19 opportunity and the employees, many structural heart patients Edwards
20 serve today also suffer from heart failure with a limited options. This
21 acquisition will expand Edwards Structural Heart portfolio into a new
22 therapeutic area to address the large unmet needs of patients suffering
23 from heart failure, which we believe has a significant long-term growth
24 opportunity.

25 Last month, Endotronix received FDA approval for Cordella, an
26 implantable pulmonary artery pressure sensor that directly measure the
27 leading indicator of congestion, following the publication of the
28 successful U.S. pivotal trial. We are pleased to enter the structural heart
therapeutic area with innovation, world-class science and clinical
evidence to provide access to life-saving technologies for patients
around the world. We anticipate this investment will strengthen its
leadership in structural heart innovation and represent long-term
growth opportunities. Minimal revenue contribution from JenaValve
and Endotronix is expected to begin late in 2025.

35. In the question-and-answer segment, Defendants elaborated on the
TAVR setback, driving home that TAVR's growth was slower than anticipated, and

1 not because of a lack of patients. In pertinent part, the following exchange
2 transpired:

3 <Q: Robert Justin Marcus, JP Morgan Chase Analyst> Two for me.
4 Maybe first, you talked about it in the script, but I was hoping you could
5 give a little more. TAVR has clearly come in below your initial
6 expectations for the year. The guidance has moved down, the U.S. is
7 slowing, OUS is facing pressure. We saw two of your smaller
8 competitors, but still competitors see pretty nice growth sequentially
9 and year-over-year so their TAVR is taking more in Europe and outside
10 the U.S., Japan. How are you thinking just about the underlying growth
11 rate of the TAVR market? And I appreciate it's a huge opportunity, and
12 it's still a lot to conquer in the future. But in, let's call it, the short to
13 medium term, how are you thinking about the overall market growth?
14 And is there anything you can do to help accelerate it?

15 <A: Larry L. Wood> Thanks, Robbie. Well, obviously, *we expected*
16 *growth rate to be higher in Q2 than it was*. We had a slow start in Q1,
17 but we were exiting March, and we felt good about where we were. So
18 *this did come as a surprise. I think when we reflect back on it and we*
19 *look more deeply at it, you have to think about all the things that have*
20 *shown up that are going to the same structural heart team at all of*
21 *these hospitals*. We're seeing rapid growth in mitral repair. *We're*
22 *seeing a lot of growth in other procedures. And we had 2 new therapy*
23 *approvals recently in the tricuspid space*.

24 I think a little bit we looked at the procedure volumes and the hospitals
25 have shown a pretty good job of being able to handle these things. *We*
26 *probably underestimated the burden of even starting these new*
27 *programs, even preparing to start these new programs because you*
28 *have to screen the patients early on, there's a lot of learning, screen*
failures, all of those things. And I think it's just taxing the teams.

29 Now in terms of things we can do to help, *there are certainly things we*
30 *can do to help. We can do a lot of imaging workups and take some of*
31 *the load off the team. We can do device prep. We can come in with*
32 *our benchmark program and teach them efficiencies and do those*
33 *things*. But once the program has been optimized, that it really does
34 come down to the hospital to add another team or add additional days
35 and do those sorts of things. So there are some things we can do, but
36 we can't do everything.

1
2 I think the other thing is, *I think, highlighting this for the clinicians. And we're very confident. This isn't some slowdown because there's*
3 *a lack of patients.* We didn't see any of the fundamentals change in
4 terms of new data that was concerning or any of these things. *I think*
5 *it's just a matter of the workflow right now. And we need to be able to*
6 *engage with hospitals, but two important things we saw is we saw an*
7 *increase in time from CT to procedure, which indicates patients are*
8 *waiting longer.*

9 *And the other thing that we saw was a sharp increase in the number*
10 *of cases being coded as emergent versus routine.* And I think that
11 speaks to these patients waiting in the queue as these workflow issues
12 sort out. So I think hospitals will certainly do that in time. These
13 patients don't wait well, and we know that there's a lot of them, but
14 we're going to have to continue to work through that with the hospitals.

15 <A: Bernard J. Zovighian> So let me add on what Larry said. *To be*
16 *fair, we are contributing a little bit on this pressure. At the same time,*
17 *we are benefiting. If you look at the TMTT growth in the quarter, so*
18 *we are contributing and benefiting at the same time.*

19 Now a big picture. We have seen this picture in the past, don't you think
20 we have similar hospital facing like more to do, more technology to
21 adopt, to be trained on new technologies and they are very good at
22 scaling, they are very good at learning, they are very good at adapting,
23 they are in their workflows in the cath lab. So we believe it is temporary.
24 And we are -- Daveen also with this team are with Larry partnering on
25 this one. So we are fully focusing on this one, helping in the hospital.
26 But we have faith, the hospital are going to do that, like they did it in
27 the last 10 years.

28 <Q: Robert Justin Marcus> Great. And maybe a follow-up to that.
Guidance implies roughly stable TAVR first half into second half. I
appreciate the need to be conservative, but it sounds like some of the
learnings you saw in second quarter could possibly help in the back half
of the year. Maybe just walk through the thought process of the 5% to
7% TAVR guide and kind of what you're baking into that?

<A: Scott B. Ullem> Yes. We're -- I mean, it's pretty straightforward,
which is we're baking into it, similar market conditions the year-over-

1 year calculation is pretty similar. ***Fourth quarter comp gets a little bit***
2 ***tougher, but we think that all things considered that 5% on the low***
3 ***end, 7% on the high end, captures the likely scenario for the second***
4 ***half combined with the first half that we've already reported.***

5 <A: Bernard J. Zovighian> We believe, to add in on that, what we
6 believe early TAVR at TCT. It will be already almost the end of a
7 quarter, Robbie, so TCT in late October. So we believe it will have a
8 very minimal impact in Q4. So it is why we didn't want to take too much
9 risk here.

10 ...

11 <Q: Travis Lee Steed – BofA Securities – Managing Director> I wanted
12 to go back and circle back on Robbie's question on TAVR. It feels like
13 there's a little bit more of a change here. Just 3 months ago, you thought
14 TAVR was going to accelerate over the course of the year. I thought
15 the 8% to 10% at the beginning of the year was supposed to be a
16 conservative guide. So I just want to understand like -- I hear what
17 you're saying on TMTT, but that's a small number of fractions versus
18 the overall TAVR centers. So I don't know if there's anything else that
19 you'd kind of call out or kind of what surprised you on the TAVR line.
20 I know there was some of the European stuff and competition there that
21 you called out last quarter. Just understanding kind of the full change
22 and why you got the initial TAVR guide wrong at the start of this year?

23 <A: Larry L. Wood> Yes. Thanks, Travis. Yes, when we exited Q1, we
24 felt we were on a good ramp and we thought we were on a good pace,
25 and that's why we reiterated guidance and we felt good about it. And
26 ***we just didn't see that play out in Q2 the way that we anticipated.*** And
27 by no means do I mean to say this is all Daveen's fault and it's all
28 EVOQUE because that's not accurate or fair when you look at the
number of procedures.

I think it's the cumulative impact of all the things that have hit the
structural heart teams over the last year. And it's one of those things.
You can always increase a little capacity, work a little harder, increase
a little capacity, work a little bit harder. But then at some point, you
reach a breakpoint when it's simply too much. And the heaviest lift for
centers is starting a program. And it's not just the procedure volume.
It's all that screening and all of the case reviews and all the interaction

1 that just consumes a lot of resources and a lot of time. And the training,
2 you don't have to go to training and observed cases in many cases and
3 all of those sorts of things. *And so I think it's just the cumulative*
4 *impact of those things that happen over time.* And we did see the
5 slowdown more acutely in large centers and small centers, which fits a
6 little bit of the model as well in terms of the centers that are most likely
7 to be looking to start these new programs and are competitive about
8 that.

9 And again, I said it earlier, but we did see a spike in emergent cases
10 over routine cases. And I think that fits what we're saying as well. But
11 that's not going to be sustainable for people. Emergent cases have more
12 complications. They don't have as good of patient outcomes and people
13 will have longer length of stay, and that's going to adversely impact
14 patients and the hospitals themselves. *So I think people will have to*
15 *adjust it over time. And we're going to have to work closely with them*
16 *to help them do that.*

17 ...

18 <Q: Matthew Charles Taylor – Jefferies LLC – Senior Analyst> I guess
19 I wanted to follow up on some of your U.S. TAVR commentary and the
20 workflow angle because I'd like to understand better why you think it's
21 showing up so acutely now, I guess, given you're still in a limited rollout
22 of EVOQUE, is this an issue that's been matriculating for a while, and
23 we're just seeing it more now? And could you help us understand your
24 history there, you talked about the impact on coronary. How long do
25 you think it will take for the hospital to adjust? Is this a 1 quarter or 3-
26 quarter issue? Does it take years? What kind of time frame would you
27 put on them adjusting to accommodate the additional workflows?

28 <A: Larry L. Wood> Yes. Thanks, Matt. The thing that I would say is,
I guess, if I were to draw an analogy, if you had a factory and you saw
demand for your product going up, you can always add a little more
hours and you always have a little bit of excess capacity and you can
adjust to those things. *I think there is just a point in time where you*
hit a wall and it's harder to do those things. And I think that's a little
bit of what we saw here. It's the cumulative effect of all of these things
that have played out over time.

1 If you look at total cath lab procedures for the structural heart team in
2 the last 3 years, it's probably close to double during that period of time,
3 which is a lot of growth that these teams are having to absorb and
4 they're having to adapt to. And I think it will take time. ***And again,***
5 ***when you're starting these new programs on these new therapies,***
6 ***that's the heaviest lift part of it. And again, I think this gets corrected***
7 ***over time, and we'll work closely with the hospitals to do that. But we***
8 ***reflected that in our guidance and just wanted to be realistic and not***
9 ***be toned after what's happened. But the same thing I'll tell you is none***
10 ***of us are happy with the growth rates. None of us are happy adjusting***
11 ***guidance, and we're going to be working as hard as we can to do***
12 ***everything we can to restore the growth to where we think it should***
13 ***be.***

14 <A: Bernard J. Zovighian> ***And we are not happy as a company. The***
15 ***patients are not happy, the physicians are not happy, the hospitals are***
16 ***not happy.*** So we are all fully aligned about it is a problem, we need to
17 solve it. So it is why also we are confident here.

18 (Emphasis added).

19 36. The aforementioned press releases and statements made by the
20 Individual Defendants are in direct contrast to statements they made during the
21 February 6, April 25, June 5, 2024 earnings and shareholder calls. On those calls,
22 Defendants continually praised their TAVR products' alleged growth, foreseeing a
23 growth ramp in the second quarter which would continue to grow into the back half
24 of the year due to their confidence in accelerating patient care through activation
25 activities designed to reach a claimed subset of untreated patients. All-the-while
26 Defendants simultaneously touted their commitment to TAVR as their key flagship
27 product and continually minimized the risks associated with competition and the
28 potential impact of the macroeconomic hospital environment on TAVR's sales
numbers.

37. Investors and analysts reacted immediately to Edwards' revelation. The
price of Edwards' common stock declined dramatically. From a closing market price

1 of \$86.95 per share on July 25, 2024, Edwards’ stock price fell to \$59.70 per share
2 on July 26, 2024, a decline of about 31.34% in the span of just a single day.

3 38. A number of well-known analysts who had been following Edwards
4 lowered their price targets in response to Edwards’ disclosures. For example,
5 Deutsche Bank, while dropping their price target, questioned the Defendants’
6 explanation for the TAVR setbacks, stating, in pertinent part:

7 Management talked about physician capacity as the issue versus
8 demand, but we struggle with that explanation. Because aortic stenosis
9 has a higher mortality than either mitral or tricuspid regurgitation,
10 *management looks to be implying that doctors could be prioritizing*
11 *lower mortality patients over higher mortality ones – which we*
12 *struggle to understand.*

(Emphasis added).

13 39. The analyst went on to posit an alternate theory: that TAVR was not in
14 as high demand as the Company claimed:

15 EW announced three acquisitions in the past few weeks: (1) JenaValve;
16 (2) Endotronix; (3) Innovalve. *When a growth company announces a*
17 *series of acquisitions as its key product begins to slow, it increases the*
18 *doubt if the TAVR market is as strong as management had previously*
19 *discussed.* When done in conjunction with this earnings release, it will
20 likely add fuel to the bear fire.

(Emphasis added).

21 40. Similarly, Canaccord Genuity, while also cutting their price target,
22 noted that “[t]he miss in Edwards’ core business certainly concerned investors,
23 evident by the stock price movement after the close and the volume of TAVR
24 questions during the conference call.”

25 41. Additionally, J.P. Morgan, while dropping their “Overweight” rating
26 down to “Neutral” and implementing a sizeable slash to their price target,
27 highlighted that the revelation of “TAVR growth decelerating” forced them to cut
28

1 predicted growth for the Company in 2025 and 2026, as they “don’t expect a quick
2 rebound” for Edwards.

3 42. The fact that these analysts, and others, discussed Edwards’ shortfall
4 and below-expectation projections suggests the public placed significant weight on
5 Edwards’ prior revenue and sales estimates. The frequent, in-depth discussion of
6 Edwards’ guidance confirms that Defendants’ statements during the Class Period
7 were material.

8 **D. Loss Causation and Economic Loss**

9 43. During the Class Period, as detailed herein, Defendants made
10 materially false and misleading statements and engaged in a scheme to deceive the
11 market and a course of conduct that artificially inflated the price of Edwards’
12 common stock and operated as a fraud or deceit on Class Period purchasers of
13 Edwards’ common stock by materially misleading the investing public. Later,
14 Defendants’ prior misrepresentations and fraudulent conduct became apparent to the
15 market, the price of Edwards’ common stock materially declined, as the prior
16 artificial inflation came out of the price over time. As a result of their purchases of
17 Edwards’ common stock during the Class Period, Plaintiff and other members of the
18 Class suffered economic loss, *i.e.*, damages under federal securities laws.

19 44. Edwards’ stock price fell in response to the corrective event on July 24,
20 2024, as alleged *supra*. On July 24, 2024, Defendants disclosed information that was
21 directly related to their prior misrepresentations and material omissions concerning
22 Edwards’ forecasting processes and growth guidance.

23 45. In particular, on July 24, 2024, Edwards announced TAVR’s growth
24 was decelerating, as the results for the second quarter of fiscal year 2024 were below
25 expectations and the Company further reduced their own prior guidance for TAVR
26 by 3%. This setback and reduction, coupled with Defendants’ explanations for the
27 result and the announcement of multiple acquisitions, suggests the demand for
28 TAVR was not as strong as Defendants previously claimed.

1 **E. Presumption of Reliance; Fraud-On-The-Market**

2 46. At all relevant times, the market for Edwards' common stock was an
3 efficient market for the following reasons, among others:

4 (a) Edwards' common stock met the requirements for listing and was listed
5 and actively traded on the NYSE during the Class Period, a highly efficient and
6 automated market;

7 (b) Edwards communicated with public investors via established market
8 communication mechanisms, including disseminations of press releases on the
9 national circuits of major newswire services and other wide-ranging public
10 disclosures, such as communications with the financial press and other similar
11 reporting services;

12 (c) Edwards was followed by several securities analysts employed by
13 major brokerage firms who wrote reports that were distributed to the sales force and
14 certain customers of their respective brokerage firms during the Class Period. Each
15 of these reports was publicly available and entered the public marketplace; and

16 (d) Unexpected material news about Edwards was reflected in and
17 incorporated into the Company's stock price during the Class Period.

18 47. As a result of the foregoing, the market for Edwards' common stock
19 promptly digested current information regarding the Company from all publicly
20 available sources and reflected such information in Edwards' stock price. Under
21 these circumstances, all purchasers of Edwards' common stock during the Class
22 Period suffered similar injury through their purchase of Edwards' common stock at
23 artificially inflated prices, and a presumption of reliance applies.

24 48. Alternatively, reliance need not be proven in this action because the
25 action involves omissions and deficient disclosures. Positive proof of reliance is not
26 a prerequisite to recovery pursuant to ruling of the United States Supreme Court in
27 *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is
28 necessary is that the facts withheld be material in the sense that a reasonable investor

1 might have considered the omitted information important in deciding whether to buy
2 or sell the subject security.

3 **F. No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine**

4 49. The statutory safe harbor provided for forward-looking statements
5 under certain circumstances does not apply to any of the material misrepresentations
6 and omissions alleged in this Complaint. As alleged above, Defendants' liability
7 stems from the fact that they provided investors with revenue projections while at
8 the same time failing to maintain adequate forecasting processes. Defendants
9 provided the public with forecasts that failed to account for this decline in sales
10 and/or adequately disclose the fact that the Company at the current time did not have
11 adequate forecasting processes.

12 50. To the extent certain of the statements alleged to be misleading or
13 inaccurate may be characterized as forward looking, they were not identified as
14 "forward-looking statements" when made and there were no meaningful cautionary
15 statements identifying important factors that could cause actual results to differ
16 materially from those in the purportedly forward-looking statements.

17 51. Defendants are also liable for any false or misleading "forward-looking
18 statements" pleaded because, at the time each "forward-looking statement" was
19 made, the speaker knew the "forward-looking statement" was false or misleading
20 and the "forward-looking statement" was authorized and/or approved by an
21 executive officer of Edwards who knew that the "forward-looking statement" was
22 false. Alternatively, none of the historic or present-tense statements made by
23 Defendants were assumptions underlying or relating to any plan, projection, or
24 statement of future economic performance, as they were not stated to be such
25 assumptions underlying or relating to any projection or statement of future economic
26 performance when made, nor were any of the projections or forecasts made by the
27 defendants expressly related to or stated to be dependent on those historic or present-
28 tense statements when made.

1 **CLASS ACTION ALLEGATIONS**

2 52. Plaintiff brings this action as a class action pursuant to Federal Rule of
3 Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who
4 purchased or otherwise acquired Edwards’ common stock during the Class Period
5 (the “Class”); and were damaged upon the revelation of the alleged corrective
6 disclosure. Excluded from the Class are defendants herein, the officers and directors
7 of the Company, at all relevant times, members of their immediate families and their
8 legal representatives, heirs, successors or assigns and any entity in which defendants
9 have or had a controlling interest.

10 53. The members of the Class are so numerous that joinder of all members
11 is impracticable. Throughout the Class Period, Edwards’ common stock were
12 actively traded on the NYSE. While the exact number of Class members is unknown
13 to Plaintiff at this time and can be ascertained only through appropriate discovery,
14 Plaintiff believes that there are hundreds or thousands of members in the proposed
15 Class. Record owners and other members of the Class may be identified from records
16 maintained by Edwards or its transfer agent and may be notified of the pendency of
17 this action by mail, using the form of notice similar to that customarily used in
18 securities class actions. As of April 25, 2024, there were 602.6 million shares of the
19 Company’s common stock outstanding. Upon information and belief, these shares
20 are held by thousands, if not millions, of individuals located throughout the country
21 and possibly the world. Joinder would be highly impracticable.

22 54. Plaintiff’s claims are typical of the claims of the members of the Class
23 as all members of the Class are similarly affected by Defendants’ wrongful conduct
24 in violation of federal law that is complained of herein.

25 55. Plaintiff will fairly and adequately protect the interests of the members
26 of the Class and has retained counsel competent and experienced in class and
27 securities litigation. Plaintiff has no interests antagonistic to or in conflict with those
28 of the Class.

1 56. Common questions of law and fact exist as to all members of the Class
2 and predominate over any questions solely affecting individual members of the
3 Class. Among the questions of law and fact common to the Class are:

4 (a) whether the federal securities laws were violated by Defendants' acts
5 as alleged herein;

6 (b) whether statements made by Defendants to the investing public during
7 the Class Period misrepresented material facts about the business, operations and
8 management of Edwards;

9 (c) whether the Individual Defendants caused Edwards to issue false and
10 misleading financial statements during the Class Period;

11 (d) whether Defendants acted knowingly or recklessly in issuing false and
12 misleading financial statements;

13 (e) whether the prices of Edwards' common stock during the Class Period
14 were artificially inflated because of the Defendants' conduct complained of herein;
15 and

16 (f) whether the members of the Class have sustained damages and, if so,
17 what is the proper measure of damages.

18 57. A class action is superior to all other available methods for the fair and
19 efficient adjudication of this controversy since joinder of all members is
20 impracticable. Furthermore, as the damages suffered by individual Class members
21 may be relatively small, the expense and burden of individual litigation make it
22 impossible for members of the Class to individually redress the wrongs done to them.
23 There will be no difficulty in the management of this action as a class action.

24 **COUNT I**

25 ***Against All Defendants for Violations of***

26 **Section 10(b) and Rule 10b-5 Promulgated Thereunder**

27 58. Plaintiff repeats and realleges each and every allegation contained
28 above as if fully set forth herein.

1 59. This Count is asserted against defendants and is based upon Section
2 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated
3 thereunder by the SEC.

4 60. During the Class Period, Defendants engaged in a plan, scheme,
5 conspiracy and course of conduct, pursuant to which they knowingly or recklessly
6 engaged in acts, transactions, practices and courses of business which operated as a
7 fraud and deceit upon Plaintiff and the other members of the Class; made various
8 untrue statements of material facts and omitted to state material facts necessary in
9 order to make the statements made, in light of the circumstances under which they
10 were made, not misleading; and employed devices, schemes and artifices to defraud
11 in connection with the purchase and sale of securities. Such scheme was intended to,
12 and, throughout the Class Period, did: (i) deceive the investing public, including
13 Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and
14 maintain the market price of Edwards common stock; and (iii) cause Plaintiff and
15 other members of the Class to purchase or otherwise acquire Edwards' securities at
16 artificially inflated prices. In furtherance of this unlawful scheme, plan and course
17 of conduct, Defendants, and each of them, took the actions set forth herein.

18 61. Pursuant to the above plan, scheme, conspiracy and course of conduct,
19 each of the defendants participated directly or indirectly in the preparation and/or
20 issuance of the quarterly and annual reports, SEC filings, press releases and other
21 statements and documents described above, including statements made to securities
22 analysts and the media that were designed to influence the market for Edwards'
23 securities. Such reports, filings, releases and statements were materially false and
24 misleading in that they failed to disclose material adverse information and
25 misrepresented the truth about the Company.

26 62. By virtue of their positions at the Company, Defendants had actual
27 knowledge of the materially false and misleading statements and material omissions
28 alleged herein and intended thereby to deceive Plaintiff and the other members of

1 the Class, or, in the alternative, Defendants acted with reckless disregard for the truth
2 in that they failed or refused to ascertain and disclose such facts as would reveal the
3 materially false and misleading nature of the statements made, although such facts
4 were readily available to Defendants. Said acts and omissions of defendants were
5 committed willfully or with reckless disregard for the truth. In addition, each
6 defendant knew or recklessly disregarded that material facts were being
7 misrepresented or omitted as described above.

8 63. Information showing that Defendants acted knowingly or with reckless
9 disregard for the truth is peculiarly within defendants' knowledge and control. As
10 the senior managers and/or directors of the Company, the Individual Defendants had
11 knowledge of the details of Edwards' internal affairs.

12 64. The Individual Defendants are liable both directly and indirectly for the
13 wrongs complained of herein. Because of their positions of control and authority,
14 the Individual Defendants were able to and did, directly or indirectly, control the
15 content of the statements of the Company. As officers and/or directors of a publicly-
16 held company, the Individual Defendants had a duty to disseminate timely, accurate,
17 and truthful information with respect to Edwards' businesses, operations, future
18 financial condition and future prospects. As a result of the dissemination of the
19 aforementioned false and misleading reports, releases and public statements, the
20 market price of Edwards' common stock was artificially inflated throughout the
21 Class Period. In ignorance of the adverse facts concerning the Company which were
22 concealed by Defendants, Plaintiff and the other members of the Class purchased or
23 otherwise acquired Edwards' common stock at artificially inflated prices and relied
24 upon the price of the common stock, the integrity of the market for the common
25 stock and/or upon statements disseminated by Defendants, and were damaged
26 thereby.

27 65. During the Class Period, Edwards' common stock was traded on an
28 active and efficient market. Plaintiff and the other members of the Class, relying on

1 the materially false and misleading statements described herein, which the
2 defendants made, issued or caused to be disseminated, or relying upon the integrity
3 of the market, purchased or otherwise acquired shares of Edwards' common stock
4 at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the
5 other members of the Class known the truth, they would not have purchased or
6 otherwise acquired said common stock, or would not have purchased or otherwise
7 acquired them at the inflated prices that were paid. At the time of the purchases
8 and/or acquisitions by Plaintiff and the Class, the true value of Edwards' common
9 stock was substantially lower than the prices paid by Plaintiff and the other members
10 of the Class. The market price of Edwards' common stock declined sharply upon
11 public disclosure of the facts alleged herein to the injury of Plaintiff and Class
12 members.

13 66. By reason of the conduct alleged herein, Defendants knowingly or
14 recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act
15 and Rule 10b-5 promulgated thereunder.

16 67. As a direct and proximate result of defendants' wrongful conduct,
17 Plaintiff and the other members of the Class suffered damages in connection with
18 their respective purchases, acquisitions and sales of the Company's common stock
19 during the Class Period, upon the disclosure that the Company had been
20 disseminating misrepresented financial statements to the investing public.

21 COUNT II

22 *Against the Individual Defendants*

23 *for Violations of Section 20(a) of the Exchange Act*

24 68. Plaintiff repeats and realleges each and every allegation contained in
25 the foregoing paragraphs as if fully set forth herein.

26 69. During the Class Period, the Individual Defendants participated in the
27 operation and management of the Company, and conducted and participated, directly
28 and indirectly, in the conduct of the Company's business affairs. Because of their

1 senior positions, they knew the adverse non-public information about Edwards’
2 misstatements.

3 70. As officers and/or directors of a publicly owned company, the
4 Individual Defendants had a duty to disseminate accurate and truthful information,
5 and to correct promptly any public statements issued by Edwards which had become
6 materially false or misleading.

7 71. Because of their positions of control and authority as senior officers,
8 the Individual Defendants were able to, and did, control the contents of the various
9 reports, press releases and public filings which Edwards disseminated in the
10 marketplace during the Class Period concerning the misrepresentations. Throughout
11 the Class Period, the Individual Defendants exercised their power and authority to
12 cause Edwards to engage in the wrongful acts complained of herein. The Individual
13 Defendants therefore, were “controlling persons” of the Company within the
14 meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in
15 the unlawful conduct alleged which artificially inflated the market price of Edwards’
16 common stock.

17 72. Each of the Individual Defendants, therefore, acted as a controlling
18 person of the Company. By reason of their senior management positions and/or
19 being directors of the Company, each of the Individual Defendants had the power to
20 direct the actions of, and exercised the same to cause Edwards to engage in the
21 unlawful acts and conduct complained of herein. Each of the Individual Defendants
22 exercised control over the general operations of the Company and possessed the
23 power to control the specific activities which comprise the primary violations about
24 which Plaintiff and the other members of the Class complain.

25 73. By reason of the above conduct, the Individual Defendants and/or
26 Edwards are liable pursuant to Section 20(a) of the Exchange Act for the violations
27 committed by the Company.
28

1 **PRAYER FOR RELIEF**

2 **WHEREFORE**, Plaintiff demand judgment against defendants as follows:

3 A. Determining that the instant action may be maintained as a class action
4 under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the
5 Class representatives;

6 B. Requiring Defendants to pay damages sustained by Plaintiff and the
7 Class by reason of the acts and transactions alleged herein;

8 C. Awarding Plaintiff and the other members of the Class pre-judgment
9 and post-judgment interest, as well as their reasonable attorneys' fees, expert fees
10 and other costs; and

11 D. Awarding such other and further relief as this Court may deem just and
12 proper.

13 **DEMAND FOR TRIAL BY JURY**

14 Plaintiff hereby demands a trial by jury.

15
16 Dated: October 14, 2024

Respectfully submitted,

17
18
19

Counsel for Plaintiff