BofA SECURITIES

Edwards Lifesciences

Notes from our Evoque check with doctor in Evoque trial

Maintain Rating: BUY | PO: 105.00 USD | Price: 88.33 USD

This doc says EVOQUE majority of TR share

Following Edwards Lifesciences (EW)'s Evoque FDA approval in February we recently spoke with an interventional cardiologist who was part of the Evoque trial. He finds Evoque works very well in the right patient and has seen good patient outcomes. He expects Evoque could have a majority share of the market (80% Evoque / 20% TriClip). Rollout will be limited initially to focus on good clinical outcomes but thinks TR volume could be similar to MitraClip volume in the next few years. Price and center capacity are the potential barriers to adoption. See below for key takeaways and inside for more.

85-90% of TR can be treated with replacement or clipping

The doctor estimates of all the TR patients he sees that only about 10-15% are not suitable for either TriClip or Evoque (i.e. 85-90% of TR can be treated with a device). The doctor expects Evoque to have 80% share because by the time patients are referred for TR the heart is too enlarged to be clipped. The enlarged heart is not an issue with Evoque since it replaces the old valve. There are 20% of patients who would not be suitable for Evoque (and go to TriClip) given patient anatomy (valve too big) or if the patient can't tolerate anticoagulants (needed for at least 6 mos with Evoque).

This doc Evoque volume close to Mitraclip in 2-3 years

Roll out of Evoque will initially be limited to centers of excellence/centers part of the trial to focus on good clinical outcomes. But this doctor has 25 patients waiting to get Evoque and expects to do 30-40 cases total this year. Overall he does 400 TAVRs in a year and 110 clips and expects his tricuspid volume to be similar to MitraClip or more in 2-3 yrs. There are 500 centers using MitraClip today and Evoque likely to be used in the same centers over the next 5 years (vs 800 TAVR centers today).

Evoque ASP ~$40k, a premium to TAVR and MitraClip

This doctor said Evoque price is ~$40k vs Sapien TAVR valve is ~$32.5k. TriClip ASP is similar to MitraClip in the $25-$30k range. Adoption will depend on payment for the valve once hospitals get coding and hospital capacity. Evoque could get a new technology add on payment which would become effective October 1st if granted.

We maintain Buy and $105 PO as we believe EW will likely sustain double-digit revenue/EPS growth going forward.

Estimates (Dec) (US$)	2022A	2023A	2024E	2025E	2026E
EPS	2.48	2.51	2.75	3.03	3.34
EPS Change (YoY)	11.7%	1.2%	9.6%	10.2%	10.2%
Consensus EPS (Bloomberg)			2.76	3.10	3.44
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	35.6x	35.2x	32.1x	29.2x	26.4x
EV / EBITDA*	26.8x	27.6x	25.1x	22.6x	20.4x
Free Cash Flow Yield*	1.8%	1.2%	3.0%	3.1%	3.4%

* For full definitions of iQmethod℠ measures, see page 13.

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Equity

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

Stephanie Piazzola
Research Analyst
BofAS
stephanie.piazzola@bofa.com

Craig Bijou
Research Analyst
BofAS
craig.bijou@bofa.com

Carolyn Huszagh
Research Analyst
BofAS
carolyn.huszagh@bofa.com

Stock Data

Price	88.33 USD
Price Objective	105.00 USD
Date Established	7-Mar-2024
Investment Opinion	B-1-9
52-Week Range	60.57 USD - 94.87 USD
Mrkt Val (mn) / Shares Out (mn)	53,113 USD / 601.3
Free Float	99.1%
Average Daily Value (mn)	401.58 USD
BofA Ticker / Exchange	EW / NYS
Bloomberg / Reuters	EW US / EW.N
ROE (2024E)	21.7%
Net Dbt to Eqty (Dec-2023A)	-8.1%
ESGMeter™	High

ESGMeter is not indicative of a company's future stock price performance and is not an investment recommendation or rating. ESGMeter is independent of BofA Global Research's equity investment rating, volatility risk rating, income rating, and price objective for that company. For full details, refer to "BofA ESGMeter Methodology".

TR = tricuspid regurgitation

TAVR = transcatheter aortic valve replacement

ASP = average selling price

*iQ*profile℠ Edwards Lifesciences

iQmethod℠ **– Bus Performance***

(US$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	20.9%	19.6%	18.1%	16.4%	15.1%
Return on Equity	26.6%	24.4%	21.7%	19.1%	17.1%
Operating Margin	33.4%	28.9%	29.5%	29.9%	30.3%
Free Cash Flow	974	643	1,580	1,647	1,784

iQmethod℠ **– Quality of Earnings***

(US$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	0.8x	0.6x	1.1x	1.1x	1.1x
Asset Replacement Ratio	1.8x	1.7x	2.0x	2.6x	2.8x
Tax Rate	14.6%	15.0%	16.5%	17.0%	17.5%
Net Debt-to-Equity Ratio	-3.0%	-8.1%	-26.1%	-37.6%	-45.7%
Interest Cover	NA	NA	NA	NA	NA

Income Statement Data (Dec)

(US$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	5,382	6,005	6,487	7,143	7,856
% Change	2.9%	11.6%	8.0%	10.1%	10.0%
Gross Profit	4,309	4,630	4,993	5,513	6,078
% Change	8.0%	7.4%	7.8%	10.4%	10.3%
EBITDA	1,930	1,874	2,060	2,290	2,535
% Change	12.1%	-2.9%	10.0%	11.2%	10.7%
Net Interest & Other Income	19	64	86	88	88
Net Income (Adjusted)	**1,551**	**1,531**	**1,670**	**1,849**	**2,039**
% Change	**10.4%**	**-1.3%**	**9.1%**	**10.7%**	**10.3%**

Free Cash Flow Data (Dec)

(US$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	1,551	1,528	1,670	1,848	2,039
Depreciation & Amortization	140	145	152	152	152
Change in Working Capital	(421)	(526)	(57)	(83)	(97)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	(51)	(251)	123	123	123
Capital Expenditure	(245)	(253)	(308)	(393)	(432)
Free Cash Flow	**974**	**643**	**1,580**	**1,647**	**1,784**
% Change	**-30.8%**	**-34.0%**	**145.8%**	**4.2%**	**8.4%**
Share / Issue Repurchase	(1,727)	(880)	0	0	0
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	0	0	0	0	0

Balance Sheet Data (Dec)

(US$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash & Equivalents	769	1,144	2,856	4,636	6,553
Trade Receivables	699	837	954	1,043	1,146
Other Current Assets	1,628	2,055	2,210	2,328	2,457
Property, Plant & Equipment	1,633	1,749	1,906	2,146	2,426
Other Non-Current Assets	3,564	3,578	3,578	3,578	3,578
Total Assets	**8,293**	**9,363**	**11,505**	**13,732**	**16,161**
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	1,022	1,195	1,412	1,535	1,671
Long-Term Debt	596	597	597	597	597
Other Non-Current Liabilities	867	851	851	851	851
Total Liabilities	**2,486**	**2,644**	**2,860**	**2,984**	**3,119**
Total Equity	**5,807**	**6,719**	**8,645**	**10,748**	**13,042**
Total Equity & Liabilities	**8,293**	**9,363**	**11,505**	**13,732**	**16,161**

* For full definitions of *iQ*method℠ measures, see page 13.

Company Sector

Medical Technology

Company Description

Edwards Lifesciences provides devices and technologies for structural heart disease, and critical care and surgical monitoring. EW is a leader in transcatheter heart valve replacement - one of the most visible, innovative and exciting markets in the medical device sector.

Investment Rationale

We are Buy rated on EW as we see TAVR growth stabilizing/recovering while Evoque/other new products adding years of growth opportunity to keep EW driving double digit EPS growth for many years.

Stock Data

Average Daily Volume	4,584,421

Quarterly Earnings Estimates

	2023	2024
Q1	0.62A	0.64E
Q2	0.66A	0.69E
Q3	0.59A	0.69E
Q4	0.64A	0.73E

Doc Call Transcript

Key Quotes on tricuspid

“I would say most of them will have to have a replacement, meaning a brand new valve like the Evoque. Less than 20% likely will benefit from a TriClip because they usually refer these patients very late advanced stages and TriClip only works in early stages.”

“I think it's probably going to be similar to mitral... I think what they're planning to do right now is just have centers that were part of the trial to show good outcomes now that it's approved commercially outside the trial.”

“There are some patients that they have very advanced disease where the heart is super weak and the anatomy is already too big for them and I can't fit an Evoque. That's the first reason not to do Evoque is where you can't fit the Evoque and we have several of those patients that are getting referred late. There are other patients where if you can't tolerate anticoagulation after the valve you might not be a good candidate for the Evoque, because you have to be on a blood thinner at least for six months so the valve doesn't clot.”

“Maybe 10% to 15% of all tricuspid patients would be untreatable. There are more technologies that are coming that might overcome that. I think the future might have to have hybrid procedures.”

“It’s the first year so we're going to try to do good cases, not just a last resource. The problem here very honestly is it just got approved so it's all about how the payment of the valve when the hospital gets coding. Maybe we'll be doing 30-40 as a start. At least in our center there is a lot of coordination with the transcatheter center in Michigan so we need to get more space to do more. There's a whole conversation within our group now and the hospital how are we going to expand timing or an extra day of OR to do this that we didn't have”

“We do 400 TAVRs a year and we do 110 clips. I would say the ratio is four to one in centers that know who to treat. It might be that it's going to be similar for Evoque or even more, sometimes we see more TR.”

“TR is probably the number two to number three reason for patients coming into office. We get more aortic valves, but also TAVR has been around for a while. It's one of the most prevalent and I only see valve patients, congenital patients as well. I think we see the same amount of patients with tricuspid and mitral valve.”

“I think the price is more expensive than TAVR valve, it’s going to be about $40,000. In medicine the way you get the revenues is how seek out the patients and how many comorbidities they have. A lot of these patients they have advanced chronic problems where you get better reimbursement”

“I would say the Evoque is a good valve. It works very well in the right patient. It's not going to explode in all the centers doing TAVR. It's likely going to be used in centers doing MitraClip. And like any first device, you're going to try to simplify it, to make it more user friendly and not just high level centers”

KOL perspectives on tricuspid

Tricupid market share expectations for Evoque vs TriClip

80% of patients expected to benefit from Evoque vs 20% TriClip given referral for TriClip is usually too late when the valve becomes too big to be clipped. Evoque may be too big for certain patient anatomies where TriClip would be better. TriClip may work in the near term but it’s not solving the problem for later on. Likely adopters of TriClip will be those using MitraClip.

“The way I see it is when we have patients with severe tricuspid regurgitation I would say most of them will have to have a replacement, meaning a brand new valve like the

Evoque. Less than 20% likely will benefit from a TriClip because they usually refer these patients in very late advanced stages and TriClip only works in early stages. So I foresee more of a market for Evoque than TriClip. But there are going to be roles for both Evoque and TriClip in my opinion.

With the tricuspid valve in general, you have leaky valve regurgitation because where the valve is implanted in your heart, it's starting to get enlarged. Sometimes it's so big that if you do a TriClip, you might put those clips where it's leaking but the natural history of the of the heart is to keep growing. So you're going to have new leaks around the clips. So you might be solving the problem today but not tomorrow. Most patients when they get referred are on advanced stages of tricuspid regurgitation, where a clip is not ideal, and they're mainly at the stage where you have to do a replacement, for example, with an Evoque.

The community doesn't refer these patients very early because patients that get symptoms from tricuspid regurgitation could take years. If you get symptoms from other valves, it might just happen in less time and they manifest much more. However the tricuspid regurgitation problem it can take years sometimes to show symptoms. What could happen is you don't have symptoms, but your heart is starting to enlarge but by the by the time you have symptoms, it's a big heart where the valve is and TriClip is not the best option, it's usually Evoque in this case. So my feeling from a patient with tricuspid regurgitation, 80% will have to have Evoque and 20% TriClip.

We're a big center here and we've been doing this. We've been exposed to Evoque for five years almost now from the early feasibility. There are actually patients that are already too big and they're in that stage where it's too advanced and nothing works. I think there's going to be a lot of education about early referral so you can get more options for patients like more TriClips. But the reality is a lot of these patients, they come when the clip is not a good option and it's better to use Evoque. That's why I'm saying 80% and 20%."

"The issue of the enlarged heart doesn't happen with Evoque, because once we put the Evoque the valve anchors and the valve itself kind of embraces the old valve. So you replace the whole valve and with TriClip you kind of patch the valve. Imagine when you're changing your tires, sometimes you can patch it and if it's the wrong one it's going to work for the next couple of miles. But then you'll have to replace it.

I think what we're going to see if the TriClip gets approved is people who are more friendly users of MitraClip, they might be using the TriClip in patients because they can, not because they should. And we'll see a lot of patients being treated with TriClip that they're going to come with failed tricuspid that either is going to be surgery or we at advanced centers will have to figure out how we put in an Evoque on top of the TriClip. You'll have to remove the clips with catheters and put in Evoque. But again in general, once something is approved, people are going to start using it. In medicine, and one of the reasons I'm in academia and not in private sometimes is people they just worry about what they can bring home and not what they are doing. And a lot of people will just do the best they can and they would never send it to the guy next door."

Tricuspid regurgitation patients not well suited for Evoque or transcatheter options in general

Evoque too big for some patient anatomies and not well suited for patients who can't tolerate anticoagulation.

"There are some patients that they have very advanced disease where the heart is super weak and the anatomy is already too big for them and I can't fit an Evoque. That's the first reason not to do Evoque is where you can't fit the Evoque and we have several of those patients that are getting referred late. There are other patients where if you can't tolerate anticoagulation after the valve you might not be a good candidate for the Evoque, because you have to be on a blood thinner at least for six months so the valve

doesn't clot. There are several points that sometimes would favor more TriClip than an Evoque. And that's when you have to use your clinical judgment. Maybe 10% to 15% of all tricuspid patients would be untreatable. There are more technologies that are coming that might overcome that. I think the future might have to have hybrid procedures."

Expectations for Evoque adoption vs what seen in mitral with MitraClip

Adoption for Evoque likely to be similar to MitraClip and initially will be limited to centers part of the trial to show good outcomes.

"I think it's probably going to be similar to mitral because I'm not sure the company itself is going to be ready to be massified right now. The valve just got approved so only Centers of Excellence are doing the valve. So I think what they're planning to do right now is just have centers that were part of the trial to show good outcomes now that it's approved commercially outside the trial. And then in medicine there's a lot of stuff like if somebody is in private practice how much time are they going to invest in replacing one valve that that is going to give you X amount of money when you can do several smaller procedures that give you more revenue. So I think it's going to be similar to MitraClip. Like any new device initially they tried to release them to advanced centers and once this is already ongoing they do a more release to other centers. Because MitraClip was the only option at the time besides surgery. So we don't have anything close besides the TriClip for tricuspid. But I do believe most patients will require Evoque more than a TriClip in general.

The company wants to go slow because they want good results. Now that it's approved, the FDA will be looking at the post-approval outcomes. If you go very massive and there are people that have never implanted one, it might be challenging. But they're probably going to go to big centers first where they have operators with more background and then go to smaller centers.

I think it's going to be similar to mitral, it's the only kind of proof. If we get more competitors on the market, we'll see how they work. But I can tell you the Evoque side is five, four years ago were much more complex because it was a brand new valve for everyone. But we've been doing them for a while as part of the trial and now we can do three cases in a day."

Existing TAVR and MitraClip volume and expectations for tricuspid volume

Ratio of four to one for TAVR to MitraClip and expected to be similar ratio for tricuspid cases.

"We do 400 TAVRs a year and we do 110 clips. I would say the ratio is four to one in centers that know who to treat. It might be that it's going to be similar for Evoque or even more, sometimes we see more TR. It could be in a center that does 400 TAVRs maybe they're going to be doing 100 tricuspid cases."

Expectations for Evoque use in the next few years

Expect to do 30-40 Evoque cases initially in a year. The main factor will be pricing and how to do more cases (more space and time for these cases).

"My center just got approved to get it commercially. We just did our first commercial today actually, but we did others as part of the continuous access trial. We have a list of 25 patients right now that we want to start getting it to. I think now that these are approved, we might get more referrals from other centers that don't have it in Michigan.

I don't think 100 cases in the first year. It's the first year we're going to try to do good cases, not just a last resource. The problem here very honestly is it just got approved so it's all about how the payment of the valve when the hospital gets coding. Maybe we'll be doing 30-40 as a start. At least in our center there is a lot of coordination with the transcatheter center in Michigan so we need to get more space to do more. There's a whole conversation within our group now and the hospital how are we going to expand timing or an extra day of OR to do this that we didn't have.

Let's say TriClip gets approved, some of them will be TriClip as well. There are some patients that Evoque is too big for their anatomy and maybe we're going to try to clip them."

Expectation for number of centers doing Evoque in 5 years

Evoque expected to be used in same centers using MitraClip today, which is about 500 centers. Pascal likely to take share from MitraClip because of ease of use.

"Probably similar to the ones that are doing clip. There are maybe 500 centers. Pascal from EW is going to take a lot of market from MitraClip. It's much easier to do and it does the same. I think there's like 500 clip centers. Because the rules to get a TAVR center are more permissive. To get a MitraClip center, you need to have some minimal that not everyone has."

TR treatment options today

Transcatheter expected to become first treatment option for TR patients given lower mortality and length of stay.

"So usually patients will only be operated with open heart surgery and usually in the context of another valve. The mortality when you operate and do open heart surgery, the tricuspid valve alone is relatively high., it's like 6%–8% every year. I think what we're seeing with these transcatheters is a much lower mortality and much lower length of a stay. So I see that there is going to be a market, so far Evoque the only valve approved and with TriClip we're going to have two options. But again, there are patients that they don't qualify for the Evoque because the anatomy is not ideal or vice versa for TriClip. But I think it's going to be like first option for a lot of these patients. If you have only tricuspid regurgitation just go to transcatheter don't go surgery. That's what I think what's going to happen."

TR patient identification and prevalence

Education on early referral will be needed but Edwards already working with centers on lectures and referral outreach. TR one of the top 3 reasons patient seek treatment at this center. Similar number of patients for mitral and tricuspid.

"That's going to be a whole new market for the companies. You'll have to do education about early referral for TR and being assessed by someone that does the valves, not just a cardiologist. They're doing that for TAVR, there's a lot of education and early referral, don't wait for the patient to be super symptomatic. I think there's going to be a good market for that. The companies are good at advertising when they get something approved. We're already talking with the companies to do some lectures and outreach, so we can get patients from not just the metro area also from other places that might not get access for those options right now.

TR is probably the number two to number three reason for patients coming into office. We get more aortic valves, but also TAVR has been around for a while. It's one of the most prevalent and I only see valve patients, congenital patients as well. I think we see the same amount of patients with tricuspid and mitral valve."

"Primary vs secondary tricuspid regurgitation not really a consideration. It depends if there's pulmonary hypertension, sometimes you don't want to treat that tricuspid regurgitation because you might shut down the right side of the heart. That's why for all these patients we do a whole analysis and hard meetings with several doctors. It's not like a solo, one doctor decision. We all talk about this. They're seen by other specialties. There's a lot of brainstorming around every patient to make sure that we're treating the right guy at the right time."

Economics of Evoque

Evoque to be about $40k, more expensive than TAVR. Better reimbursement expected as use expands.

"I think the price is more expensive than TAVR valve, it's going to be about $40,000. In medicine the way you get the revenues is how seek out the patients and how many comorbidities they have. A lot of these patients they have advanced chronic problems where you get better reimbursement. That's something that we're talking about right now. The margin might not be ideal. In private practice, might not be a big deal to do it because you might not get much margin. The valves are really going to be more expensive than the TAVR valves and I'm not sure how much you're going to get reimbursed.

They might get an add on payment like a new technology, but it isn't happening right now. I think there is going to be some changes in terms of payment and coding to get better reimbursement as this expands."

Overview of Evoque procedure

Procedure time with Evoque is 2-3hrs while TAVR and mitral is about 30mins, though more doctor experience with TAVR and mitral and procedure times vary based on patient anatomy. Private practice less incentivized to do more complex cases.

"It's done from the groin with the patient under general anesthesia. Most patients can go home the next day. They get extubated the same day. The only thing that might happen, you might need a pacemaker from the from the valve, and that could buy you an extra day. The procedure is, is two to three hours. It's very variable, some cases could be two to three hours, others could be an hour and a half, half of the time. There's a lot of variation based on heart anatomy. That's why you have different sizes of Evoque.

I just did a TAVR in 30 minutes, but the TAVR we do them awake, in and out without general anesthesia. The MitraClip, I'm an advanced implanter, so it might take me 30 minutes but there are cases that can take you two to three hours so it's very variable. A lot of minor institutions send patients to us. I'm salary based so I don't care if I take five hours or one hour, I don't get paid more or less. In places where you're dependent on what you produce, the tendency is not to do complex cases because, in terms of money, it's not worth for you to do a very complex case for X amount of money as you can do three simple cases for more money in the same time. But that's very variable in terms of the practice decision."

"When you do a Evoque, you just treat the valve as a single procedure. A lot of these patients, they have other problems like blocked arteries, sometimes they have other valves that are leaking. And in general you fix one at a time with transcatheter. The only way to fix all of them, at one time, is with open heart surgery. So all these technologies that they came out like TAVR those kind of procedures they are one valve at a time. I believe that the Evoque is going to be a game changer because we didn't have anything and now we have a valve for patients that were not surgical candidates or high risk. You can be a low risk and you still can have the valve with Evoque. Doesn't mean like this is only going to be for failed surgical patients."

Experience with Evoque so far

Evoque works very well in the right patient and results from the trial have been good. However, it is not going to explode in all of the centers doing TAVR and will likely be used by those using MitraClip.

"I would say the Evoque is a good valve. It works very well in the right patient. It's not going to explode in all the centers doing TAVR. It's likely going to be used in centers doing MitraClip. And like any first device, you're going to try to simplify it, to make it more user friendly and not just high level centers. The results in my opinion, are pretty

good. We did three last week all part of the trial. I think it has a future unless there's something new coming with all the other valves from intrepid Medtronic we need to see what they're doing."

Cardiac surgeons vs interventional cardiologists doing the procedure

"The cardiac surgeons are not very enthusiastic about operating on someone. Most of these patients when they get referred their right ventricle is the one that contracts so the heart beats and the blood comes out. The right ventricle is the one that is connected with the tricuspid valve. When the heart beats it sends blood to the lungs. A lot of these patients when they are referred the right ventricle is weak. We're not really competing with surgeons because they don't want to put on their bypass and open the chest if someone might not come out of the machine. So that's why I think they're better sending these patients to transcatheter where it's just in and out with two or three hours and you're done."

Thoughts on TriClip and lack of hard endpoints in TRILUMINATE data

One year data not long enough and more meaningful differences besides QoL could be seen longer term. QoL benefits alone is enough for some patients. However, being part of the EFS, this KOL believes longer term results not good with TriClip.

"The issue with tricuspid regurgitation is it takes years to show. Though you fix the mechanical problem, your heart already has changes that you might not notice a change the next two to four or five years. I think one year is not too much to see such changes. I think if we have longer follow up we might see a more meaningful difference besides quality of life and survival. Patients want good quality of life so you offer them one day admission and improve their quality of life, it's not bad in my opinion. Not everything is about living longer. Sometimes they want quality only."

"I was part of the EFS and the problem with TriClip is you might get good results today, but the heart will continue to get enlarged and you might not see good results later. So I don't think it's going to be a huge volume for TriClip. There are going to be patients that might just benefit from it."

KOL perspectives on TAVR

SMART trial

Expect to see higher gradients with Edwards' Sapien but unlikely to translate to more use of Medtronic's Evolut. Longer term data out to five years needed to see impact of a high gradient. No data so far to show a difference in mortality at one year.

"This has been a debate for a while. It's a trial that wants to see if the gradient that you get after putting the valve, does affect mortality, and there's so far no study to show at one year that you have a difference. I think what's going to happen, we're going to see higher gradients with Sapien, we know that they have higher gradients, but I'm not sure that's going to translate on a more use of Evolut. To see the actual impact of a high gradient, you have to wait five years, in my opinion, to see if that's going to be clinically meaningful. In medicine, we use a lot of p values, we call it significant, but there are some significant things that doesn't have a meaningful clinical significance. If you told me the valve gradient is 12 and the other one is ten, they're both low, I don't care. Sure it's clinically statistically significant 10 versus 12, however is that clinically relevant, zero. In my opinion unless the trial shows that there's more mortality, more strokes, more heart failure that could be more meaningful.

It might change some practice in some centers, but at the same time, you have to remember, if you're putting this Evolut valve in younger guys, after 10 years when they

need another valve and they will be older, you might be hosting them to a surgery at an older age because you're not going to be able to put a new valve on top of the old one. One of the benefits that Sapien has by being shorter is that you can have several valves in the future placed inside.

TAVR in TAVR with Sapien vs Evolut

TAVR in TAVR better and only approved with Sapien vs Evolut

"With Sapien you can do TAVR in TAVR. When someone has a TAVR the only FDA approved is Sapien in Sapien. An Evolut in Sapien is not FDA approved, it has been done off label but in general it's not so reproducible.

You have more chances of getting a TAVR later on with the Sapien that we don't have with Evolut. At some point there's a game balance between gradients versus reproducibility versus getting access into the coronary. How relevant is the difference in gradient, if the patients are dying more it will be relevant. Then and there will be a conversation. How difficult will it be the second valve in terms of getting the benefit of the gradients, that's what we'll have to see."

Sapien vs Evolut

Edwards' Sapien has 70% market share in the US. Sapien is an easier valve to deploy/use/teach.

"The market I think for the valve is like 70% Sapien in the US and 30% Medtronic, acurate is coming and Navitor. But if you ask me the difference between Sapien and the other valves, Sapien is a very easy valve to deploy. I travel a good amount sometimes in the country to help with other cases. And Sapien is one that you can teach much more easily than an Evolut or any other valve. I think that's why people use more Sapien in the US. It's an easier valve to deploy to use."

Views on Accurate and Navitor share potential

Boston Scientific's Accurate and Abbott's Navitor likely to take market share from Medtronic given similarity in how they are deployed vs Edwards.

"I think Navitor and Acurate, they're just going to take market share from Medtronic likely. I don't think they will take much market share from Sapien right now. Because those valves are similar in terms of the way the way they get deployed. And the same when you're planning the second valve, you have to ask yourself, how easy is it going to be to put a second valve after I put an Acurate or a Navitor."

Sapien 3 Ultra Resilia

Sapien 3 Ultra Resilia used on all patients though longer term data to five years needed to see if durable or not.

"We have data on surgical valves with Resilia. All the data that we have is from surgical valves. I put all my patients with Resilia because I think "well I'm not the one that is going to be picking on Resilia." It's $1,000 more expensive than the other one for now, unless they drop the price. So I put everyone on Resilia. I kind of incorporate that surgical data into my TAVR data. We'll have to wait five years and see what happens with the Resilia, do we see durability or not. Because Edwards is coming with a new valve that they're incorporating this commissural alignment to make reproducible the next TAVR in TAVR."

Sapien x4

Edwards next-gen valve Sapien 4 incorporates changes in commissural alignment to improve reproducibility and lifetime management of TAVR patients.

"I'm part of the trial. It's too early right now, to be honest. Different mode of deployment. They incorporate some of the same steps. I'm not sure I can tell you a

difference from the actual technology besides commissural alignment. Pretty much you align the valve to the arteries of the heart so when you do a second valve, you could protect those arteries easily. Edwards is kind of approaching into what is called lifetime management to facilitate the lifetime management of someone that needs several valves or couple, three valves."

Views on TAVR market

Continues to see growth in TAVR market but varies center to center. Some centers see better profits with surgery vs TAVR.

"The TAVR market is growing and growing every year. We already surpassed the amount of surgical valves. It depends on every center. I get referrals from patient cases that can't be done in other centers. I kind of approach TAVR first in general, unless there's a clear indication where surgery is better. That's why I think it's very local. I think the hospitals might get more money by doing surgery. If the surgeons have more power, than surgery might be more prevalent. It's very cultural.

Our volume, I think, as a system, because we were so busy in downtown where we had the only center, we opened two daughter hospitals where we do low risk cases of TAVR. But we only do TAVRs. Those operators, they don't have the expertise for a MitraClip or Evoque. When we expanded to the other centers, all these cases that were done in downtown, now are not done in downtown so we got more slots to treat mitral and tricuspid.

We've been involved with TAVR from the very beginning of TAVR, was part of the trial, we were enrolling patients in low risk and we were doing low risk bicuspid valve. It's like a different morphology of valve we were part of a registry. I think the increase in volume was different than to other centers because the other centers, they just got it approved when the fda approved it. It's going to grow. I'm not sure if all the companies are trying to get more aortic patients sooner or later. I think as we get older, we all have more chance to get it."

EARLY trial and Asymptomatic TAVR

EARLY TAVR trial results expected to be neutral or positive and as long as results show no harm to patients then there will be a push to treat these patients. Likely won't change the number of TAVRs done since asymptomatic patients not very common, 5 out of 100 patients truly asymptomatic.

"The way I see it is if you wait for symptoms, it's not that you're going to get gradually get worse, you can go from 0-100 in terms of severity. It's not something predictable sometimes. Or if you get any other problem like a bad flu with severe valve, you might still get not very well compensated. I think there's more tendency to treat severe aortic valve. I think if the trials show that there's no improvement in survival, but there's no harm, I think maybe, there's going to be a push to treat asymptomatics because you're not harming them. So we'll see what trial shows, but I don't think there's going to show harm in general. Probably is going to show neutral results or positive. That's my feeling.

I don't think positive data will really change the number of TAVRs I'm doing. The majority are not asymptomatic. From 100 you might get five asymptomatic truly. And to prove that they're asymptomatic, we made them walk on the treadmill. I don't think it's a big number. A lot of the patients they reach the severity they might be already having symptoms. They're not very common in my opinion."

KOL perspectives on mitral

Pascal for mitral vs MitraClip

Pascal expected to take over the market since it is easier to learn how to use. KOL has switched from 100% MitraClip to 60% Pascal.

“I think it's going to overcome the market. Vs MitraClip I don't think there are differences in how you do the devices. Maybe the Pascal has some better niche than the MitraClip in certain anatomies. But the main difference is it's much easier to learn how to do Pascal than to do MitraClip. I trained doctors, and when they're doing a MitraClip, there's so many steps. Assemble the clip, put it in the body. That's compared to a Pascal is much simpler. The guys that are graduating out of college I think they’ll use Pascal. We switched our practice from 100% MitraClip before Pascal and now we're already 60% Pascal. That's because it's easy to use. “

Degenerative mitral regurgitation (DMR) vs functional mitral regurgitation (FMR)

Pascal only approved for DMR which is limiting use of Pascal but there is likely off label use of Pascal in FMR.

“Degenerative is just the problem with the mitral valve itself. Functional is when the mitral fails because the heart dilates, so they don't get together the valves. They are different animals, that's why the FDA is having a trial for the functional.

We follow the book here, so we have someone with functional MR, we can’t offer Pascal, only as part of the trial. If someone has primary MR we offer Pascal or MitraClip. I think the adoption is being limited because if you clearly have someone with functional and you do a Pascal, it's not approved for that scenario. It's all about the wording. People call them functional degeneration but functionality but they're truly functional. It happened with MitraClip before it was approved for functional people were using a functional.”

Price objective basis & risk

Edwards Lifesciences (EW)

Our PO of $105 is based on a 35x PE multiple on our 2025E EPS. We assume with high single digit revenue growth, good margins/cash flow/balance sheet and some upside TAM potential, EW deserves a 35x forward EPS (five turn premium to SYK).

Risks to our PO are: 1) the TAVR market slows if the TAM is not as big as we expect or new populations do not benefit from TAVR, 2) the mitral/tricuspid market does not materialize, 3) EW faces setbacks with its clinical trials or pipeline, 4) the TAVR market becomes more competitive.

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US - Medical Technology & Devices Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	Abbott Laboratories	ABT	ABT US	Travis Steed
	Axonics	AXNX	AXNX US	Travis Steed
	Bausch & Lomb	BLCO	BLCO US	Craig Bijou
	Becton Dickinson	BDX	BDX US	Travis Steed
	Boston Scientific	BSX	BSX US	Travis Steed
	Dexcom	DXCM	DXCM US	Travis Steed
	Edwards Lifesciences	EW	EW US	Travis Steed
	Inari Medical	NARI	NARI US	Travis Steed
	Inspire Medical	INSP	INSP US	Travis Steed
	Insulet	PODD	PODD US	Travis Steed
	Intuitive Surgical	ISRG	ISRG US	Travis Steed
	Medtronic	MDT	MDT US	Travis Steed
	Paragon 28	FNA	FNA US	Craig Bijou
	Procept BioRobotics Corporation	PRCT	PRCT US	Craig Bijou
	RxSight	RXST	RXST US	Craig Bijou
	Shockwave Medical	SWAV	SWAV US	Travis Steed
	Si-Bone	SIBN	SIBN US	Craig Bijou
	Stryker	SYK	SYK US	Travis Steed
	The Cooper Companies	COO	COO US	Craig Bijou
NEUTRAL				
	Baxter International Inc	BAX	BAX US	Travis Steed
	Conmed	CNMD	CNMD US	Travis Steed
	GE HealthCare	GEHC	GEHC US	Craig Bijou
	Integer Holdings Corporation	ITGR	ITGR US	Craig Bijou
	Merit Medical	MMSI	MMSI US	Craig Bijou
	Teleflex Incorporated	TFX	TFX US	Craig Bijou
	Zimmer Biomet	ZBH	ZBH US	Travis Steed
UNDERPERFORM				
	Embecta	EMBC	EMBC US	Travis Steed
	Globus Medical	GMED	GMED US	Craig Bijou
	Integra Lifesciences	IART	IART US	Craig Bijou
	Nevro	NVRO	NVRO US	Travis Steed
	Outset Medical	OM	OM US	Travis Steed
	Silk Road Medical	SILK	SILK US	Travis Steed
	Tandem Diabetes Care	TNDM	TNDM US	Travis Steed

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Business Performance	Numerator	Denominator
Return On Capital Employed	NOPAT = (EBIT + Interest Income) × (1 – Tax Rate) + Goodwill Amortization	Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill Amortization
Return On Equity	Net Income	Shareholders' Equity
Operating Margin	Operating Profit	Sales
Earnings Growth	Expected 5 Year CAGR From Latest Actual	N/A
Free Cash Flow	Cash Flow From Operations – Total Capex	N/A

Quality of Earnings	Numerator	Denominator
Cash Realization Ratio	Cash Flow From Operations	Net Income
Asset Replacement Ratio	Capex	Depreciation
Tax Rate	Tax Charge	Pre-Tax Income
Net Debt-To-Equity Ratio	Net Debt = Total Debt – Cash & Equivalents	Total Equity
Interest Cover	EBIT	Interest Expense

Valuation Toolkit	Numerator	Denominator
Price / Earnings Ratio	Current Share Price	Diluted Earnings Per Share (Basis As Specified)
Price / Book Value	Current Share Price	Shareholders' Equity / Current Basic Shares
Dividend Yield	Annualised Declared Cash Dividend	Current Share Price
Free Cash Flow Yield	Cash Flow From Operations – Total Capex	Market Cap = Current Share Price × Current Basic Shares
Enterprise Value / Sales	EV = Current Share Price × Current Shares + Minority Equity + Net Debt + Other LT Liabilities	Sales
EV / EBITDA	Enterprise Value	Basic EBIT + Depreciation + Amortization

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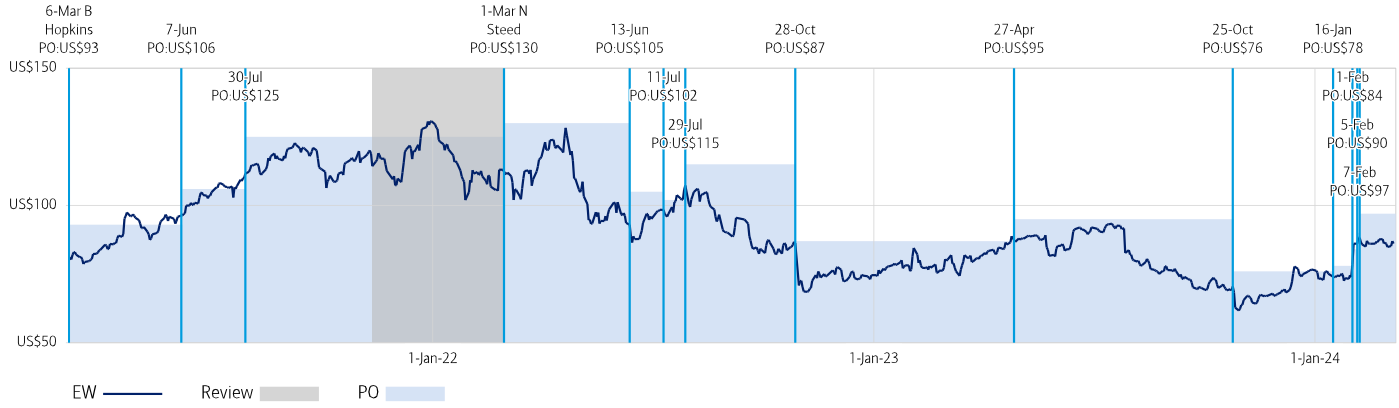
Edwards Lifesciences (EW) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

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Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)

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

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

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Investment rating	Total return expectation (within 12-month period of date of initial rating)	Ratings dispersion guidelines for coverage cluster[R2]
Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

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