BofA SECURITIES

EU Medtech & Healthcare Services

Alzheimer's Disease for Imaging

Industry Overview

Newly approved AD drugs create more need for scans

Novel drugs for Alzheimer's Disease (AD) recently approved by the FDA require imaging at each stage of treatment. MRI and PET scans are used to confirm patient eligibility pre-treatment, monitor progress and side effects during treatment, and examine further development post-treatment. By 2026, we estimate 1.5m patients in the US can benefit from these drugs. If 200k use them, we believe the total number of required imaging scans (PET and MRI combined) could reach >2m.

SHL is the market leader for PET radioactive tracer

Siemens Healthineers is the US market leader for the production and distribution of PET tracers, used to confirm the presence of beta-amyloid, a key marker for Alzheimer's. Currently the retail price for tracers is $2,500, but we estimate this to normalise towards $600 by 2026. By FY26E, Alzheimer tracers can add c1ppt to SHL's Imaging revenues and EBITA, a sizeable opportunity for the medium term.

BofA hosts expert to discuss potential opportunities

On 20th February, we are hosting Jake Dubroff, Associate Professor of Radiology at the University of Pennsylvania, to further dive into the topic. We will discuss potential uptake of the drugs, reimbursement landscape, how this might impact the install base of existing imaging equipment, and how pricing and volume of tracers might evolve.

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Equity
Europe
Medical Technology

Julien Ouaddour >>
Research Analyst
MLI (UK)
+44 20 7995 5049
julien.ouaddour@bofa.com

Marianne Bulot >>
Research Analyst
MLI (UK)
+44 20 7996 1033
marianne.bulot@bofa.com

Monica Zhuang >>
Research Analyst
MLI (UK)
monica.zhuang@bofa.com

Refer to important disclosures on page 8 to 10.

Alzheimer's disease: a sizeable mid/long-term opportunity for Imaging

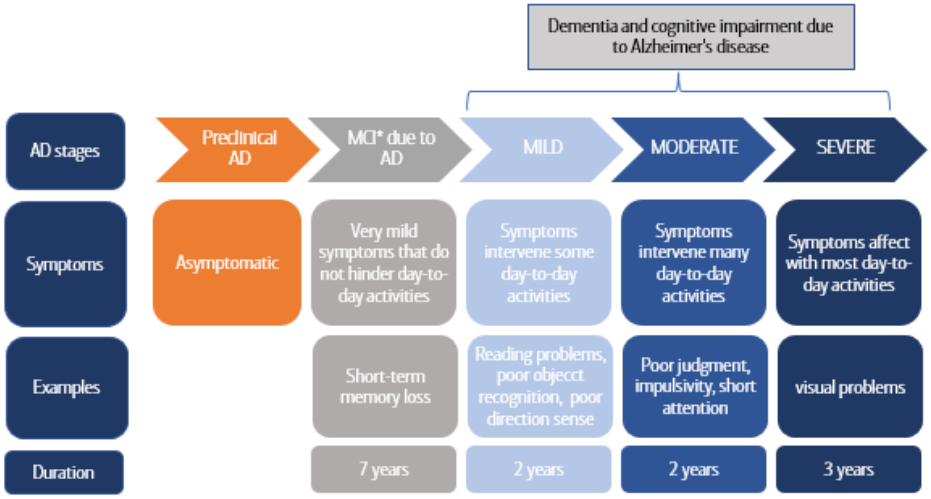
Some 141 drugs ae being tested in clinical trials for the treatment of Alzheimer's disease (AD), of which 78% are designed to slow its progress. Newly approved and upcoming drugs (lecanemab and donanemab) create an important mid/long-term opportunity for imaging diagnosis, which is entirely part of the treatment (pre-, during and post-treatment). Our analysis leads to 200k US AD patients on novel drugs in 2026E, which should generate c.1.9m extra imaging scans (MRI and PET combined) in the year. As SHL is the US leader for PET tracers production and distribution, we believe the incremental Alzheimer's revenues and EBITA contribution (for the US only) could be c1ppt for the Imaging business by FY26E.

Alzheimer's: new therapies on the rise

Amyloid – one of the root causes of Alzheimer's

The causes of Alzheimer's disease (AD) are complex, but one key origin is the build-up of two substances inside the brain called amyloid and tau, forming respectively what are called plaques and tangles. Plaques are composed of a protein called beta-amyloid, which abnormally clumps together, making it harder for the brain to work properly.

Exhibit 23: Dementia and cognitive impairments due to AD start from the mild stage
Evolution of Alzheimer's disease (AD) through different stages



Source: BofA Global Research
*MCI = Mild Cognitive Impairment

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Large pharma companies have made good progress recently to slow AD

For a large part of the past three decades, amyloid clumps (e.g., plaques, a hallmark of the disease) have been the prime target for most Alzheimer's researchers – either getting rid of plaques or preventing their build-up could slow cognitive decline.

Pharmaceutical company Biogen had hopes for its experimental Aduhelm drug, which received FDA approval in January 2022 (despite contradictory trial results), but in April, the CMS (Centers for Medicare & Medicaid Services) refused to cover Aduhelm under Medicare, given the lack of efficacy and safety concerns.

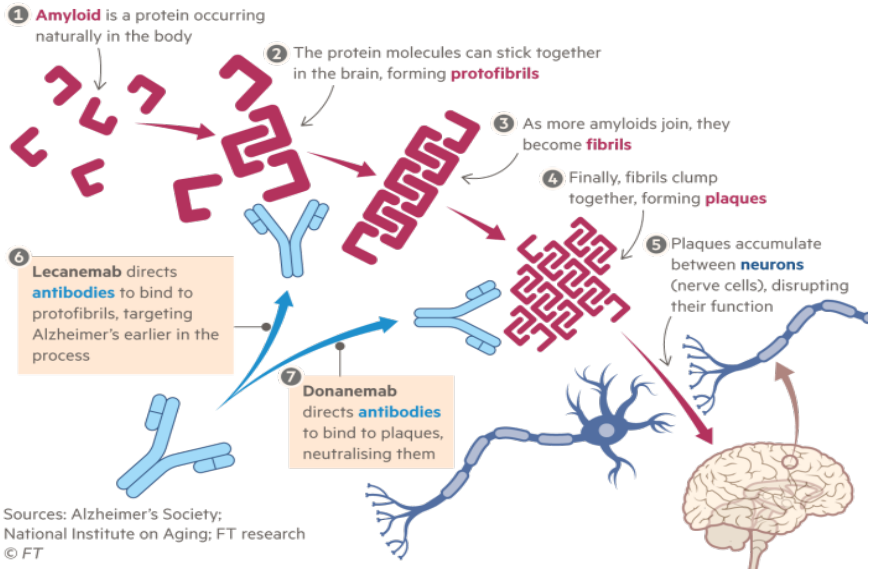
Since then, Eisai/Biogen received full FDA approval for Leqembi (e.g., lecanemab) in July 2023 (accelerated approval granted in January) with a serious probability that the drug will be reimbursed by major public sector payors. In addition, Eli Lilly published positive PIII trial results for its drug (e.g., donanemab) in July 2023 and filed an application for full

FDA approval. A decision is expected by the first quarter of 2024. Both lecanemab and donanemab drugs show they can slow cognitive and functional decline with early symptomatic Alzheimer's disease (MCI and Mild AD) by around 30-60%, depending on how early the drug is administered.

Lecanemab and donanemab: what is the main difference?

The immunotherapy drugs lecanemab and donanemab are disease-modifying treatments. This means that rather than just relieving the symptoms of Alzheimer's, they tackle one of the root causes. In principle, immunotherapy drugs (mostly for treating cancers) tell the body's immune system to attack and get rid of foreign cells or proteins. Lecanemab/donanemab teach the immune cells to recognise and remove a protein called amyloid, which is one of the causes of Alzheimer's as it is toxic to brain cells, causing them to get sick and to eventually die. Although both drugs target amyloid protein, they do so at different stages. Lecanemab targets amyloid as it begins to form fibres, whereas donanemab binds to amyloid once the fibres have clumped together to become a larger build-up or plaque in the brain.

Exhibit 24: Both lecanemab and donanemab direct the immune system against amyloid proteins
Immunotherapies for Alzheimer disease: mechanism of action for lecanemab and donanemab drugs



Source: Alzheimer's Society, National Institute on Aging, Financial Times

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Some limits persist: side effects, access, and cost

Serious side effects occur for small number of patients with the treatment

As with all drug treatments, there have been some side effects associated with lecanemab and donanemab. Most were asymptomatic or mild (e.g., headaches, fluid formation or brain swelling due to amyloid). However, a small number of patients experienced more severe brain swelling, with symptoms like confusion and visual disturbance.

Access to the drug slowed by availability of specialists and cost

The CMS announced in June 2023 that it will cover the costly drugs (US list price of $26,500 per year) once they get full FDA approval, for patients enrolled in Medicare Part B that meet the criteria. That criteria includes patients' physicians and clinical teams participating in registries to collect evidence on how the drugs work in the real world. Patients may be delayed access to the drug because of the relative shortage of specialists capable of conducting cognitive tests or managing the drug and participating in the clinical study.

Despite insurance coverage, the registry requirement could limit access to the drug. According to estimates from the Institute for Clinical and Economic Review, in addition to the price of Leqembi at $26,500 pa, treatment could cost US taxpayers $82,500 per patient per year, on average, for genetic tests and frequent brain scans, safety monitoring, and other care. To cover extra costs, the CMS could increase monthly premiums for Medicare patients. In addition, studies show that patients without supplemental Medicare coverage will have to pay about $6,600 out-of-pocket for each year of treatment, putting the drug's reach at risk in the country.

A mid-/long-term opportunity for Imaging

How to track the beta-amyloid protein in the brain?

There is no single test that can determine if a person is living with Alzheimer's or another dementia, and studies show that neurodegenerative diseases, including AD, start years before symptoms appear (e.g., beta-amyloid can begin to form plaques 20-25 years before the clinical onset of the disease). To make an accurate diagnosis, physicians use diagnostic tools (neurological exams, cognitive and functional assessments) combined with medical history, as well as brain imaging (MRI, CT, PET), cerebrospinal fluid or blood tests. Because build-up and accumulation of amyloid-β (Aβ or beta-amyloid, also called plaques) are found in all patients with AD, it has been suggested that beta-amyloid plays an important role. Levels of beta-amyloid can now be measured in the brain (using positron emission tomography (PET) imaging) and in cerebrospinal fluid (via lumbar puncture).

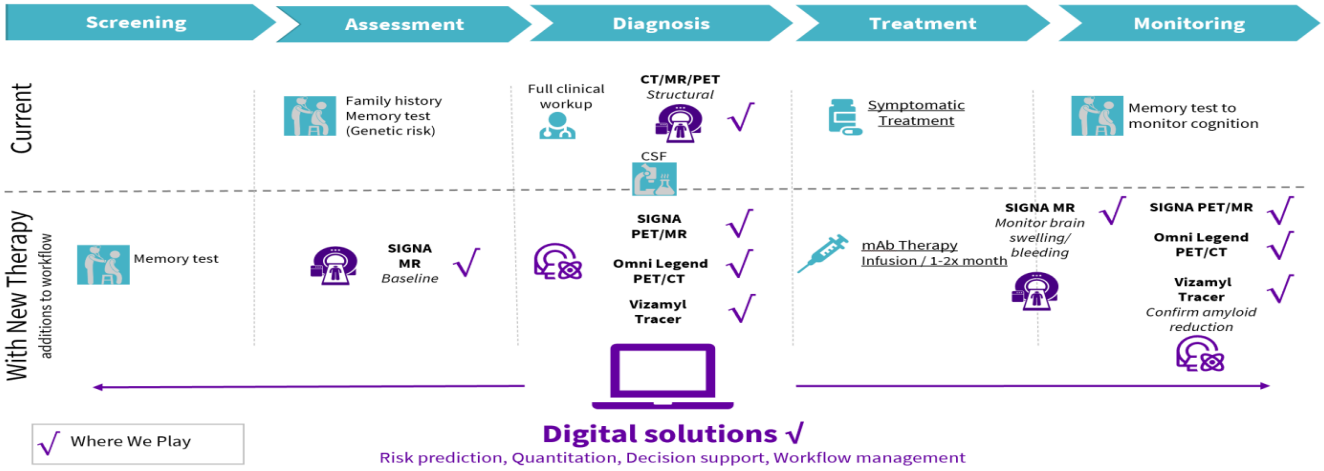
Beta-amyloid can be detected in three ways, but PET scans remain the gold standard:

- **PET-CT scan**: high accuracy, amyloid location and concentration.
- **Spinal fluid test**: high accuracy, no location information, cheaper, but unpleasant and contraindicated in some patients.
- **Blood test**: some in phase-three trials, but currently less reliable, so could be a useful initial screening tool.

Imaging diagnosis is required pre, during, and post treatment

AD's drugs should play an important role for imaging since diagnosis is required at every step of the treatment. While an MRI scan must be done pre-treatment without showing evidence of multiple microhaemorrhages, a PET scan using an amyloid imaging agent (e.g. tracer) should confirm the presence of amyloid-beta proteins. During treatment, MRI scans are needed for surveillance of side effects (three in the first year) and PET scans to confirm the diminution of amyloid-beta in the brain (at least three). Post treatment, additional MRI scans could be needed to monitor the brain.

Exhibit 25: New therapies for Alzheimer's patients enable growth opportunities for imaging players, mostly in MR and CT
GE Healthcare focus for Alzheimer's patients



Source: GE Healthcare presentation

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One PET scan reimbursed today, CMS looks to increase coverage

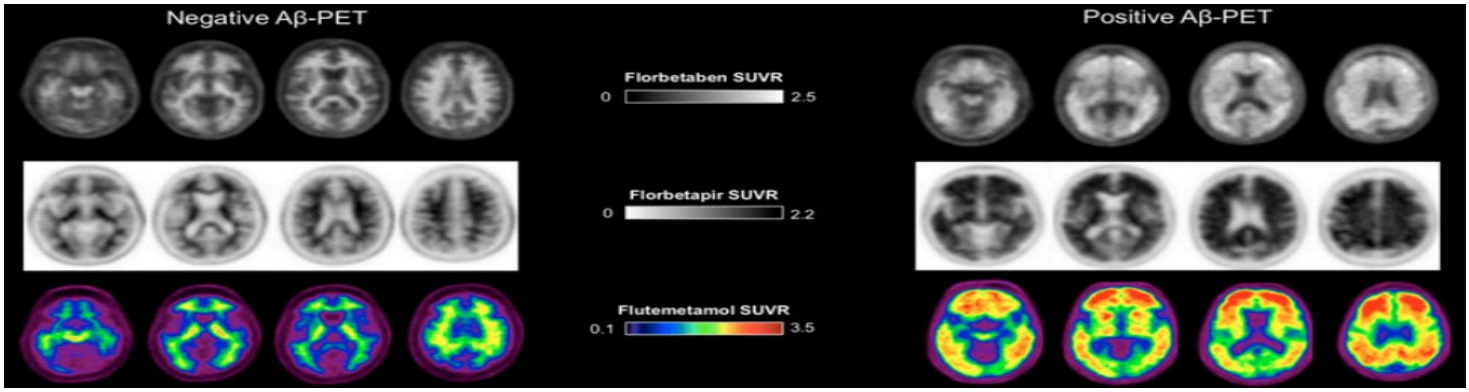
At the moment, CMS has a once-per-lifetime limit on beta-amyloid PET scans per patient, which had restricted their use to clinical trials only. However, in July 2023, the US agency opened the way for a broader coverage as patients must have evidence of the protein in their brain to qualify for treatment.

Radiopharmaceutical tracer's opportunity, relevant for SHL

Amyloid-beta is detected thanks to a radioactive tracer, which is designed to stick to amyloid-beta neuritic plaques in the brain for a short amount of time. When used with a PET scanner, the tracer can reveal the presence or absence of plaques, which is required for the patient to be eligible for the drug. Only three tracers are currently approved by the FDA: 1) Life Healthcare's NeuraCeq® (florbetaben F18); 2) Eli Lilly's AMYViD™ (florbetapir F18); and 3) GE Healthcare's Vizamyl™ (flutemetamol F18).

While Siemens Healthineers doesn't develop the radiopharmaceutical tracer, the company is the US market leader for production and distribution, with more than 50% market share, we believe. Due to its complicated production and distribution process (the tracer has a very short lifetime, which requires local production and scale for fast distribution), we believe SHL can share the tracer revenues equally with the developer.

Exhibit 26: GE Healthcare has the only FDA approved amyloid-beta tracer for color image
Examples of negative and positive amyloid-beta PET findings using different FDA approved tracers



Source: The Journal of Nuclear Medicine

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We estimate 200k US patients in 2026, generating c.1.9m scans pa

Total Addressable Market for AD: we see 1.5m US patients in 2026E

Drugs targeting Alzheimer's disease (AD) have only been tested on Mild Cognitive Impairment (MCI) patients and people with Mild AD. In order to assess the total addressable patients pool in the US for Alzheimer's drugs and, based on our US team's estimates, we split the analysis into:

- **MCI patients (1.1m patients in 2026):** Among the >65 population, a systematic review of more than 30 studies reported that c17% of patients had MCI. Among these, a study from JAMA showed that c55% had positive amyloid PET results. In line with our US team, we expect an increase in the number of diagnosed patients (from 5% in 2022 to 24% in 2030), stressing that it can be challenging to diagnose them due to symptoms (depression) or lack of diagnosis (e.g. waiting time for PET scan, lack of blood-based biomarkers, etc.).

- **Mild AD patients (0.4m patients in 2026):** According to the Alzheimer's Association, there are 6.7m AD patients in the US as of 2023. We estimate this is growing +2.5% pa and that of this number, around 30% have mild symptoms. Positive amyloid PET is higher than for MCI, given patients are in a more advanced stage of the disease (88%) and the share of diagnosed patients is also higher.

Exhibit 27: With more diagnosed patients, we believe TAM for Alzheimer patients could reach 1.5m people in the US by 2026
Market sizing for Alzheimer's drugs

	2021A	2022A	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Alzheimer Disease (AD) - market sizing										
Addressable patients with MCI										
Total US population (mn)	332.7	334.2	335.2	336.2	337.3	338.3	339.3	340.3	341.3	342.3
% growth		0.5%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
% population >65 years	17%	17%	17%	18%	18%	19%	19%	19%	20%	20%
% MCI	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%
% with positive amyloid PET scan	55%	55%	55%	55%	55%	55%	55%	55%	55%	55%
# of people >65y MCI + amyloid (mn)	5.2	5.4	5.5	5.6	5.7	5.9	6.0	6.1	6.3	6.4
% diagnosed patients	5%	5%	9%	13%	16%	18%	20%	22%	23%	24%
# Addressable MCI diagnosed patients (mn)	**0.3**	**0.3**	**0.5**	**0.7**	**0.9**	**1.1**	**1.2**	**1.3**	**1.4**	**1.6**
Addressable patients with Mild AD										
# of cases of AD (mn)	6.4	6.5	6.7	6.9	7.0	7.2	7.4	7.6	7.8	8.0
% Mild AD	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
% with positive amyloid PET scan	88%	88%	88%	88%	88%	88%	88%	88%	88%	88%
# of Mild AD patients + amyloid (mn)	1.7	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.1	2.1
% diagnosed patients	15%	15%	18%	20%	21%	23%	24%	25%	26%	27%
# Addressable MCI diagnosed patients (mn)	**0.3**	**0.3**	**0.3**	**0.4**	**0.4**	**0.4**	**0.5**	**0.5**	**0.5**	**0.6**
Total addressable patients (mn)	**0.5**	**0.5**	**0.8**	**1.1**	**1.3**	**1.5**	**1.7**	**1.8**	**2.0**	**2.1**
% growth		**2.5%**	**54.1%**	**31.0%**	**21.0%**	**15.5%**	**12.1%**	**9.7%**	**8.1%**	**6.9%**

Source: BofA Global Research estimates

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200k patients using drugs would result in 1.9m scans pa in 2026E

Despite imaging companies refusing to put a number on the potential benefit from Alzheimer's drugs for their businesses, we try to picture the potential impact. In our scenario – and assuming lecanemab/donanemab increase market share over time (based on our US team's estimates) – we believe the total number of required imaging scans (PET and MRI combined) could reach >2m in 2026E.

Given amyloid is not only detected using PET scans (spinal fluid or blood tests possible), we assume only one-third is discovered with imaging technology today, which is in-line with a study from the European Journal of Nuclear Medicine and Molecular Imaging. To reflect the potential increased coverage for PET scans, we assumed more penetration (up to 68% in 2030). Overall, we believe Alzheimer's could account for close to 25% of the total number of annual PET scans in the US in 2026 and up to c70% in 2030.

For MRI, the required several scans (e.g., mostly to monitor side effects) would imply that c1.4m are performed in 2026 (5% of total number of scans) and even 3.5m in 2030 (12%).

Exhibit 28: Increasing adoption of Alzheimer drugs could require 1.9m scans (PET and MRI combined) in 2026, or close to 5m in 2030
Bottom-up analysis on Alzheimer's drugs and the impact for imaging diagnostics

	2021A	2022A	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Alzheimer Disease (AD) - Imaging opportunity										
lecanemab & donanemab										
Total addressable patients (mn)	0.5	0.5	0.8	1.1	1.3	1.5	1.7	1.8	2.0	2.1
lecanemab market share	0%	0%	1%	3%	5%	8%	10%	11%	13%	14%
donanemab market share	0%	0%	0%	2%	4%	6%	7%	8%	9%	10%
# patients under treatment ('000)	**0.0**	**0.0**	**4.1**	**47.9**	**115.8**	**199.2**	**281.8**	**360.7**	**434.4**	**502.4**
% growth				n.a	142%	72%	41%	28%	20%	16%
Opportunity for PET scans										
Initial PET scan for amyloid-beta detection	1	1	1	1	1	1	1	1	1	1
Additional PET scans to monitor amyloid	3	3	3	3	3	3	3	3	3	3
% amyloid-beta diagnostics using PET	33%	33%	33%	50%	55%	60%	62%	64%	66%	68%
# PET scans required ('000)	**0.0**	**0.0**	**5.4**	**95.7**	**254.8**	**478.0**	**698.9**	**923.5**	**1,146.9**	**1,366.5**
# Total number of PET scans ('000)	**2,200**	**2,310**	**2,426**	**2,547**	**2,674**	**2,808**	**2,948**	**3,096**	**3,250**	**3,413**
% Alzheimer as of total scans	**0.0%**	**0.0%**	**0.2%**	**3.8%**	**9.5%**	**17.0%**	**23.7%**	**29.8%**	**35.3%**	**40.0%**
Opportunity for MRI scans										
MRI scan for evaluation pre-treatment	1	1	1	1	1	1	1	1	1	1
MRI prior infusions during first year	4	4	4	4	4	4	4	4	4	4
Potential additional MRI scans post treatment	2	2	2	2	2	2	2	2	2	2
# MRI scans required ('000)	**0.0**	**0.0**	**28.4**	**335.0**	**810.7**	**1,394.2**	**1,972.7**	**2,525.1**	**3,041.1**	**3,516.8**
# Total number of MRI scans ('000)	**30,000**	**31,500**	**33,075**	**34,729**	**36,465**	**38,288**	**40,203**	**42,213**	**44,324**	**46,540**
% Alzheimer as of total scans	**0.0%**	**0.0%**	**0.1%**	**1.0%**	**2.2%**	**3.6%**	**4.9%**	**6.0%**	**6.9%**	**7.6%**

Source: BofA Global Research estimates

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Incremental sales/EBITA from Alzheimer tracers could add c1% in FY26E

While it is uncertain if/when Alzheimer's can really drive the imaging installed base, we look at the potential contribution from the tracers for SHL given its >50% market share in the US. Based on our previous PET scan assumptions for Alzheimer's, we presume the current retail tracer price is $2,500 (based on our conversations with industry experts), but should normalise towards the high-end of the usual tracer price range of $100-600 over time. Overall, we believe that by FY26E, Alzheimer tracers can add c1ppt to SHL's Imaging revenues and EBITA, which suggests a sizeable opportunity for the company in the mid/long-term. We stress that this analysis shouldn't be taken as exact science, but more as a good exercise to size the Alzheimer's opportunity for SHL.

Exhibit 29: Incremental revenues/EBITA from Alzheimer tracers could add c1ppt to SHL's Imaging business by FY26, accelerating towards 2ppt by FY30
Incremental revenues and EBITA contribution from Alzheimer for Siemens Healthineers, which is the market leader in production and distribution in the US

	2021A	2022A	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Number of tracers required ('000)	0.0	0.0	5.4	95.7	254.8	478.0	698.9	923.5	1,146.9	1,366.5
Cost by tracer ($)			$2,500	$2,000	$1,000	$600	$570	$542	$514	$489
SHL market share	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Implied incremental Alzheimer revenues ($m)			7	96	127	143	199	250	295	334
Implied incremental Alzheimer revenues (EURm)			**6**	**88**	**117**	**131**	**182**	**229**	**270**	**306**
% growth contribution to SHL Imaging revenues			0.1%	0.7%	0.9%	1.0%	1.3%	1.5%	1.7%	1.8%
Assumed EBITA margin			20%	20%	20%	20%	20%	20%	20%	20%
Implied incremental EBITA (EURmn)			**1**	**18**	**23**	**26**	**36**	**46**	**54**	**61**
% growth contribution to SHL Imaging EBITA			0.1%	0.7%	0.8%	0.9%	1.1%	1.3%	1.5%	1.6%

Source: BofA Global Research estimates

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Disclosures

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Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

[R1]Ratings dispersions may vary from time to time where BofA Global Research believes it better reflects the investment prospects of stocks in a Coverage Cluster.

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