AgNovos BIOSCIENCE

A regenerative technology company pioneering novel treatments for bone disease

Introductory Investor Materials

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AgNovos at a glance

AgNovos has developed a novel, regenerative targeted treatment for weak bone at risk for fracture to address a significant, global unmet need in bone health

Traction:

- ✓ Agreement from FDA on approval pathway
- ✓ Hip treatment included in pan-European treatment guidelines
- ✓ Commercial with adopters in Germany, Switzerland, Belgium, Spain and Italy
- ✓ 225+ procedures performed across 10 countries
- ✓ Spine product received Breakthrough Designation and IDE
- ✓ In-house production capability

Roadmap:

- → Pivotal trials for U.S. approval in hip and spine underway
- → New CE mark under MDR anticipated early ‘23 paving the way for expanded commercialization across Europe
- → U.S. hospital in-patient and outpatient coding submissions underway

1. The treatment, known as AGN1 LOEP, is not yet approved in the U.S.; currently sold in Europe under general indication; RESTORE trial underway to demonstrate fracture risk reduction

A woman’s risk of breaking her hip is equal to her combined risk of breast, uterine and ovarian cancer

600+ million women and men are impacted by osteoporosis and are at risk of fragility fracture

Osteoporosis: global burden with significant unmet need

A degenerative bone disease that reduces bone quality, architecture and strength resulting in increased fracture risk

$100+ Billion spent annually on osteoporosis and fragility fractures

Normal bone

Osteopenia

Osteoporosis

Bone fracture

Current treatments
are an incomplete solution

1. **At least 12 – 18 months of compliant use needed to gain measurable protection**

   patients are ~12x more likely to refracture immediately following the first fracture

2. **Low usage and compliance, even in highest-risk patients**

   ~50% of patients stop taking medication within 6 – 12 months, never reaching any meaningful protection

3. **>45% residual risk remains even with perfect drug therapy compliance**

   the best therapies are still a "coin flip", and the rate of fractures continues to increase every year in spite of the drugs being available for decades

The impact of fractures on patients is profound

Significant Mortality

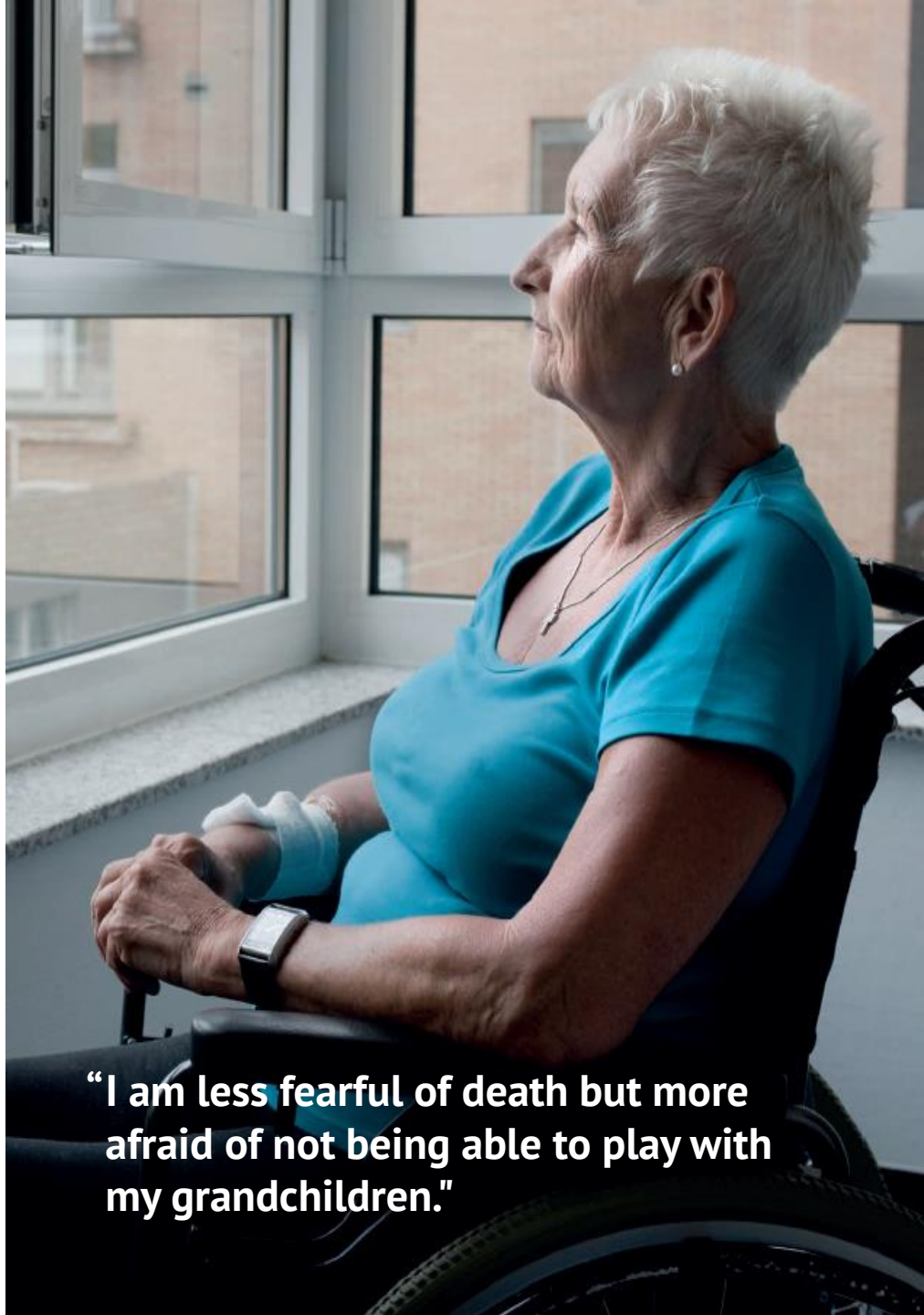
25%

25% of hip fracture patients aged 50 and over die in the year following fracture

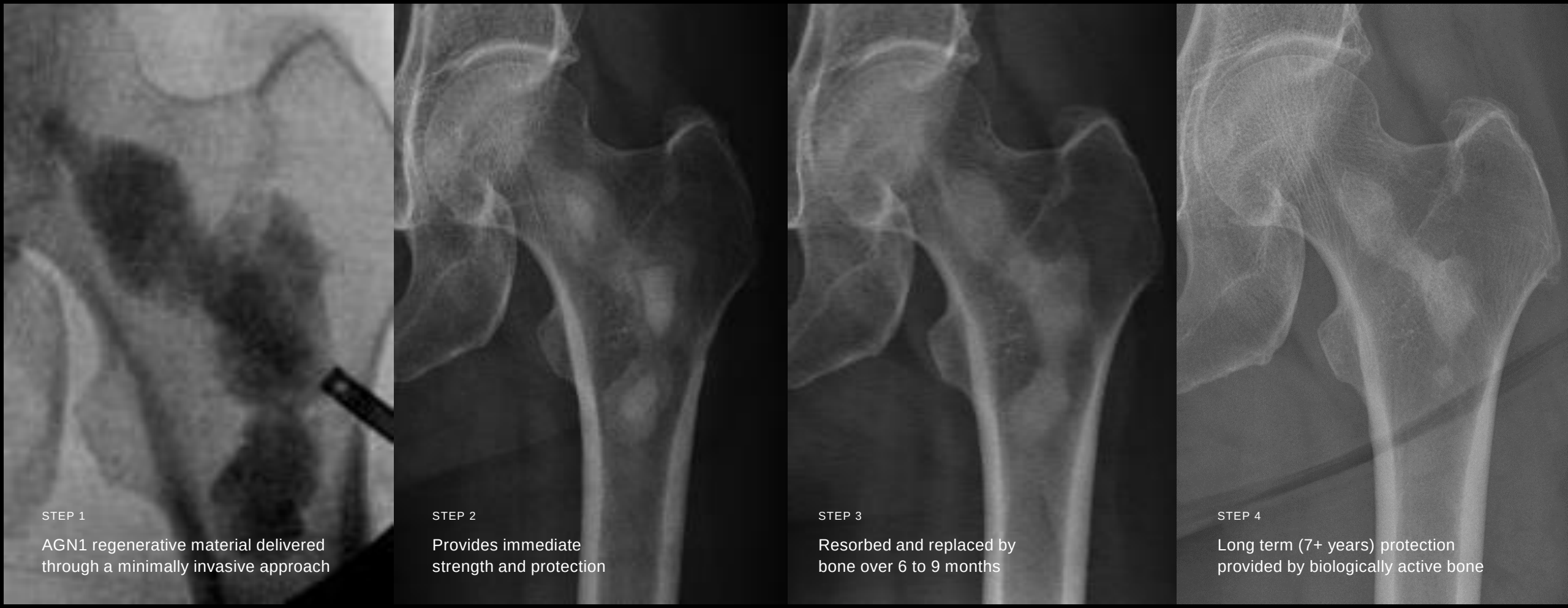
Increased Disability and Reduced Quality of Life

40%

40% of patients no longer able to walk independently following fracture



AgNovos Solution: Local Osteo-Enhancement Procedure is a targeted therapy designed to reduce fracture risk



STEP 1

AGN1 regenerative material delivered through a minimally invasive approach

STEP 2

Provides immediate strength and protection

STEP 3

Resorbed and replaced by bone over 6 to 9 months

STEP 4

Long term (7+ years) protection provided by biologically active bone

See footnote 1

2. Howe et al., Osteoporos Int, 2019

PATENT PROTECTED

AgNovos HEALTHCARE

Treatments integrate well into existing patient care pathways

AGN1 LOEP for Hip a minimally invasive treatment with quick recovery to keep patients mobile

Concomitant: same surgical procedure as hip fracture repair

- AGN1 LOEP treatment performed during the same operative session as the hip fracture repair
- Patients presenting with hip fragility fracture are known to be high risk
- Treatment managed by orthopedic surgeon – single stakeholder

Stand Alone: scheduled surgical procedure to perform LOEP

- AGN1 LOEP performed as a scheduled procedure either on one or both hips
- Multiple modalities and channels exist to identify patients as high risk
- Osteoporosis care and treatment managed by multiple stakeholders

Pioneering the next generation treatments in Spine

First Indication: Vertebral Compression Fractures (VCF)

- Awarded FDA “Breakthrough Device” designation as a resorbable solution to treat painful spine fractures
- Expected to overcome many of the shortcomings with PMMA, possibly including a reduction in adjacent fractures

Vertebral Body Strengthening (LOEP)

- Strengthens weak bone to stop the cascade of spine fractures and improve patient outcomes

Spinal Devices

- Introduces a resorbable biologic solution to improve surgical outcomes and benefit younger, more active patients

Building clinical evidence to transform the standard of care

8 Clinical Studies

Generating clinical evidence globally, including in the U.S., Europe, Hong Kong and Japan, with over 200 years of patient follow-up

FDA Pivotal Trials ***(blinded, randomized, controlled)***

RESTORE
Enrolling
(~800 pts.) Clinically establish AGN1 LOEP hip fracture reduction comparative to standard of care control

STAND
Enrolling
(408 pts.) VCF pain reduction, improved function and AGN1 resorption/bone formation comparative to PMMA

RECONFIRM
Enrolling
(150 pts.) stand-alone procedural safety and efficacy

GRACE
Enrolling
(55 pts.) commercial patient long-term follow-up

STRONG
Completed
(13 pts.) concomitant procedural safety and efficacy

CONFIRM
Long-term follow-up
(60 pts.) stand-alone procedural safety and efficacy

Copley
Completed
(12 pts.) “first in man” study with long-term follow-up

RISE
Enrolling
(100 pts.) VCF procedural safety and efficacy

Hip inidication, fracture reduction, is transformational

with approval, AGN1 LOEP would be **the only** approved, targeted treatment for fracture risk reduction

- Access to a **large, therapeutic end-market**
- "Drug-level" data **enables quick adoption**
- Supports **payor approvals**
- Significant **barrier to entry**

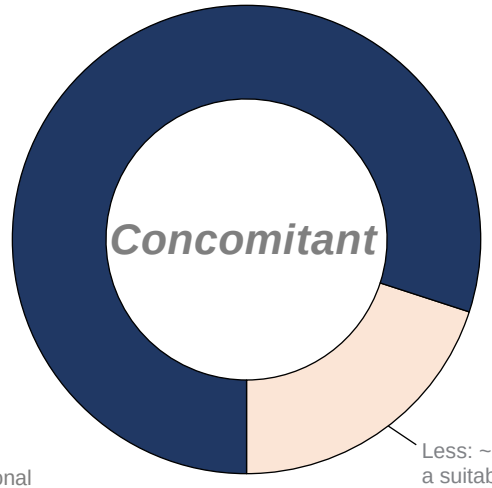
Hip Market Opportunity[3]

$120 Billion

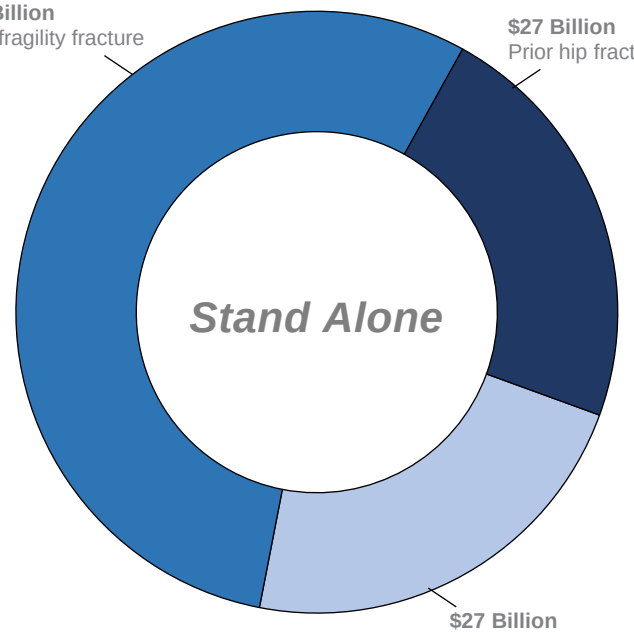
60,000,000+ women and men at high risk due to prior hip or other fragility fracture, DXA, FRAX, or other risk measure

$4+ Billion

2,000,000 hip fractures occur annually
Annual "flow" of new hip fractures is a recurring opportunity



Less: ~20% of patients would not be a suitable candidate due to prior hip fracture or surgical stability[4]



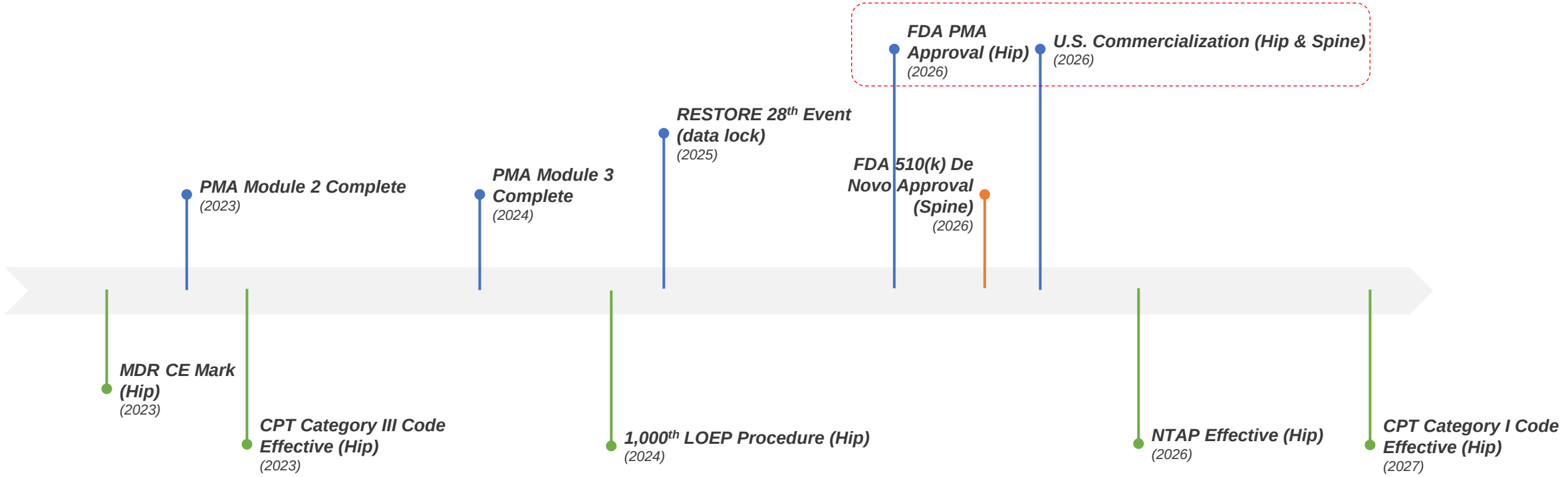
3. Source data includes IOF Compendium of Osteoporosis 2019; Kanis 2021 (SCOPE); National Osteoporosis Foundation
4. Patient exclusion percentage based on RESTORE study screening

Commercial strategy
to access global markets

US	FDA approvals in hip and spine targeted for 2026	>	CMS pathways for coverage, coding and payment are underway
Europe	New CE mark under MDR expected in early 2023	>	Currently commercial, building adoption across E.U. big 5
Japan	PMDA approval in hip targeted for 2025	>	Commercial distribution partner, Asahi Kasei, already secured

Realize the economic potential through achievement of milestones

Historical de-risking establishes the foundation for future success



5. Estimated dates subject to change and based on management's expectations

Investment highlights

Large global market with significant unmet need

Osteoporosis impacts over 600 million patients worldwide with $100+ billion in global annual spending on treatment and care. Existing treatments are moderately effective and have significant real and perceived side effects[6] resulting in a continued upward growth of new fractures each year.

Realistic pathway to success

Commercialization in Europe underway with FDA and PMDA agreement on regulatory pathway approval and pivotal studies launched. U.S. Breakthrough designation and IDE approval for spine product. Strong, global IP on material and method.

Unique and highly innovative product with compelling data

Minimally invasive, targeted approach designed to treat osteoporosis at the highest risk sites of the hip and spine through the creation of strong, healthy, functioning bone that provides lasting protection.

Experienced leadership team and board

Board of Directors and management team with a proven track record. Operations and infrastructure established to support long-term growth.

See footnote 1

6. Ferrari et al., Arch Osteoporosis, 2016


Patients are waiting.
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www.agnovos.com
New York, Rockville, Frankfurt, Dallas