



NOVADIP

Accelerated Healing for Better Living



Overview

01 OFFERING HOPE FOR A SINGLE CURATIVE TREATMENT

02 3M³ TISSUE REGENERATION PLATFORM

03 THERAPEUTIC PROGRAMS FOR TISSUE REPAIR

04 FINANCIAL POSITION/
INVESTMENT HIGHLIGHTS

Safe Harbor Disclaimer

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

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Accelerated Healing of Bone Defects and Injuries

Patients with critical size bone defects and trauma often face **permanent loss of mobility and even amputation**

Risk of nonunion is >50% across all bones due to fracture severity, co-morbidities (diabetes, obesity, smoking and other conditions) and medication use¹

>600,000 spine fusion procedures are performed annually

Our Mission

Develop a new class of regenerative tissue products that accelerate healing of large bone defects, bone non-union and spine fusion in a single treatment



Novadip's Journey From Concept to Pre-Commercial Company

Founded
2013
Belgium

Team
45+
FTE

Clinical
Stage

Total
Addressable
Market
\$13.5B

\$88M
Series A/B + Non-
Dilutive Funding



9
Patents
covering
products &
technology

50
Procedures for
bone
reconstruction

1
FDA Priority
Review
Voucher

3
Therapeutic
Product
Classes

Novadip is reimagining the standard of care for tissue regeneration with a single treatment cure

Inspirational Leadership Team and Expert Advisors Guiding Strategic Growth

Executive Leadership Team



Denis Dufrane, MD, PhD

Co-Founder, Chief Executive Officer and Board Member



Virginie Cartage

Chief Financial Officer



Nicolas Theys, PhD

Chief Technology Officer



Siegfried Ebner, PhD

Chief Operations Officer



Hara Episkopou, PhD

Head of Discovery

Board of Directors



Eric Paul Paques, PhD

Chairman



Gil Beyen

Board Member



Jean-Pierre Bizet

Board Member



Philippe Durieux

Board Member



Philippe Monteyne, MD, PhD

Board Member



Jason Zhou, MD

Board Member



Christina Franssen, PhD

Board Member

Chairman of Clinical Advisory Board



Gunnar B. J. Andersson, MD, PhD

Department of Orthopedic Surgery Rush University Medical Center

Chairman of Scientific Advisory Board

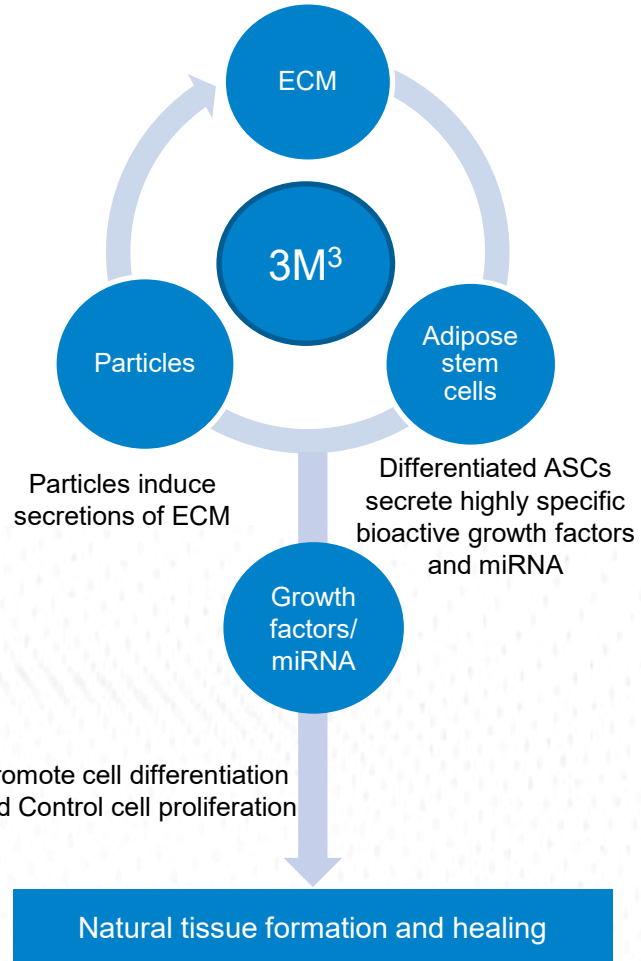


Aaron W. James, MD, PhD

Professor of Pathology Johns Hopkins University

3M³ Tissue Regeneration: Accelerated Healing through Single Treatment Cures

3-dimensional, extracellular matrix (ECM) uses adipose-derived stem cells (ASCs) to generate highly differentiated bioactive molecules that promote tissue regeneration



3M^{AUTO}: Autologous ASC Products

- Single treatment for long-term union/stability of critical size bone defects
- Orphan drug & rare pediatric disease designations for accelerated approval; eligible for priority review voucher worth more than \$100Mn
- Established clinical POC - >50 pediatric & adult patients treated to date

3M^{ALLO}: “Off the Shelf” Allogeneic Matrix Products

3M^{ALLO-REG}: Bone Regeneration

- Accelerated, stable bone union in >90% engraftment procedures
- Superior safety and bioactivity compared to other bone grafting platforms
- Clinical studies in spinal fusion/trauma begin in 2022
- Addresses \$7+Bn bone substitution market

3M^{ALLO-ONCO}: Solid Tumor

- Reduction of tumor progression
- Superior delivery of specific microRNA and proteins
- Pre-clinical in vivo evaluation
- Addresses a \$60+Bn Solid Tumor Market

3M^{EXO}: Allogeneic Exosome Products

- Discovery program targeting oncology and rejuvenation

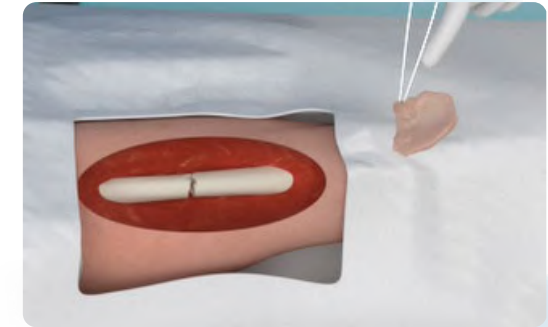
3M^{AUTO}: Autologous ASCs for critical bone and large tissue reconstruction



**Adipose
collection
(autologous)**




**3D Product
Manufacturing**



NVD-003

**Moldable, cellular, large
volume (>10cc) graft
for direct implantation**

- Cell collection to implantation in 3 months
- Robust osteogenic capacity driven by adipose stem cells
- Balanced “cocktail” of growth factors needed to drive critical size tissue repair
- Enriched in specific bioactive molecules to drive bone-healing pathways

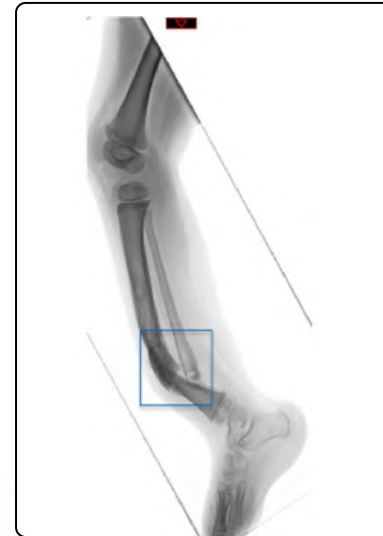
3M^{AUTO}: Potential single treatment cure of rare paediatric bone defects

Congenital Pseudarthrosis of Tibia (CPT)

- 1 in 150,000 births
- High disease burden: fracture, loss of mobility, amputation
- Standard of care is surgery, with autologous bone graft, which is associated with poor long-term outcomes, high risk of chronic pain, infection, blood loss/transfusion, and persistent risk of amputation

3M^{AUTO} Lead Candidate: NVD-003

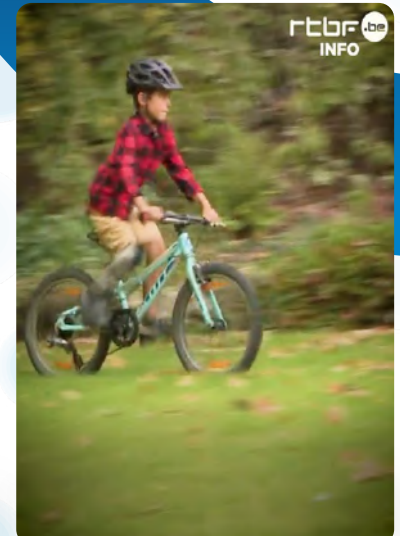
- Potential single treatment to save limb/restore mobility
- Active cells in autologous graft help achieve union in critical size defects
- Achieved durable bone fusion at 24 months
- 13 patients fully mobile at 4 year follow up
 - Compassionate use in 4 CPT patients supported IND submission
- Phase 1a/2b study initiation in US and EU in 2022



CPT leading to high risk of amputation



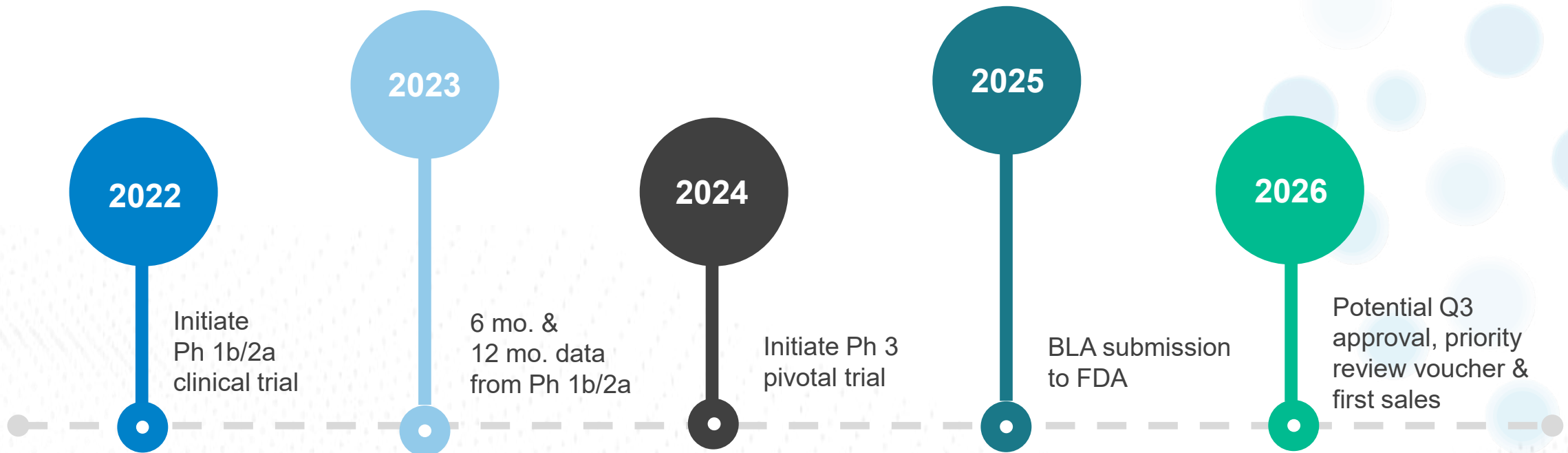
Autologous implant mimics and accelerates natural healing



age 3: unable to walk
age 7: active life/play

3M^{AUTO}: NVD-003 Clinical Development Timeline for CPT

- August 2022: Ph 1b/2a data readout for 2nd line treatment in BNU, results inform FDA interaction on Ph 3 CPT trial design
- Q3-Q4 2022: Ph 1b/2a clinical trial in CPT begins
- Q2-Q3 2023: FDA interaction to determine pivotal Ph 3 study design
- Q3-Q4 2023: First assessment of safety at 6 months FU, followed by >12-month safety and efficacy data



Priority Review Voucher (PRV) Eligibility

What does it mean for the company?

Upon FDA approval of NVD-003, Novadip can expect to receive a PRV, an asset valued at >\$100M

bluebird unveils \$2.8m price for gene therapy Zynteglo on FDA approval

August 18, 2022

bluebird also gets a priority review voucher from the FDA as a result of the approval, which could also bolster its finances as they can be worth \$100 million or more if sold on to other companies.

Rhythm Pharmaceuticals Announces Sale of Priority Review Voucher for \$100M

BOSTON, Jan. 05, 2021 (GLOBE NEWSWIRE) -- Rhythm Pharmaceuticals, Inc. (Nasdaq:RYTM), a biopharmaceutical company aimed at developing and commercializing therapies for the treatment of rare genetic diseases of obesity, today announced that it has entered into a definitive agreement to sell its Rare Pediatric Disease Priority Review Voucher (PRV) for \$100M.

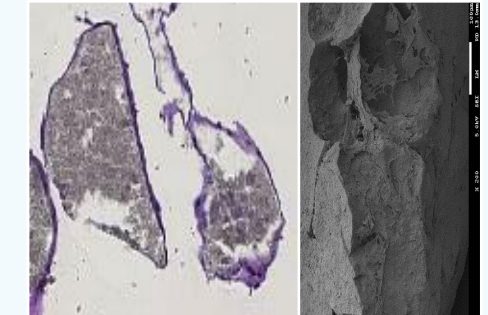
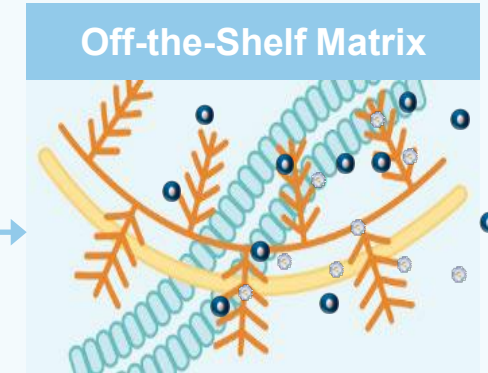
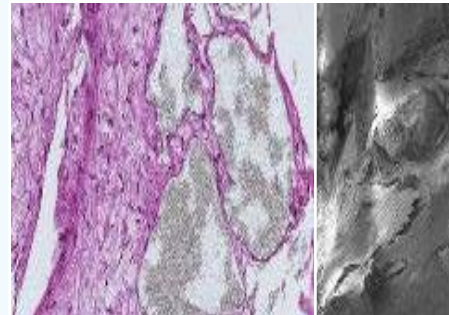
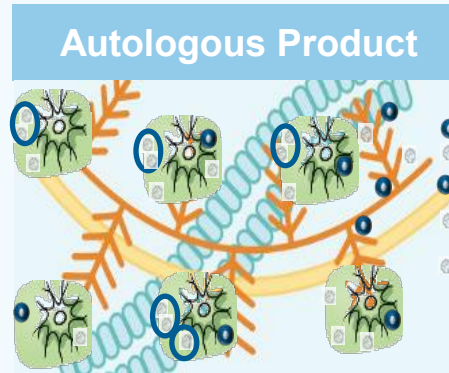
Novo strikes \$110M deal for regulatory fast pass

Published July 15, 2022

Danish drugmaker Novo Nordisk has agreed to pay \$110 million to acquire a voucher that speeds up Food and Drug Administration reviews, reaching a deal with Pennsylvania-based Marinus Pharmaceuticals that was disclosed Thursday.

3M^{ALLO}-REG: Groundbreaking “Off-the-shelf” product for common orthopedic conditions

- Disrupting the \$7Bn Bone Graft Market
- Validated and de-risked by clinical experience with 3M^{AUTO} program
- Lead asset NVD-X3 poised to enter clinical development in 2022
- 3M^{ALLO} matrix contains multiple bioactive factors at physiological concentrations to induce tissue healing
- Superior intraoperative handling characteristics
- Off-the-shelf product can be shipped and stored at room temperature
- Competitive COGS profile supports broad distribution and expanded patient access



Lyophilization
and sterilization
removes ASCs
to enable
off the shelf use

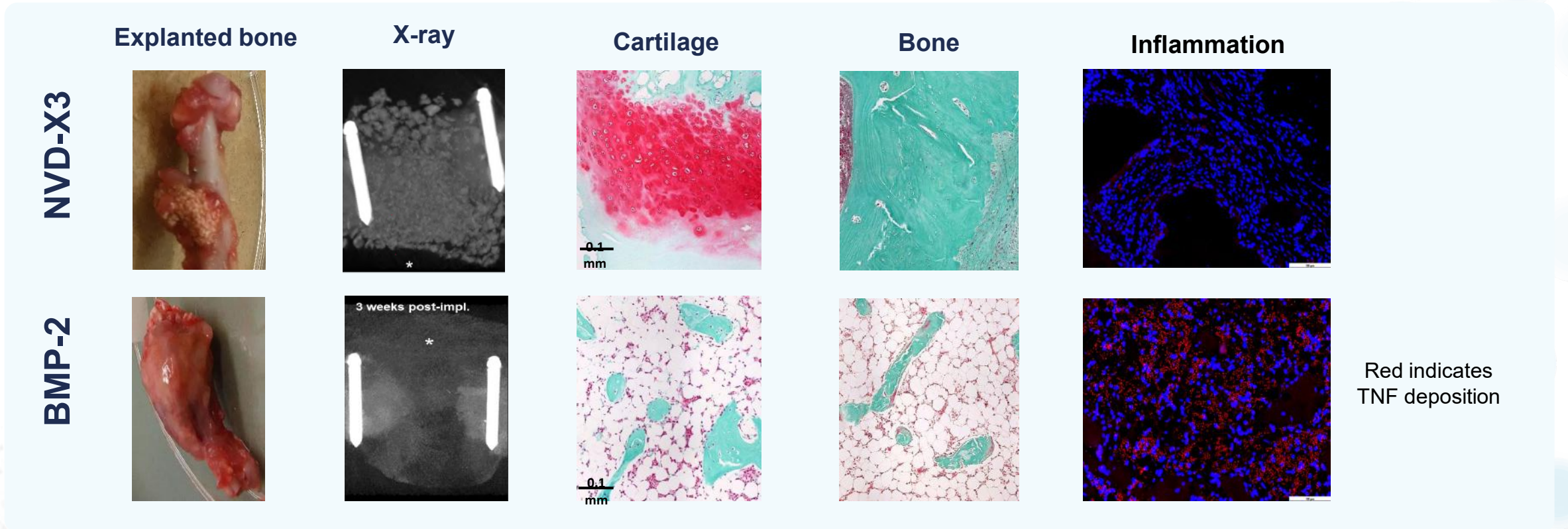
NVD-X3: Preclinical Studies Suggest Superior Safety & Efficacy vs. rhBMP-2*

- Avoids undesirable bone formation/resorption observed with BMP-2, with superior bioactivity to BMP-2

	rhBMP-2	NVD-X3
Safety	<ul style="list-style-type: none"> - Undesirable bone formation outside of treatment site (heterotopic ossification) - Undesirable resorption within treatment site - Adverse inflammatory reaction (edema, etc.) - Not indicated for pediatric use 	<ul style="list-style-type: none"> - Physiological control of bone formation - No heterotopic ossification - Osteoclasts inhibition by the osteoprotegerin (OPG) - No inflammation - Applicable for both adult and pediatric use
Efficacy	No Autologous bone harvesting: Quicker bone graft surgery, Minimized inconvenience, No pain, Faster recovery time	
	Biological activity: <ul style="list-style-type: none"> - Osteoinduction for trabecular bone formation 	Biological activity: <ul style="list-style-type: none"> - Faster (in 1 month) and better new bone formation by the endochondral osteo-induction
	Need of Hardware - due to low mineral content	No Need of Hardware

* Based on comparative preclinical in-vivo and in-vitro studies

NVD-X3: Preclinical Studies Suggest Superior Safety & Efficacy vs. rhBMP-2



- NVD-X3: higher and faster mineralization and bone union, no heterotopic muscular formation or inflammatory response
- BMP-2: no early bone union and low mineralization, heterotopic muscular formation and significant inflammatory response (edema, extravascular infiltrates) observed

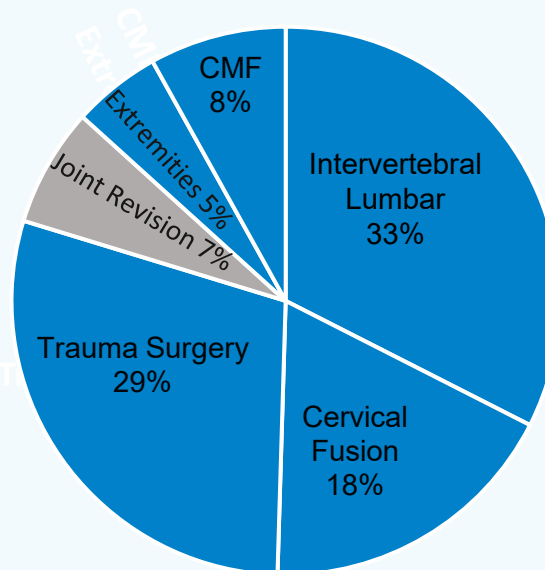
3M^{ALLO-REG}: NVD-X3 Can Benefit More Patients Requiring Bone Grafting Procedures

1.6Mn Bone Grafting Procedures Annually

- Intervertebral Lumbar 33% **51 % spine fusion**
- Cervical Fusion 18%
- Trauma Surgery 29%
- CMF 8%
- Extremities 5%
- Joint Revision 7%

NVD-X3 addresses 93 percent of bone grafting procedures

On Label*: ca. 93%

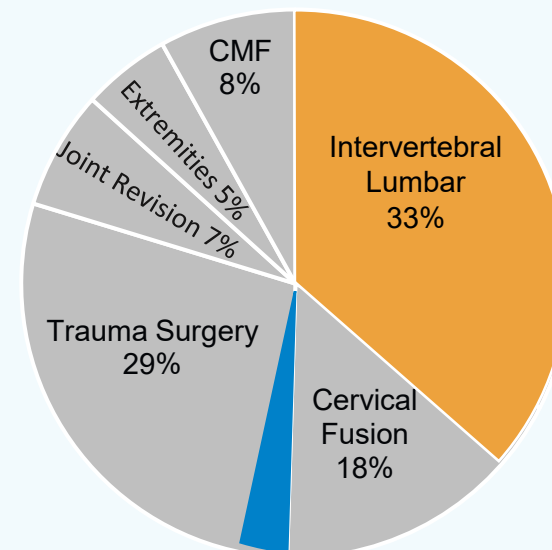


(*) clinical program requirements to pursue broader product label will be discussed with FDA

BMP-2 addresses less than half of bone graft market

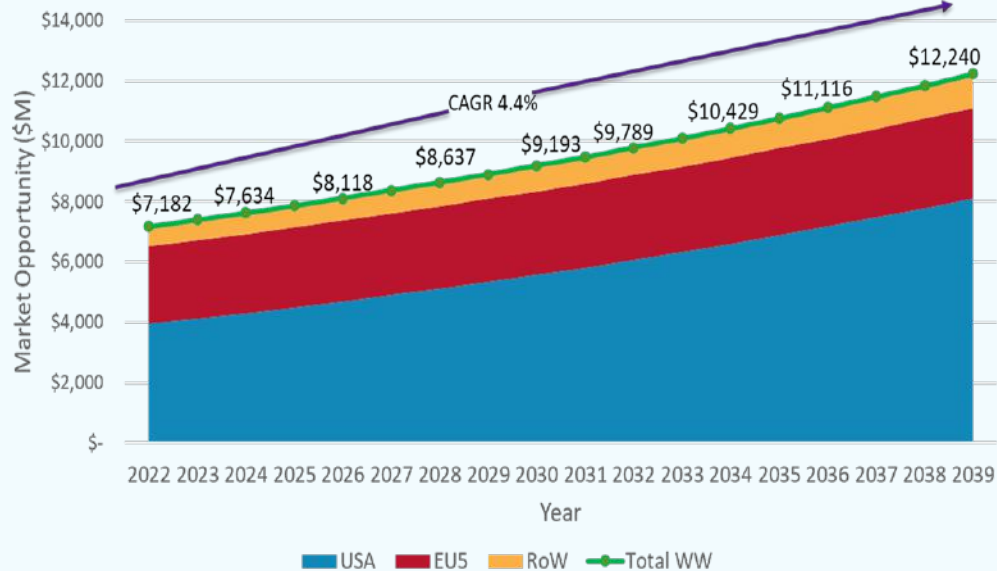
On Label: ca. 13%

Off Label: ca. 30%



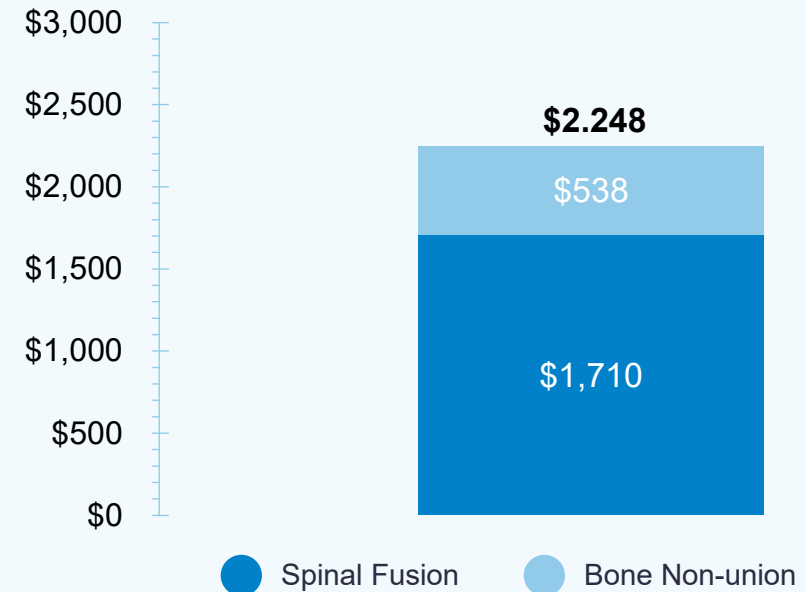
Worldwide Market Opportunity for NVD-X3: Spinal Fusion and Bone Non-union

**WW Spinal Fusion and Bone Non-union
Market Opportunity**



- Spinal Fusion and Bone Non-union procedures make up majority of the bone graft market (60-70%)
- US is the leading market ~60%

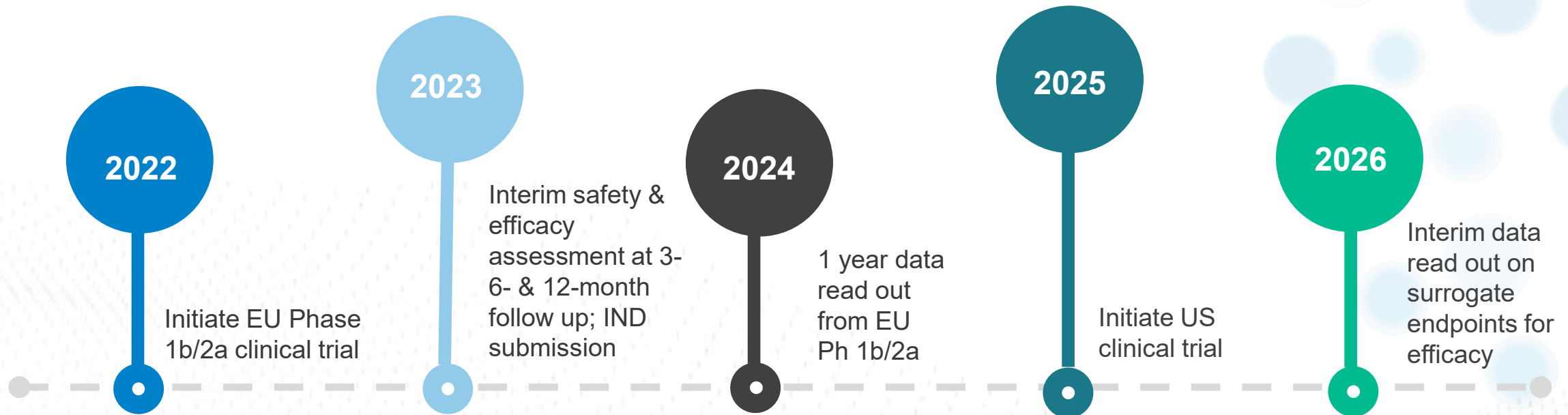
Global Peak Year Net Revenues (2039)



- Choice of clinical indications (BNU and SF) for NVD-X3 addresses the majority of the bone graft market (60-70%)
- Gross Margin of ~90% and EBITDA > 30% is feasible

3M^{ALLO-REG}: NVD-X3 Clinical Program for BNU & Spine Fusion

- Sept. 2022: Initiation of Ph 1b/2a trial in EU
- Q1 2023: Pre-IND meeting with FDA
- Q4 2023: IND submission
- Mid-2024: 1 year data read out from EU Ph 1b/2a trial
- 2025: Initiate US trial based on FDA determination
- 2026: Interim read out on surrogate endpoints in US trial
- 2029: Potential FDA approval/first sales

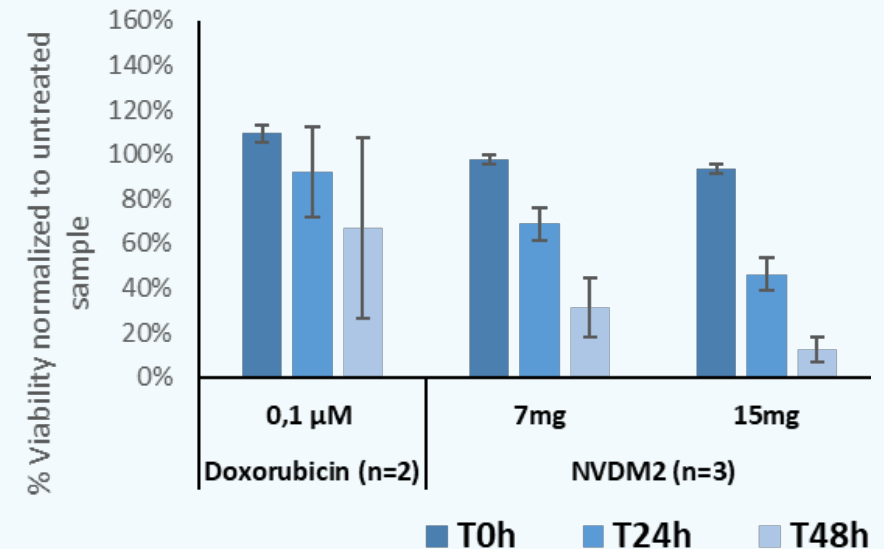


3M^{ALLO-ONCO}: Cutting-edge approach to treat solid tumors

- A unique model to manufacture **highly specific and reproducible miRNAs/proteins delivered by matrisome**
- Potential to address **solid tumor indications**
 - Native Bone Tumors such as osteosarcoma, melanoma, glioblastoma and Metastasis related to Solid Tumors (Breast, Prostate, Lung)
- Significantly **differentiated approach** compared to other cell therapy companies

\$60+Bn market opportunity in solid tumors

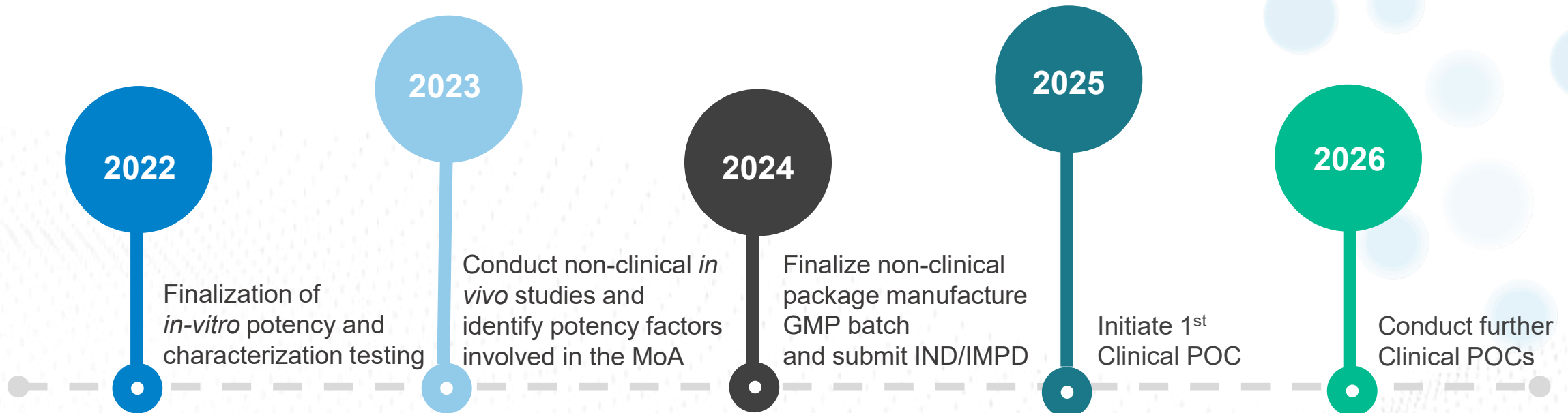
Impact on viability of 143B OS cells



Novadip's miRNAs have been shown to have powerful anti-proliferative effects on cancer cells

3M^{ALLO-ONCO}: NVD-M2 program towards POC in Native Bone Tumor and Metastasis related to Solid Tumors

- Q4 2022: Selection of miRNAs/cellular targets
- Q1 2023: Execute *in vivo* POC studies, determination of MoA
- Q4 2024: Complete GMP manufacturing
- Q4 2024: Complete CMC and non-clinical package
- Q2 2025: Initiate 1st Clinical POC



Manufacturing and Supply Chain with Global Reach

- Novadip's GMP-certified manufacturing facility and supply chain platform can rapidly deliver stable autologous and allogeneic tissue repair products around the globe



Starting Material

Low starting material variability and no rejection of any manufactured batch



QC/Characterization

Extensive in-house characterization and quality control testing



Process Ready

Process ready for optimization and scale-out



Capacity

Current capacity supports near-term clinical programs for 3M^{AUTO} and 3M^{ALLO}



Financial Highlights/ U.S. IPO Pathway

- \$28 Mn Series A in 2015
- \$24 Mn non-dilutive financing since founding
- \$36 Mn Series B in 2022
 - Support completion of Ph 1/2 trials for NVD-003 and NVD-X3
 - Anticipated 2024/2025 IPO in U.S. Markets
- Priority Review Voucher eligibility poised to add >\$100Mn in revenue in 2026

Investment Highlights

Disruptive Product Platform

- Novel utilization of adipose cells for single treatment cures
- Potential to address unmet clinical needs in tissue repair and oncology
- Multi-billion-dollar market opportunity across three product classes

Strong Foundation

- Clinical outcomes in 50+ patients provide platform validation
- Patents across nine families; additional patents pending worldwide
- Established GMP production can be leveraged across platforms

Management Strength

- Passionate leadership supported by renowned scientific advisory board
- Demonstrated ability to raise capital in Series A/B rounds
- Secured eligibility for priority review voucher worth >\$100M

Significant Investment Upside Potential

- Portfolio offers multiple partnering, licensing and acquisition opportunities
- Substantial non-dilutive funding provides leverage to secure new investment
- Planned IPO in 2024/2025 provides exit opportunity



NOVADIP

*Reimagining the Standard of Care
in Tissue Regeneration with a
Single Treatment Cure*

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