UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

For the month of September 2019

Commission File Number 001-37626

Mesoblast Limited

(*Exact name of Registrant as specified in its charter*)

Not Applicable
(*Translation of Registrant's name into English)*

Australia
(*Jurisdiction of incorporation or organization)*

Silviu Itescu
Chief Executive Officer and Executive Director
Level 38
55 Collins Street
Melbourne 3000
Australia
(*Address of principal executive offices*)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:

Form 20-F ☑ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes ☐ No ☑

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes ☐ No ☑

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On September 10, 2019, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement and investor presentation, which are attached hereto as Exhibit 99.1 and Exhibit 99.2, and are incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly organized.

MESOBLAST LIMITED

/s/ Charlie Harrison

Charlie Harrison
Company Secretary

Dated: September 11, 2019

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated September 10, 2019.
99.2	Investor presentation of Mesoblast Ltd, dated September 10, 2019.

Joint Press Release

Grünenthal and Mesoblast Enter Strategic Partnership for Europe and Latin America to Develop and Commercialise Innovative Cell Therapy for the Treatment of Chronic Low Back Pain

Aachen, Germany, and Melbourne, Australia, 10 September 2019 – Grünenthal, a global leader in pain management, and Mesoblast Limited (ASX: MSB; Nasdaq: MESO), a world leader in allogeneic cellular medicines for inflammatory diseases, today announced that they have entered into a strategic partnership to develop and commercialise MPC-06-ID, a Phase III allogeneic cell therapy candidate for the treatment of chronic low back pain due to degenerative disc disease in patients who have exhausted conservative treatment options. Under the partnership, Grünenthal will have exclusive commercialisation rights to MPC-06-ID for Europe and Latin America.

Mesoblast will receive up to US$150 million in upfront and milestone payments prior to product launch, as well as further commercialisation milestone payments. These payments include commitments up to US$45 million within the first year comprising US$15 million on signing, US$20 million on receiving regulatory approval to begin a confirmatory Phase III trial in Europe, and US$10 million on certain clinical and manufacturing outcomes. Cumulative milestone payments could exceed US$1 billion depending on the final outcome of Phase III studies and patient adoption. Mesoblast will also receive tiered double digit royalties on product sales.

Mesoblast is completing a Phase III trial for MPC-06-ID in the U.S. which will read out in 2020. In a previous U.S. Phase II trial, Mesoblast demonstrated that a single intra-discal injection of MPC-06-ID using a unit dose of 6 million allogeneic mesenchymal precursor cells (MPCs) resulted in meaningful and durable improvements for patients in pain intensity and functionality for at least three years[1].

Grünenthal and Mesoblast have agreed on an overall development plan for MPC-06-ID to meet European regulatory requirements. As part of this plan, the companies will collaborate on the study design for a confirmatory Phase III trial in Europe. The results of the two Phase III trials are expected to support both U.S. FDA and European EMA regulatory approvals for MPC-06-ID in chronic low back pain due to degenerative disc disease.

1 https://www.mesoblast.com/product-candidates/spine-orthopedic-disorders/chronic-discogenic-low-back-pain; https://www.mesoblast.com/clinical-trial-results/mpc-06-id-phase-2

Grünenthal's CEO Gabriel Baertschi said: "This is an exciting day for Grünenthal. Cell-based therapies offer a novel approach in pain management. They can potentially deliver meaningful lasting improvements to patients beyond symptomatic treatment by maintaining or even restoring physiological function. By teaming up with Mesoblast for the next generation of pain therapies for chronic low back pain due to degenerative disc disease we are diligently executing our strategy: leveraging promising new therapeutic modalities and addressing patients with high unmet medical needs. This is an important next step in working towards our vision of a world free of pain."

Mesoblast Chief Executive Dr Silviu Itescu stated: "We are very pleased to enter into this strategic partnership with Grünenthal, a world leader in innovative approaches to pain management. Together with Grünenthal we plan to bring an important new class of therapy for pain management to the many patients suffering with degenerative disc disease. This partnership is in line with our corporate strategy to team up with best in category commercial leaders to maximise market access for our innovative cellular medicines for the treatment of patients suffering from debilitating or life-threatening inflammatory conditions."

MPCs have generated great interest in clinical science and medicine due to their immunomodulatory effects and their role in tissue repair and regeneration. These cells have been shown to be effective in reducing inflammation and promoting the regeneration of host tissues through cell-to-cell interactions and secretion of a wide range of endogenous analgesic and anti-inflammatory molecules[2,3]. Furthermore, in degenerative disc disease, these cells could contribute to regenerating physiological disc tissue by promoting the proliferation of host chondrocytes and their secretion of tissue matrix components[4]. Among key characteristics of MPCs are their capacity for significant expansion in culture and their relative lack of immunogenicity. These properties facilitate their use as allogeneic, or "off-the-shelf", therapeutics with well-defined release criteria and batch-to-batch reproducibility that meet stringent regulatory requirements.

About Chronic Low Back Pain due to Degenerative Disc Disease (CLBP)

Over 7 million patients in Europe are thought to suffer from CLBP caused by degenerative disc disease[5,6,7,8], a disease which involves inflammation and degeneration of the intervertebral discs due to various factors like age, trauma or genetic pre-disposition. The lack of 'cushioning' as one of the major physiological functions of the disc in turn can result in spinal instability,

2 Chen et al. J Clin Invest. 2015 Aug;125(8):3226-4
3 Lantero A et al. J Neurosci. 2014 Apr;34(15):5385-95
4 Sharma RR et al. Transfusion. 2014 May;54(5):1418-37
5 Andersson GBJ. Epidemiological features of chronic low-back pain. Lancet 1999; 354: 581-85
6 Freburger et al. The Rising Prevalence of Chronic Low Back Pain. Arch Intern Med 2009; 169 (3): 251-258
7 Malanga G et al. Epidemiology In: Cole & Herring eds. The Low Back Pain Handbook: A Guide for the Practicing Clinician. 2nd ed. Philadelphia, Pa.: Hanley and Belfus, 2003: 1-7
8 DePalma MJ et al. What is the source of chronic low back pain and does age play a role? Pain Med 2011; 12:224-233

mechanical stress and bony changes of the spine which finally cause significant pain and loss of function[9]. In addition, the inflammation of the disc can cause severe pain, which is poorly responsive to systemic pain treatment[10]. Most existing therapies do not address the underlying mechanisms of these changes and provide limited symptomatic relief. Patients would typically suffer for several years already at a relatively young age, without being able to sufficiently address their pain[11]. Invasive therapies, including surgeries like spinal fusion, are sometimes a last resort for these patients, however, the limited evidence of their long-term effects remains a matter of concern[12]. If clinical trial results from Phase II are confirmed, MPC-06-ID could offer a new treatment option to patients otherwise considered unresponsive to conservative therapy, which can provide relief for at least 3 years and aims to retain the natural function and anatomy of the disc. MPCs offer the possibility to support and promote the existing regenerative potential inherent in host tissues and are expected to deliver superior long term outcomes compared to purely symptomatic treatments[13].

About Grünenthal

Grünenthal is a global leader in pain management and related diseases. As a science-based, privately-owned pharmaceutical company, we have a long track record of bringing innovative treatments and state-of-the-art technologies to patients worldwide. Our purpose is to change lives for the better – and innovation is our passion. We are focusing all of our activities and efforts on working towards our vision of a world free of pain. Grünenthal is headquartered in Aachen, Germany, and has affiliates in 30 countries across Europe, Latin America and the US. Our products are available in more than 100 countries. In 2018 Grünenthal employed around 4,900 people and achieved sales of € 1.3 bn.

More information: www.grunenthal.com

Follow us on:

LinkedIn: Grunenthal Group

Twitter: @grunenthalgroup

Instagram: @grunenthal

About Mesoblast

Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a world leader in developing allogeneic (off-the-shelf) cellular medicines. The Company has leveraged its proprietary technology platform to establish a broad portfolio of late-stage product candidates with three product candidates in Phase III trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). www.mesoblast.com

Follow us on:

LinkedIn: Mesoblast Limited

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[9] Rider SM et al. Spine Surg Relat Res. 2018 Apr;3(1):1-11

[10] Nguyen QT et al. ACS Biomater Sci Eng. 2017 Nov

[11] Grünenthal internal data on file

[12] Gibson AJN, Waddell G. Spine 2005; 30: 2312– 2320

[13] Fernandez-Moure J, et al. SAGE Open Med. 2018 Mar;6:2050312118761674

Joint Press Release

Twitter: @Mesoblast

Forward-Looking Statements by Mesoblast

This announcement includes forward-looking statements that relate to future events or Mesoblast's future financial performance and involve known and unknown risks, uncertainties and other factors that may cause Mesoblast's actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward- looking statements. Mesoblast makes such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Forward-looking statements include, but are not limited to, statements about the timing, progress and results of Mesoblast's preclinical and clinical studies in CLBP; Mesoblast and its collaborators' ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals for CLBP; and the pricing and reimbursement of Mesoblast and its collaborators' product candidates, if approved. You should read this press release together with Mesoblast's risk factors, in Mesoblast's most recently filed reports with the SEC or on Mesoblast's website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. Mesoblast does not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

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# # #

mesoblast
the regenerative medicine company

Chronic Low Back Pain: MPC-06-ID

Strategic Development & Commercialization Partnership with Grünenthal for Europe & Latin America

10 September 2019

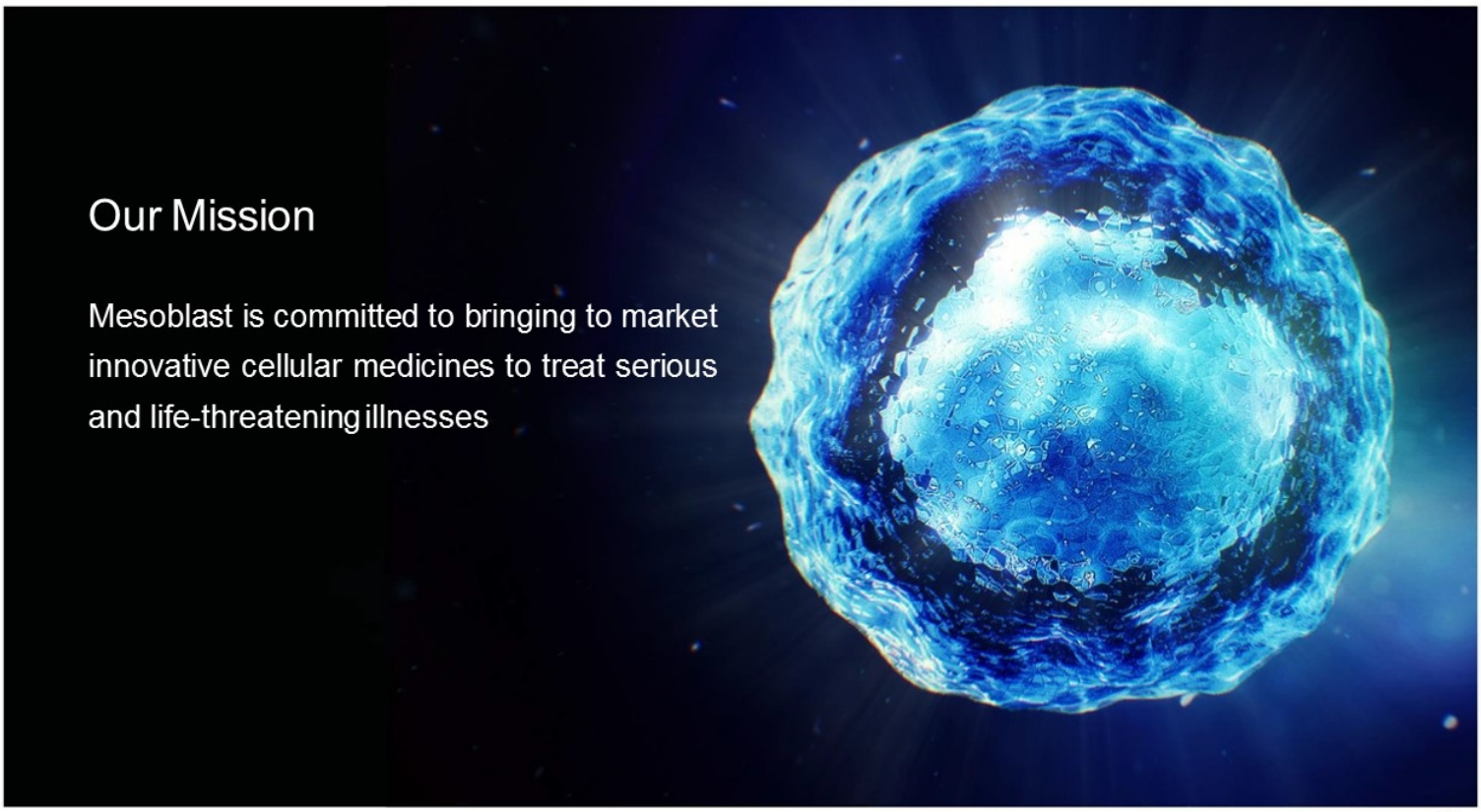
Nasdaq: MESO ASX: MSB

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this presentation are forward-looking statements. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "could," and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events , recent changes in regulatory laws, and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. These statements may relate to, but are not limited to: expectations regarding the safety or efficacy of, or potential applications for, Mesoblast's adult stem cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's regulatory approval process, and the scalability and efficiency of manufacturing processes; expectations about Mesoblast's ability to grow its business and statements regarding its relationships with current and potential future business partners and future benefits of those relationships; statements concerning Mesoblast's share price or potential market capitalization; and statements concerning Mesoblast's capital requirements and ability to raise future capital, among others. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this presentation together with our financial statements and the notes related thereto, as well as the risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, include, without limitation: risks inherent in the development and commercialization of potential products; uncertainty of clinical trial results or regulatory approvals or clearances; government regulation; the need for future capital; dependence upon collaborators; and protection of our intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Our Mission

Mesoblast is committed to bringing to market innovative cellular medicines to treat serious and life-threatening illnesses



Corporate History

Over a decade of scientific, manufacturing, clinical development and corporate development experience targeted at bringing to market allogeneic, off-the-shelf cellular medicines for inflammatory diseases

2004: Mesoblast founded in Melbourne, Australia and listed on the ASX

2010: Entered into strategic alliance with Cephalon to develop and commercialize MPC therapeutics

2011: Entered into manufacturing partnership with Lonza Group in Singapore for MPC medicines

2013: Acquired MSC business from Osiris Therapeutics with trailing earn-out and milestone payments

2014: Granted manufacturing pioneer status by Economic Development Board of Singapore

2015: Dual listed onthe Nasdaq

2016: TEMCELL® HS Inj (MSC medicine) launched in Japan by Mesoblast licensee JCR

2017: Entered licensing agreement with Takeda for the treatment of certain fistulae; in 2018 Alofisel® received approval in EU

2018: Entered into partnership agreement with Tasly for cardiovascular assets in China

2019: Smith & Nephew acquired Osiris Therapeutics, became Mesoblast's licensor for the MSC business

2019: Strategic Partnership in Chronic Low Back Pain in Europe & Latin America with Grünenthal

2019: Initiated first BLA submission to US FDA: remestemcel-L (MSC) for steroid refractory acute graft versus host disease (aGVHD)

Premier Global Cellular Medicines Company

Innovative Technology Platform[1]	Late Stage Pipeline	Commercialization
▪ Innovative technology targets some of the most severe disease states refractory to conventional therapies ▪ Well characterized multimodal mechanisms of action ▪ Underpinned by extensive, global IP estate	▪ Initiated rolling filing with US FDA for approval for steroid-refractory aGVHD ▪ Two Phase 3 product candidates – heart failure and back pain – with near term US trial readouts ▪ Heart failure Phase 3 product candidate partnered in China	▪ Building US sales force for aGVHD launch, if approved ▪ Industrial-scale manufacturing to meet commercial demand ▪ First approved products commercialized by licensees in Japan[2] and Europe[3] ▪ Continued growth in royalty revenues from strategic partnerships

1. Mesenchymal precursor cells (MPCs) and their culture-expanded progeny mesenchymal stem cells (MSCs).
2. Licensee JCR Pharmaceuticals Co., Ltd. received the first full PMDA approval for an allogeneic cellular medicine in Japan and markets this product under its trademark, TEMCELL® Hs Inj.
3. Licensee Takeda received first central marketing authorization approval from the European Commission for an allogeneic stem cell therapy and markets this product under its trademark Alofisel®.

Commercial Scale Manufacturing Capability

- Scalable allogeneic “off-the-shelf” cellular medicine platform
- Manufacturing meets stringent criteria set by international regulatory agencies including FDA and EMA
- Robust quality assurance processes ensure final product with batch-to-batch consistency and reproducibility
- Culture expansion scalable for near term commercial needs
- Proprietary xeno-free technologies being developed to enable sufficient yields for long term global commercial supply
- Next generation processes using 3D bioreactors to reduce labor and drive down cost of goods

Lonza contract manufacturing facility in Singapore

Global IP Estate Provides Substantial Competitive Advantage

- ~995 patents and patent applications (68 patent families) across all major jurisdictions
- Covers composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells
- Enables licensing to third parties for different indications, when in alignment with our corporate strategy e.g. TiGenix (subsequently acquired by Takeda)
- Provides strong global protection against competitors seeking to develop products in areas of core commercial focus

Commercial and Late-Stage Product Pipeline

PLATFORM	PRODUCT	THERAPEUTIC AREA		APPROVAL	COMMERCIAL RIGHTS	
MSC (Bone Marrow)	TEMCELL® HS Inj[1]	Acute Graft Versus Host Disease	1st allogeneic regen med approved in Japan	✓	JCR Japan	MARKETED
MSC (Adipose)	Alofisel®[2]	Perianal Fistula	1st allogeneic regen med approved in Europe	✓	Takeda Global	

PLATFORM	PRODUCT CANDIDATE	THERAPEUTIC AREA	PRE-CLINICAL / PHASE 2 / PHASE 3		COMMERCIAL RIGHTS	
MSC suite	Remestemcel-L	Acute Graft Versus Host Disease		BLA submission to FDA underway	mesoblast	IN DEVELOPMENT
		Crohn's Disease				
		Knee Osteoarthritis				
MPC suite	Revascor	Advanced HF (Class II/III) End-Stage HF (Class III/IV)			TASLY China; mesoblast ROW	
	MPC-06-ID	Chronic Low Back Pain			GRÜNENTHAL Europe Lat Am; mesoblast ROW	
	MPC-300-IV	Rheumatoid Arthritis Diabetic Nephropathy			mesoblast	

This chart is figurative and does not purport to show individual trial progress within a clinical program

1. TEMCELL® Hs. Inj. is a registered Trademark of JCR Pharmaceuticals Co Ltd
2. Alofisel® is a registered Trademark of Takeda Pharmaceuticals

Key Terms of the Strategic Partnership with Grünenthal GmbH

Grünenthal takes exclusive license to develop and commercialise MPC-06-ID

- **Indication:** for discogenic chronic back pain, disc degeneration and/or functional disability
- **Territory:** Europe and Latin America/Caribbean

In consideration, Mesoblast will receive

- **Up to US$150 million** in upfront and milestone payments prior to product launch, as well as further commercialisation milestone payments.
- Payments include commitments up to **US$45 million within the first year** comprising US$15 million on signing, US$20 million on receiving regulatory approval to begin a confirmatory Phase III trial in Europe, and US$10 million on certain clinical and manufacturing outcomes
- **Cumulative milestone payments could exceed US$1 billion** depending on the final outcome of Phase III studies and patient adoption.
- Mesoblast will also receive **tiered double digit royalties** on product sales.
- Mesoblast retains the rights for the rest of world, including the US and Japan markets

Transaction Benefits to Mesoblast

- ✓ **Strong commercial partner**
  - Delivers commercialization, distribution, sales & marketing
  - Field force comprises around 1,600 people across Europe, Latin America & US – overall focus is on pain – visited nearly 300,000 stakeholders in 2018 (physicians, pharmacists & health administrators)
  - Provides knowledge and knowhow in manufacturing, regulatory affairs (Europe in particular)
- ✓ **Advances approval pathway**
  - Provides funding for Phase 3 trial in Europe reducing Mesoblast cash outflow
  - Mesoblast and Grünenthal will collaborate on the study design for a confirmatory Phase 3 trial in Europe
  - Confirmatory European and US (currently ongoing) Phase 3 trials are expected to support regulatory approval in both Europe and US
- ✓ **Transaction focuses on Europe**
  - Mesoblast maintains rights to all other geographic markets, including US, Japan and China for additional partnering opportunities to maximize shareholder return
- ✓ **Third party endorsement provides validation of technology platform**

Grünenthal – Global Leader in Pain Management

#2 Europe[1]

#1 Latin America[1]

Overview

- Grünenthal is a global leader in pain management and related diseases, with 50 years in pain research
- A long track record of bringing innovative treatments and state-of-the-art technologies to patients worldwide
- Strong and capable team with c. 4,900 employees worldwide
- Solid revenue base with € 1.3 billion in 2018 (c. US$1.5 billion)
- Commercial presence in 30 countries across Europe, Latin America and the US
- Products are sold in more than 100 countries

Source: Grünenthal
1. The ranking based on corporation sales (fixed EUR acc. IQVIA – Status 2018-Q4) in the area of major centrally acting analgesics.

MPC-06-ID for Chronic Low Back Pain due to Degenerative Disc Disease – Commercial Opportunity

MPC-06-ID: A New Paradigm for Treatment of Chronic Low Back Pain Due to Degenerative Disc Disease

Burden of Illness

- Back pain causes more disability than any other condition[1]
- Inflicts substantial direct and indirect costs on the healthcare system[1], including excessive use of opioids in this patient population

Minimal Treatment Options

- Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for CLBP

Unmet Need

- Disease modifying therapy for durable improvement in pain and function has potential to prevent progression to opioid use or surgical intervention

Market Opportunity

- Over 7m patients are estimated to suffer from CLBP due to degenerative disc disease (DDD) in each of the U.S. and E.U.5 [3,4,5]
- MPC-06-ID development program targets over 3.2m patients in U.S. and 4m in E.U.5 with moderate to severe disease

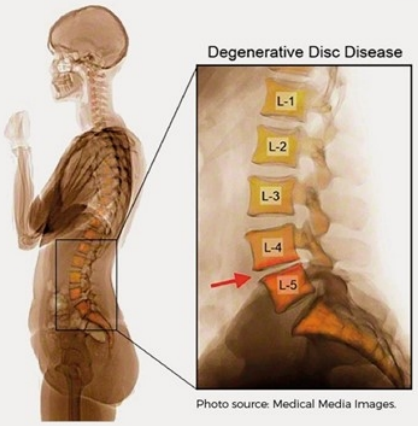
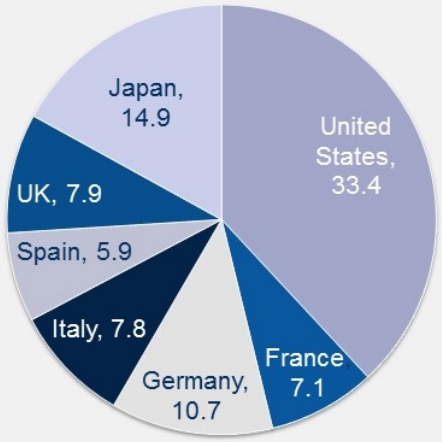


Photo source: Medical Media Images.

1. Williams, J., NG, Nawi, Pelzter, K. (2015) Risk factors and disability associated with low back pain in older adults in low-and middle-income countries. Results from the WHO Study on global ageing and adult health (SAGE). PloS One. 2015; 10(6): e0127880., 2. Simon, J., McAuliffe, M., Shamim, F. (2015) Discogenic Low Back Pain. Phys Med Rehabil Clin N Am 25 (2014) 305–317., 3. Decision Resources: Chronic Pain December 2015., 4. LEK & NCI opinion leader interviews, and secondary analysis., 5. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014., 6. HealthCare Utilization and Cost of Discogenic Lower Back Pain in the US – Anthem/HealthCore.

Approx. 10 – 15% of Adult Population Suffers from Chronic Lower Back Pain Across the 7 Major Pharmaceutical Markets

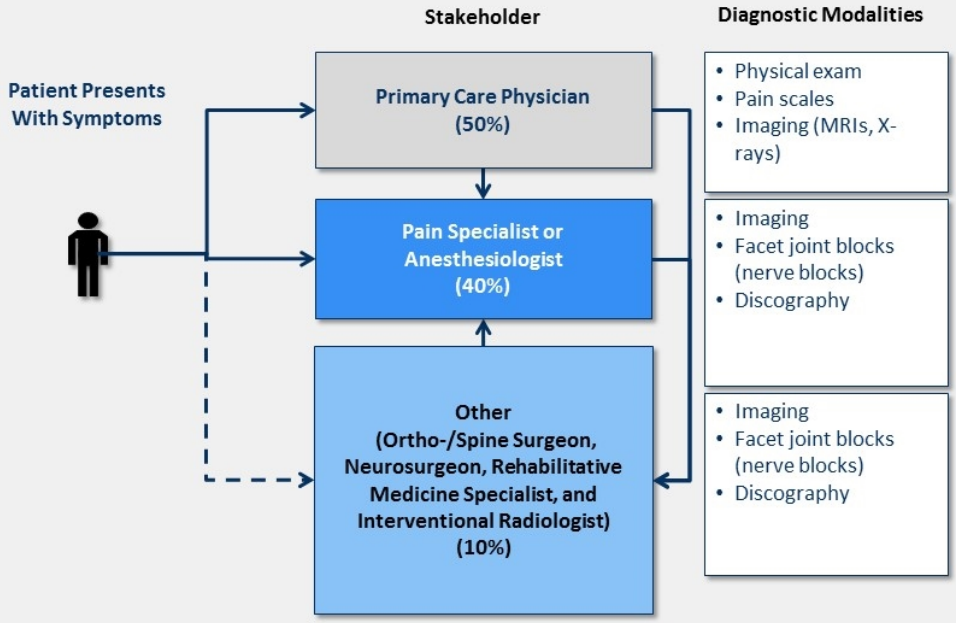
Prevalence of Chronic Lower Back Pain (millions)[1]



- US prevalence 33.4 million, EU5 39.4 million, Japan 14.9 million
- Growth in the prevalence of CLBP in the U.S. going forward will likely mirror the growth rate of the overall population[2]
- CLBP is most common within the 45-64 age group
- CLBP is nearly twice as common in women as in men in the same age group
- Higher percentage of CLBP patients seeking medical care in the EU3 (~70-80%) compared to the U.S. (~55 – 60%) mainly driven by the broader healthcare coverage in the EU3
  - "… Most of the patients with CLBP will see a doctor, because medical care is free in Germany …"
    Orthopedist, Private practice,

[1] Decision Resources: Chronic Pain Report 2015
[2] LEK Primary / Secondary Research 2013

US/EU Patient Journey – 50% of Patients With Moderate-to-Severe CLBP Progress To Specialists For Diagnosis And Treatment Of Discogenic Cause



Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014.

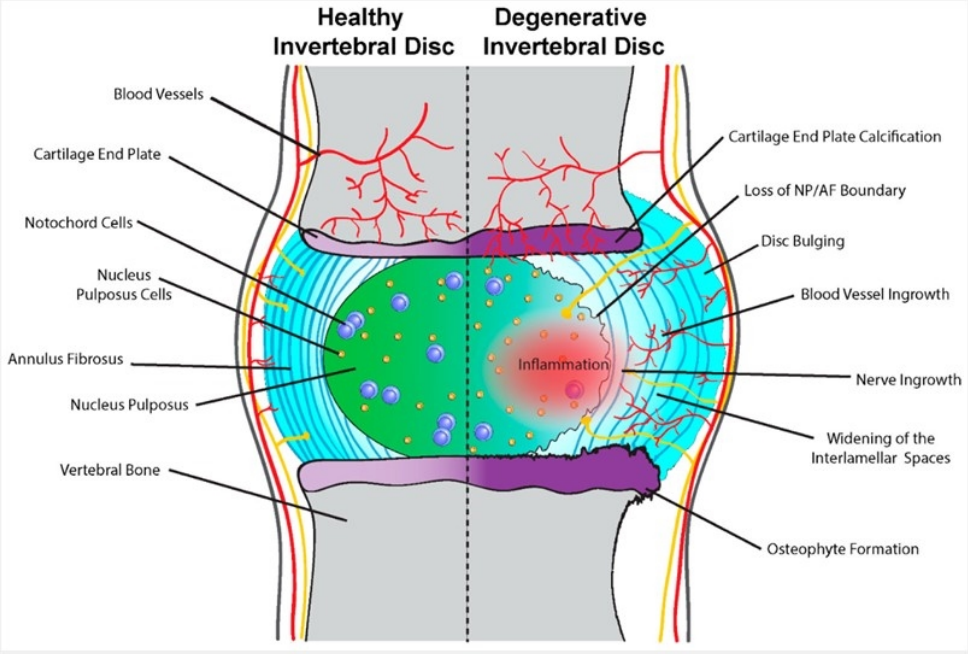
Current Patient Treatment Journey (US/EU) for Discogenic CLBP (DCLBP): MPC-06-ID Potential First-Line for DCLBP Refractory to Conservative Treatments

MPC-06-ID: targeting moderate-to-severe DCLBP

	Conservative treatments	Opioid analgesics	Interventional therapies	Surgeries
Products	▪ NSAIDs ▪ Physical therapy ▪ Chiropractic treatments ▪ Acupuncture ▪ Anticonvulsants (e.g., gabapentin)	▪ Weak opioid analgesics (e.g., tramadol) ▪ Strong opioid analgesics (e.g., oxycodone)	▪ Epidural steroid injections (off-label) ▪ Radio frequency ablation ▪ Spinal cord stimulation ▪ Intrathecal pumps	▪ Spinal fusion ▪ Disc replacement

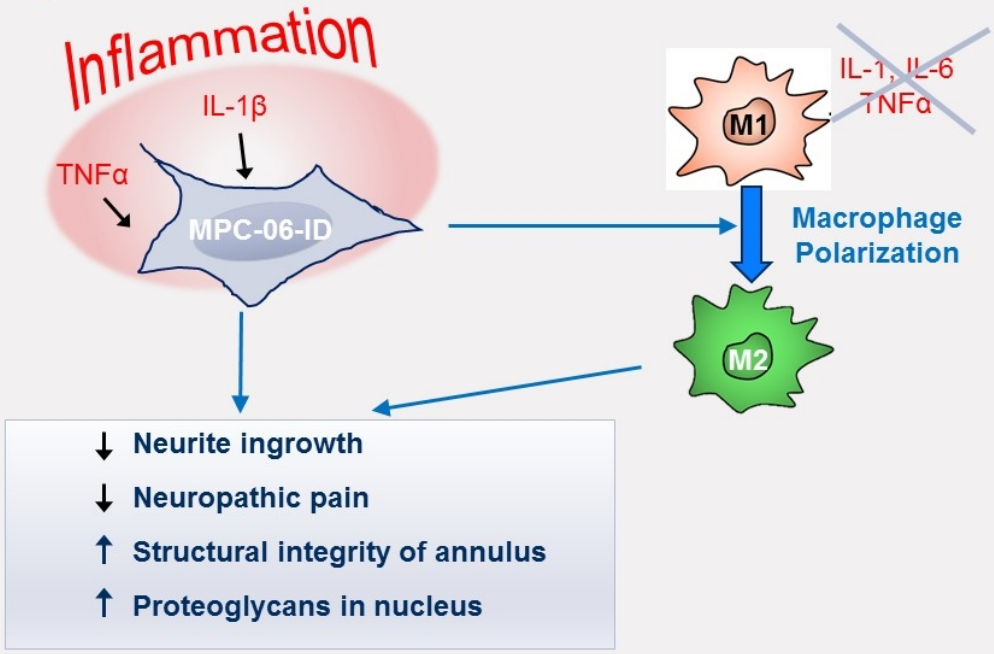
Chronic Low Back Pain

Inflammation is at the Core of Degenerative Disc Disease



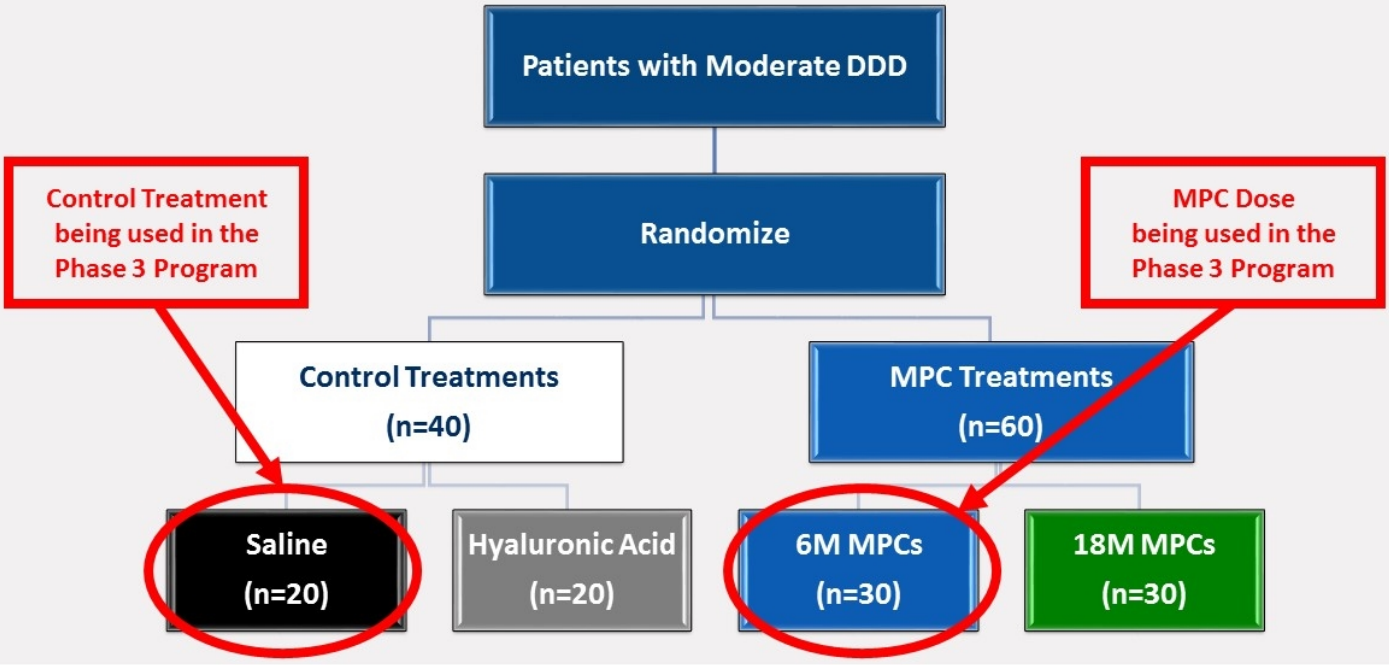
McCann MR and Seguin CA. Notochord Cells in Intervertebral Disc Development and Degeneration. J. Dev. Biol. **2016**, *4*(1), 3; doi:10.3390/jdb4010003

MPC-06-ID: Potential Mechanisms of Action in Treating Inflammatory Disc Disease



- ↓ Neurite ingrowth
- ↓ Neuropathic pain
- ↑ Structural integrity of annulus
- ↑ Proteoglycans in nucleus

Phase 2 Clinical Trial – Randomized Patient Allocation



Phase 2 Clinical Trial

Clinical Study Patient Population

A prospective, multicenter, double blinded, controlled clinical study comparing two doses of immunoselected, culture-expanded, nucleated, allogeneic MPCs when combined with hyaluronic acid to two control intradiscal injections in subjects with chronic low back pain (> 6 months) due to moderate DDD at one lumbar level from L1 to S1 and unresponsive to conservative therapy for at least 3 months (including physical therapy)

Inclusion Criteria

- DDD with back pain >6 months
- Failed 3 Months Non-Operative Care
- Patients with a modified Pfirrmann score of 3, 4, 5 or 6
- With or without contained disc herniation up to a 3mm protrusion with no radiographic evidence of neurological compression
- Disc height loss of <30% compared to a normal adjacent disc based upon radiographic evaluation
- VAS Back pain >40
- ODI Score >30

Exclusion Criteria

- Modified Pfirrmann score of 1 & 2 or 7 & 8
- Clinically significant nerve or sacroiliac joint pain
- Clinically significant facet pain as determined by a diagnostic medial branch block or facet joint injection
- Symptomatic involvement of more than one lumbar disc level
- Discs with full thickness tears with free-flowing contrast through the annulus fibrosis
- Lumbar intervertebral foraminal stenosis at the affected level(s) resulting in clinically significant spinal nerve root compression

Phase 3 Responder Criteria Used in Post-Hoc Assessment of Phase 2 Clinical Trial Results

FDA Guidance on Minimally Important Change (MIC) for Pain and Function[1] using a composite endpoint consistent with the CDRH IDE guidance for spinal systems (i.e. spine fusion & artificial disc replacement

Questionnaire	Scoring Range	MIC (Absolute Cutoff)	MIC (% Improvement from Baseline)	MSB Phase 3 Cutoff
Visual Analog Scale (VAS)	0-100	15 points	30%	50%
Oswestry Disability Index (ODI)	0-100	10 points	30%	15 points

Mesoblast Phase 3 VAS and ODI Cutoffs

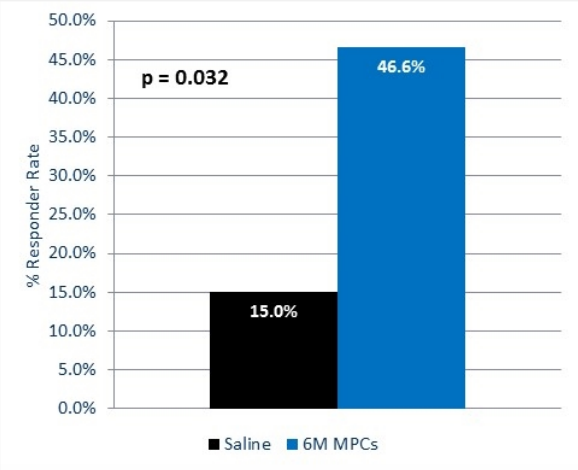
- 50% VAS reduction based upon KOL, regulatory, and payer input
- 15 point ODI reduction based upon previous FDA approvals of spine products, such as artificial disc replacements and spine fusion devices

1. Ostelo et al. (Spine Vol 33,no1.pp90-94) established MICs for the most frequently used questionnaires to evaluate pain and function in patients with chronic low back pain

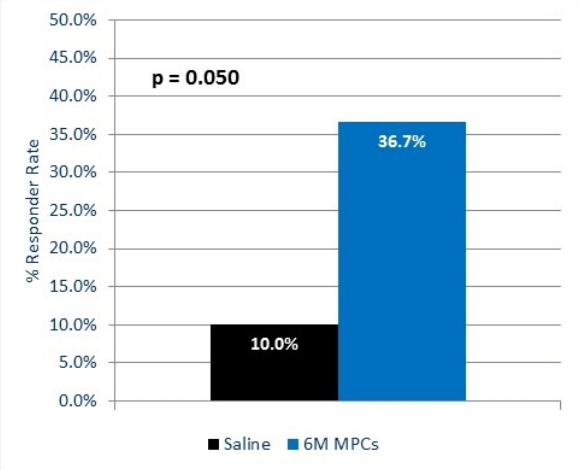
Chronic Low Back Pain

MPC-06-ID – Post-Hoc Phase 2 results provide target endpoints for Phase 3 trial

A: Phase 2: Treatment Success Responders[1,2] at 12 Months



B: Phase 2: Treatment Success Responders[1,2] at both 12 & 24 Months



1. Subjects with missing data are classified as non-responders.
2. Treatment Success Responders have a 50% reduction in LBP as measured by VAS AND a 15 point improvement in function as measured by ODI at a) 12 months, and b) both 12 and 24 months and no intervention through 24 months.

Phase 2 Clinical Trial – 36 Month Results

MPC therapy provides durable results through 36 months

- **Over 36 months:**
  - 82% of the 6 million MPC group who achieved the Phase 3 primary endpoint composite over 24 months maintained treatment success[1]
  - 86% of the 6 million MPC group who successfully met the Phase 3 pain responder criteria (50% pain reduction with no additional intervention at both 12 and 24 months) remained pain responders[2]
  - 92% of the 6 million MPC group who met the Phase 3 functional responder criteria (15-point reduction in ODI and no additional intervention at both 12 and 24 months) remained functional responders[3]

- **There were no significant differences in safety events cell-treated patients and controls over 36 months**

1. Composite Responder must have an optimal pain (50% reduction in VAS) AND function (15 point reduction in ODI) response AND no additional intervention.
2. Pain Responder must have an optimal pain response (50% reduction in VAS) AND no additional intervention.
3. Functional Responder must have an optimal functional improvement (15 point reduction in ODI) AND no additional intervention.

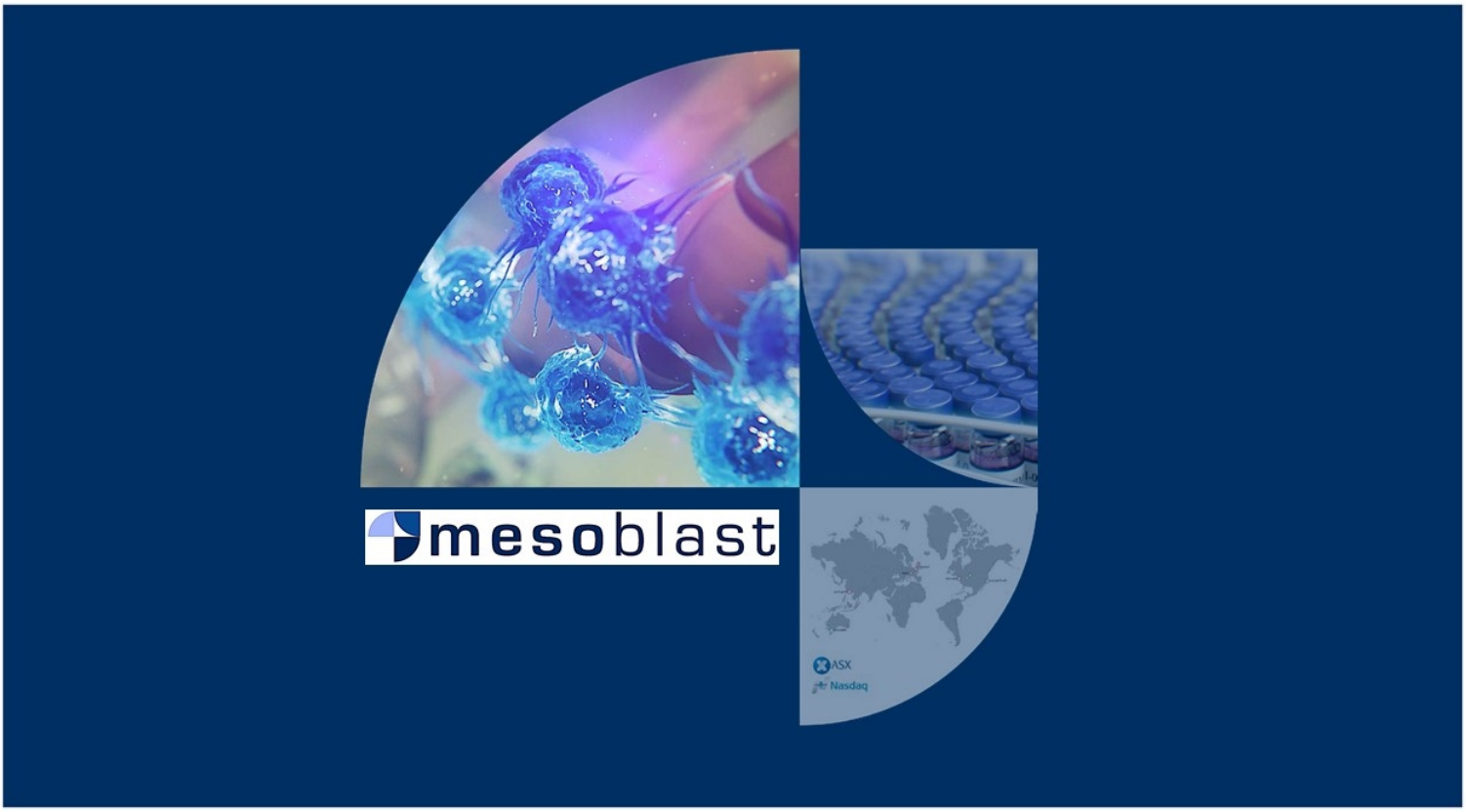
MPC-06-ID – Ongoing US Phase 3 Clinical Trial

- Three-arm study comparing 6-million MPC with or without hyaluronic acid (HA) against saline control
- Primary efficacy endpoint agreed to with FDA:
  - Overall Treatment Success Composite at both 12 and 24 months as measured by:
    - At least 50% reduction from baseline in Visual Analogue Scale (VAS) pain score at both 12 and 24 months post-treatment; and
    - At least a 15 point decrease from baseline in Oswestry Disability Index (ODI) function score at both 12 and 24 months post-treatment; and
    - No interventions affecting the treated disc through 24 months
- Study powered to show efficacy for both 6-million MPC arms (with and without HA)

404 patient 2:1 randomized Phase 3 trial completed enrollment March 2018; all patients have completed 12 month safety and efficacy follow-up

MPC-06-ID – Development Strategy for US & Europe

- Phase 3 trial in chronic low back pain completed enrollment in March 2018 with 404 patients randomized to receive MPC-06-ID or placebo. All patients have now completed at least 12 months of safety and efficacy follow-up.
- Follow-up continuing to a 24-month assessment of safety and efficacy by the first quarter of CY 2020, with readouts planned mid-CY2020
- Initiate confirmatory Phase 3 trial in Europe in partnership with Grünenthal
- Complete commercial manufacturing in partnership with Grünenthal
- Results of confirmatory Phase 3 clinical trials in US and Europe, together with commercial manufacturing, expected to support regulatory approval and commercial launches in both Europe and US for MPC-06-ID in chronic discogenic low back pain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