DAWSONJAMES SECURITIES

INSTITUTIONAL RESEARCH
Regenerative Medicine
INITIATION REPORT

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Toll-Free: 561-391-5555 ♦ www.DawsonJames.com ♦ 1 North Federal Highway - Suite 500 ♦ Boca Raton, FL 33432

Mesoblast (NASDAQ/MESO, ASX/MSB)

December 19, 2019

BUY: Next at Bat: Will it be a Single, a Double, Grand Slam, or KO? Filing in GvHD, with P3 Data in Heart Failure & DDD Soon.

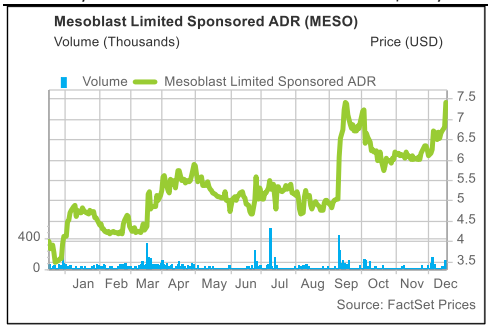
Jason Kolbert
Healthcare Research
jkolbert@dawsonjames.com

Mesoblast is on the precipice of becoming a U.S. commercial entity as the company prepares to file for approval in GvHD. Pivotal trial results in Heart Failure and Back-pain are in the queue for early 2020. Good data in either indication drives both a new treatment paradigm and ushers in the era of Regenerative Medicine. We are initiating coverage with a Buy rating and $14.00 target.

Current Price	**$7.42**
Price Target	**$14.00**

Estimates	F2019E	F2020E	F2021E
Expenses ($000s)	$ 97	$ 92	$ 133
1Q March	$ 28	$ 21	$ 30
2Q June	$ 27	$ 22	$ 32
3Q September	$ 23	$ 23	$ 33
4Q December	$ 19	$ 26	$ 37
	F2019E	F2020E	F2021E
EPS (diluted)	$ (0.72)	$ (0.61)	$ (0.69)
1Q March	$ (0.19)	$ (0.06)	$ (0.16)
2Q June	$ (0.05)	$ (0.17)	$ (0.16)
3Q September	$ (0.20)	$ (0.18)	$ (0.17)
4Q December	$ (0.28)	$ (0.20)	$ (0.19)
EBITDA/Share	($0.91)	($0.53)	($0.68)
EV/EBITDA (x)	-7.8	-11.2	-8.6

Stock Data	
52-Week Range	$3.35 - $7.59
Shares Outstanding (mil.)	107.3
Market Capitalization (mil.)	$796
Enterprise Value (mil.)	$825
Debt to Capital	10%
Book Value/Share	$6.02
Price/Book	1.1
Average Three Months Trading Volume (K)	79
Insider Ownership	23.1%
Institutional Ownership	28.9%
Short interest (mil.)	0.2%
Dividend / Yield	$0.00/0.0%



Investment Highlights

The Hippocratic Oath – Do No Harm. Regenerative Medicine is in a unique space and often is confused and compared to CAR-T and Gene Therapy. One reoccurring theme that differentiates the Regen. Space is Risk versus Reward. We can view this as safety versus efficacy and the commercial potential for clinical success versus valuation. We feel confident that the safety profile of both allogeneic (other people's) cells and autologous (your own cells) has been very well understood and established. We see this as a differentiator in comparison to other cell and gene therapy therapeutics, where we must carefully balance the adverse events versus the efficacy (& its sustainability). We also see distressed valuations often stacked against therapeutics that are addressing blockbuster markets. Mesoblast has established a strong clinical record with a series of Phase 1, Phase 2, and now pivotal trials that have demonstrated the safety profile and which address blockbuster markets such as Heart Failure.

Heart Failure (HF) is a Blockbuster Opportunity. Advanced stage and end-stage heart failure impact more than eight million people in the U.S. alone. Treatment options today tend to work on easing symptoms with just a modest effect on the therapeutic course of the disease. Advanced stage heart failure has the highest event rate, costing the U.S. healthcare system $115B per year and accounts for more than two-thirds of all hospital expenditures. Mesoblast is close to completing its Phase 3 trial of Revascor in HF. This is an event-driven trial, and the trial has now surpassed the number of events required (for trial completion). Final study visits for patients should occur next month, January 2020.

A New Treatment Paradigm in Back Pain – Moving Beyond Steroids and Opiates. From the time man crawled out of the primordial ooze and stood upright as a biped, back-pain followed. Chronic lower back pain (CLBP) likely results in more disabilities than just about any other condition. With the recognition of the hazards of prescribing opiates to treat pain (the symptom), versus addressing the underlying cause, such as a herniated disc and in its final stages spinal fusion (surgery), a new modality is needed. Mesoblast's CLBP could be the solution, literally swapping cells for steroids for injection into the intra-vertebral space, supporting repair of the underlying cause, disc herniation, and the resulting inflammation.

The Year-End Countdown - Ready to File in Acute Graft versus Host Disease (aGvHD). We expect to see Mesoblast file for approval before the end of the year in pediatric aGvHD. That could set a timeline where we could see a U.S. commercial launch late next year. We expect Europe to be a year behind the U.S., followed by expansion from pediatric to the adult marketplace. We provide our model and assumptions for each product. Suffice to say, success in GvHD alone, in our opinion, supports the current valuation of the company, but that's just the tip of the iceberg.

The Achilles Heel of Cell Therapy - Manufacturing, Manufacturing, and Manufacturing. Mesoblast has been working with Lonza (LZAGY-Not rated) on developing and perfecting the process for manufacturing. Tightly controlling the doublings and number of passages, without compromising cell integrity. Given the size of the markets (CHF, DDD), the ability to have an off-the-shelf ready product is likely to be a key area of concern for the regulators. We have carefully noted over the years, the effort behind the process, and the time and resources that Mesoblast has allocated with Lonza to achieve production goals. What's important to understand is that as an allogenic product, the process, while arduous, is not comparable to the obstacles presented in gene Therapy and or the CAR-T space.

3 X 3 - Commercialization is Right Around the Corner. With three products in Phase 3 trials, commercialization is coming soon. Add it up, the low risk of adverse events, the ability to manufacture millions of doses, and the unmet medical needs in blockbuster market opportunities such as HF and DDD. We could see an industry shift as regenerative Medicine is recognized.

Efficiently Raising the Capital to Get There – Multiple Levers to Pull. Mesoblast has already accomplished what no other regenerative medicine company has done, in terms of capital raising through a range of methods from a who's who list of partnerships, creative loans, and smart raises down under (Australia) with an eye towards managing shareholder value and dilution. Along the way, the company is building institutional relationships from its retail base established in their home country and here too. We are not concerned about the transition we see ahead (retail to institutional), which we believe is data-driven, exactly as it was for the CAR-T companies like Kite (KITE-Not rated), Juno (JUNO-Not rated) and BlueBird (BLUE Not Rated).

Partnerships. The most recent addition to Mesoblast's ever-growing list of partnerships is Grunenthal (ALM-Spain – Not rated) for Europe & Latin America. Roughly Grunenthal agreed to $150M in upfront payments and milestones ($45M in year one with $15M on signing) for DDD indication. The deal follows the Tasly Pharmaceuticals (600535-Shanhai – Not Rated) partnership for China. Back in 2011 a manufacturing partnership with Lonza (facility is on the ground in Singapore) and in 2010, the first partnership with cephalon (CEPH-Not Rated, acquired by Teva-Teva Not rated) which supported the CHF program until Teva as (in our opinion), as result of Teva's own internal chaos, terminated the partnership relinquishing all rights after investing millions and initiating the pivotal CHF program.

IP Too … & it has Already Paid off. In 2013, Mesoblast acquired Prochymal, known today as Mesoblast's Remestemcel and in Japan, Mesoblast's partner, JCR Pharma's (TO:4552-Not Rated) sells the product as TEMCELL for GvHD. This happened as a result of a deal struck with Osiris (OSIR-Not Rated). In the process, Mesoblast substantially strengthened its existing IP estate. So much so that when Japanese Pharma giant Takeda (TAK-Not rated) acquired EU company Tigenix (TIG – Not rated), they needed to pay Mesoblast (licensing agreement) as a result of infringing on Mesoblast's substantial IP estate.

Valuation. This is a complex discussion in terms of how does one value a company with both a commercially approved product, multiple partnerships, and 3 x 3 (three products in three pivotal trials, GvHD, Back Pain, and CHF). We model each product out to 2030. We provide a detailed explanation of our assumptions (pricing, timing) for each therapeutic model, and then "haircut" our estimates by a probability of success factor, based on the clinical stage of development and our assessment of the indication. For well-established companies with highly predictable revenues, we typically select a risk rate (r) of 10 percent, for early-stage growth companies like Mesoblast, we select our maximum risk rate of 30%. We assume dilution (we never let the projected balance sheet go negative) and use a fully diluted 2030 projected share count. These factors are then applied to our Free Cash Flow to the Firm (FCFF), Discounted EPS (dEPS), and Sum-of-the-Parts (SOP) models, which are equally weighted and rounded to the nearest whole number to derive a $14.00 price target.

How Does Clinical Success Change the Projected Valuation? For example, we only assume a 25% success probability in the CHF indications. If Mesoblast announces positive clinical data, it suggests the probability goes up. At 100%, this change alone would drive a target increase from $14.00 to $34.00. As such, we believe our valuation metrics are conservative.

Risk to our thesis, include the following: (1) clinical and regulatory; (2) commercial; (3) employee; (4) financial; (5) legal and intellectual property; and (6) partnership. We review these and other risks in the risk section of this report.

Company Overview. Mesoblast is committed to bringing to market innovative cellular medicines to treat serious and life-threatening diseases where there are unmet medical needs. Mesoblast is using its proprietary technology platform to develop and commercialize innovative cellular medicines to treat complex diseases in which inflammation plays a central role and are resistant to the conventional standard of care. Its broad portfolio of late-stage product candidates comprises three product candidates in Phase 3 development – Remestemcel-L for acute graft versus host disease, Revascor for advanced heart failure, and MPC-06-ID for chronic low back pain due to degenerative disc disease. Additionally, Mesoblast has a promising emerging pipeline of Phase 2 product candidates and next-generation technologies. The company has leveraged its technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a portfolio of late-stage product candidates. Mesoblast was founded in 2004 and is currently based out of Melbourne, Australia.

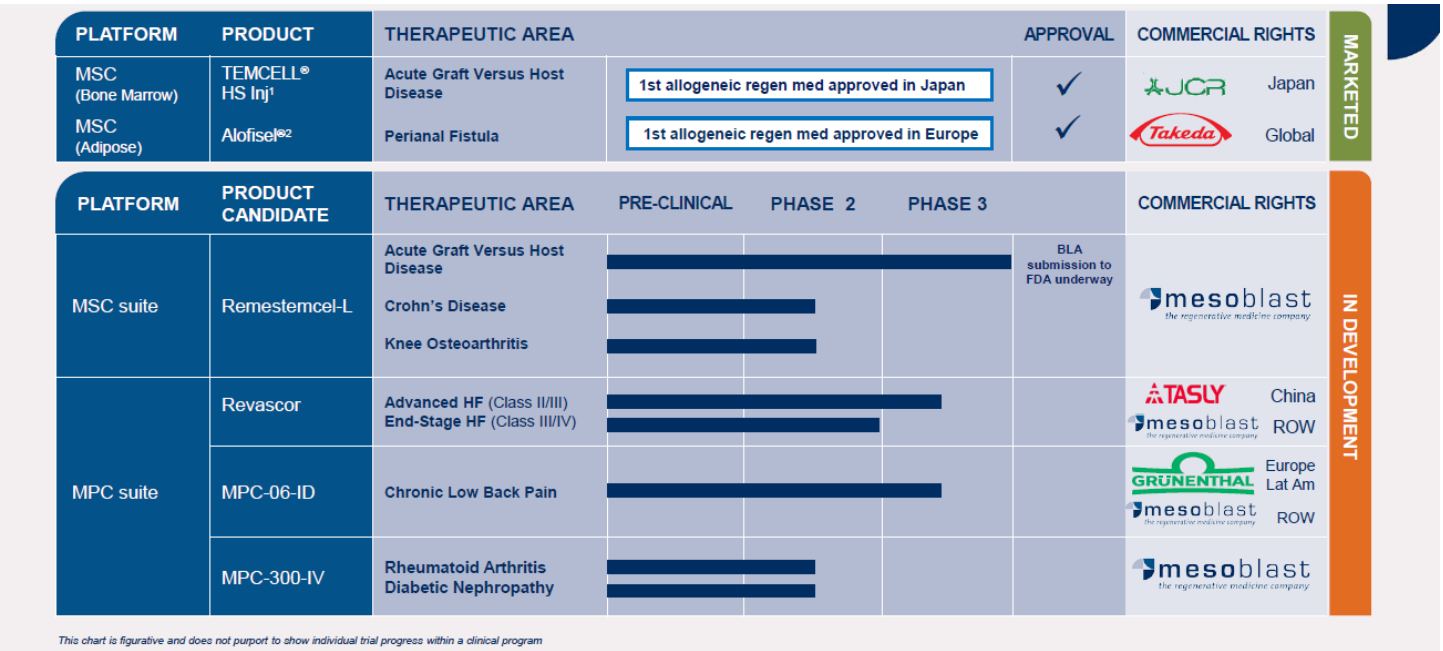
Exhibit 1. Mesoblast Catalysts.

Product	Indication	Event	Timeline	Impact	Peak Sales
MSC-100-IV	Pediatric Acute GvHD	U.S. Filing	YE2019	+	$200M
MSC-100-IV	Pediatric Acute GvHD	FDA Approval	Mid. 2020	+++	
MSC-100-IV	Pediatric Acute GvHD	Commercial Launch	YE2020	++	
MSC-100-IV	Pediatric Acute GvHD	EU Filing	YE2020		
MSC-100-IV	Pediatric Acute GvHD	EU Launch	Jul-05		
MPC-150-IM	ClassII/III DREAM Heart Failure	P3 N=566 Enrolled			$3-$4B
MPC-150-IM	ClassII/III DREAM Heart Failure	Trial "locked" at 531 Events	YE2019		
MPC-150-IM	ClassII/III DREAM Heart Failure	Top-Line Data	Mid. 2020	+++	
MPC-06-ID	Chronic Low Back Pain	P3 Trial Complete Enrollment	completed		$500M
MPC-06-ID	Chronic Low Back Pain	Trial is Fully Enrolled	Mid. 2018		
MPC-06-ID	Chronic Low Back Pain	Top line Data 24 Months Data	Mid. 2020	+++	

Stock Significance Scale: + of moderate importance; ++ higher level; +++ highly important.

Source: Dawson James

Exhibit 2. Mesoblast Pipeline & Commercial Products



Source: Mesoblast

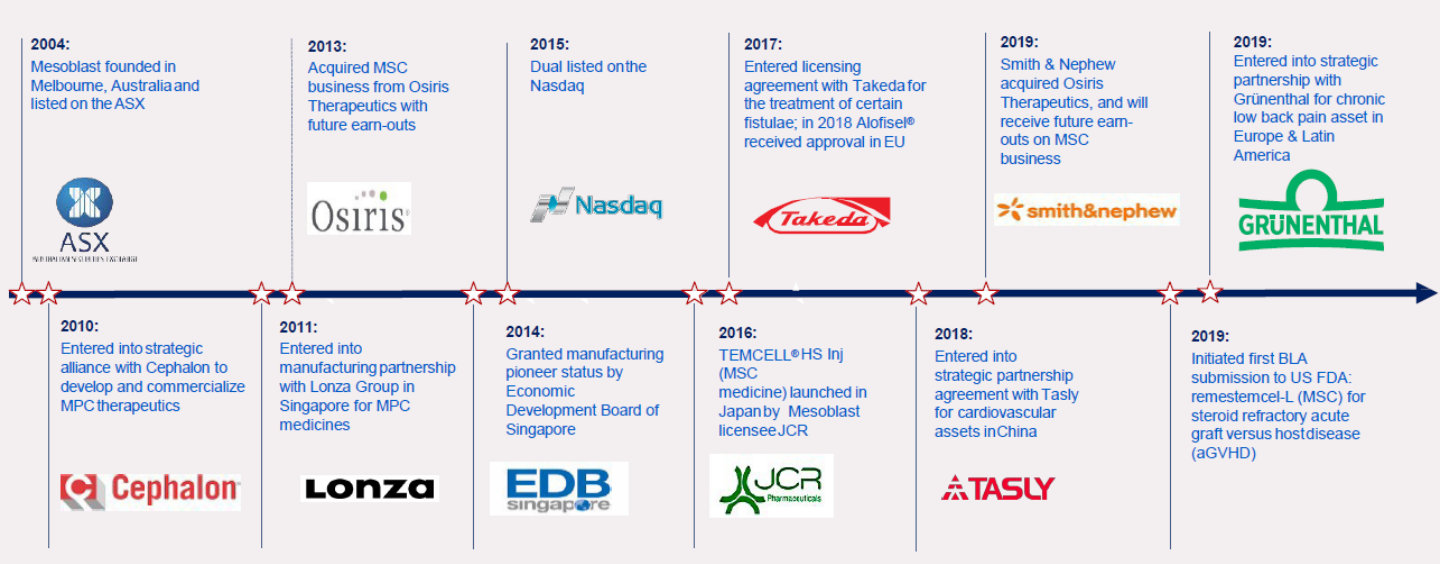
Bull Case. Mesoblast is on the verge of success with no less than three products in Phase 3, pivotal trials. The opportunity is in the heart failure space alone represents one of the largest, if not the largest market, which today still represents an unmet medical need. The promise that Mesoblast holds is to change the course of the disease. While there are multiple therapeutic regimens to address heart failure, few treat the underlying cause, ischemia in the muscle, (the heart). This is one of the promises of stem cell therapy to promote vascularization, followed by a reduction in inflammation and promoting healing. These selected stem cells have demonstrated their ability to tap into the body's own teleological response and turn the healing process on. Mesoblast's products today include Remestemcel-L for Acute Graft Versus Host Disease (GvHD), Revascor for both Advanced Heart Failure (HF-Class II/III) now in a pivotal trial and End-Stage HF, Class III/IV and MPC-06-ID for Chronic Lower Back Pain, or Degenerative Disc Disease (DDD). Remestemcel-L is currently approved in Japan and being marketed by Mesoblast's partner, JCR Pharma. The U.S. BLA submission is "underway," and we expect to see expansion from pediatric to adult indications in time, in the U.S. and Europe. The heart failure and back-pain trials are both completely enrolled with very similar timing, data by the first half of next year. The designs of both trials are smart, and in particular, we like the event-driven HF study. Success is not factored into the current valuation. Positive outcomes in the HF or DDD study could be transformative to patients, doctors who treat them, and for the company. As a result, we could see Regenerative Medicine finally arrive as did CAR-T, with valuations reflective of the commercial opportunity.

Bear Case. Mesoblast acquired Remestemcel through the acquisition of the product from Osiris (OSIR-Not Rated). The product has not generated meaningful sales in Japan, and bears will argue it is unlikely to significantly change treatment paradigms in the U.S., where the initial approval will be narrow, focused on the pediatric market. The more meaningful opportunity is in the adult market, which is likely to require another trial. Europe is staggered now, behind the U.S. Beyond Remestemcel, the outlook of the current pivotal trials is back-pain, and heart failure is uncertain. The heart failure trial was managed by Teva, which has since relinquished the product rights back to Mesoblast. If Teva is not a believer in the product's potential, why should we believe? Mesoblast has seen partners like Teva and Celgene (CELG-Not Rated) pass on licensing opportunities. Bears will site the historic failures in the regenerative space and the long road (the past 30 years) of an under-capitalized sector of the biotechnology market that has struggled to find its niche.

Our Take. We see significant catalysts ahead in GvHD (BLA filing by year-end 2019) with commercialization by 2020 possible. This is followed by top-line data in Heart Failure (HF) and Back-pain (DDD). We have high confidence that GvHD is likely approved. Our confidence is driven by the data, the fact that the product is approved and being used now in Japan, the desperate unmet medical need of the disease in children coupled with the very high safety profile of regenerative medicine cell therapy. In terms of the outcomes in HF and DDD, we are less sure. We appreciate the event-driven design of the HF trial and believe the company has given itself the best possible chance of success. We are believers in the cell therapy space based on almost 30 years of data that suggests cells have activity at promoting new blood vessel growth, reducing inflammation, and promoting healing. So, the key question is not if cells work, but have the trials been properly designed and managed. We have a similar outlook for degenerative disease (DDD). For us, it comes down to risk versus reward. From a regulatory view, we see minimal risk. The adverse event profile of these cells is benign. Couple this with the unmet medical need, and from a regulatory view, we see a very favorable risk-reward profile. In terms of pharmacoeconomics, we also see a very favorable view, as the cell address the underlying cause of the disease versus symptomatic treatment. Mesoblast has a proven track record of good (non-dilutive deals) that have raised precious operating capital at favorable terms. In our opinion, clinical success is not factored into Mesoblast's valuation. Success here could represent a paradigm shift similar to what we have seen previously in the CAR-T space. With a series of catalysts coming in GvHD, HF, and DDD, and given the current valuation, coupled with a strong balance sheet ($100M Pro-forma cash), we are bullish.

Financials. Mesoblast reported a cash position of $35M in Sept 2019 (1Q20) but a Pro-forma cash position of $100M. The company has just over 100M shares outstanding (U.S. ADR). Our model assumes additional raises, and as such, our valuation is based on a fully diluted, out-year (2030) share count of 144M shares.

Exhibit 3. A History of Deals



Source: Mesoblast

Exhibit 4. Manufacturing with Lonza. Mesoblast is investing in efficient manufacturing operations now with Lonza in anticipation of approvals. The manufacturing question represents a key critical factor for regulators.

- 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

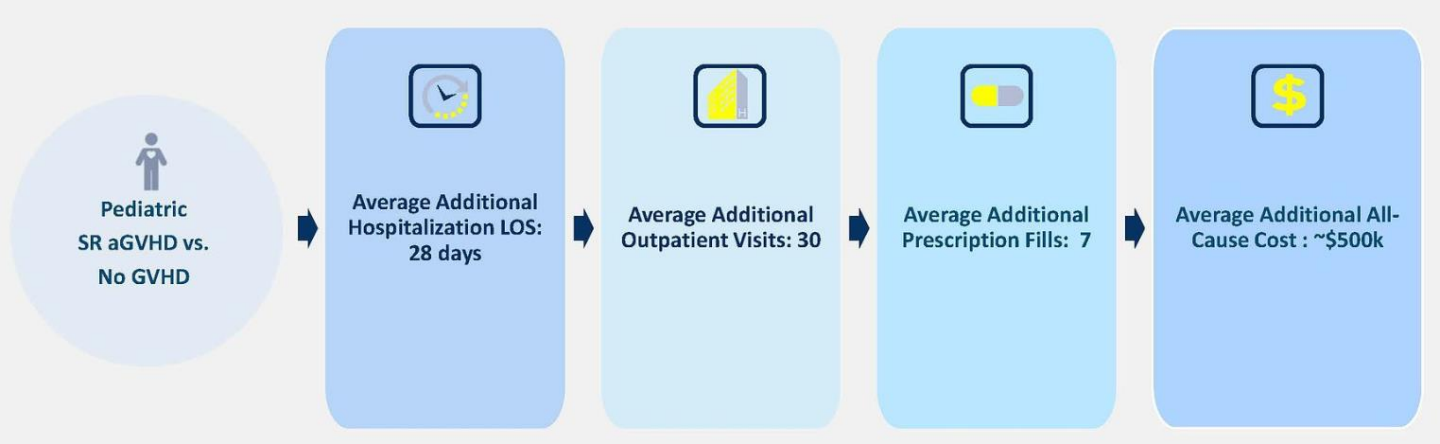
Lonza contract manufacturing facility in Singapore

Source: Mesoblast

Acute Graft Versus Host Disease (aGvHD) is a life-threatening condition that is the result of an allogeneic bone marrow transplant. Globally, more than 30,000 bone marrow transplants are performed each year, with aGvHD being the leading cause of post-BMT death. In addition, about 20% of these BMTs are pediatric. The most severe form of this disease is labeled grade C/D, leading to the highest mortality and increased multi-organ involvement. This can affect the skin, gastrointestinal system, and other organs. Day 100 mortality can reach up to 70%, with month 12 mortality reaching as high as 90%.

Causes of aGvHD. About 50% of patients receiving a bone marrow transplant are led to this complication. This condition occurs when the donor bone marrow attacks the recipient's immune system. This can lead to mouth ulcers, abdominal pain, or a rash varying in severity. After diagnoses, mortality rates reach as high as 95% and present a significant financial burden on hospitals and patients.

Exhibit 5. Additional Burden of Illness in Children. The additional burden of illness in children who have developed steroid-refractory aGvHD versus those who did not develop aGvHD is not only economical but also affects their quality of life.



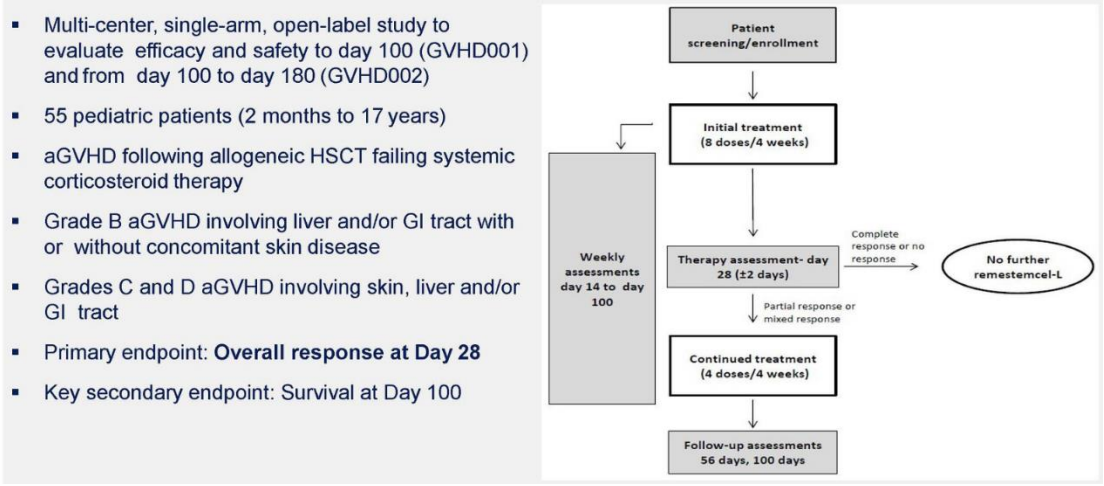
Source: Mesoblast Presentation

Current Treatments for aGvHD. Currently, there is only one treatment for aGvHD disease on the market (within the U.S.) However, there are no approved treatments for children under 12 years old, outside of Japan. This limited treatment option leaves room for a new product to gain a sizeable market share.

Remestemcel-L is an MSC-based product intended for the treatment of aGvHD. This drug has already received approval in Japan and has been licensed under the product TEMCELL HS by JCR Pharmaceuticals. Thus far, they have already been reimbursed roughly $195,000. The drug is delivered intravenously in order to regulate inflammatory responses related to aGvHD. It delivers 100M stem cells within 60-minute infusions over the course of 4-8 weeks. This process is meant for regulating the production of pro-inflammatory cytokines to reduce the inflammatory response.

Phase 3 Pediatric Trial. Mesoblast's Phase 3 pediatric trial was conducted with 55 children, with the primary endpoint being Overall Response at Day 28. The trial's secondary endpoint was survival at Day 100. Within this group, 89% of patients had the most severe form of the disease (one with up to 95% mortality rate). The trial met its primary endpoint, reaching an 87% survival rate. At Days 100 and 180, survival was 75% and 69%, respectively. Survival rates for children with C/D (the most severe form) after failure to respond to current steroid treatments were 10-30%.

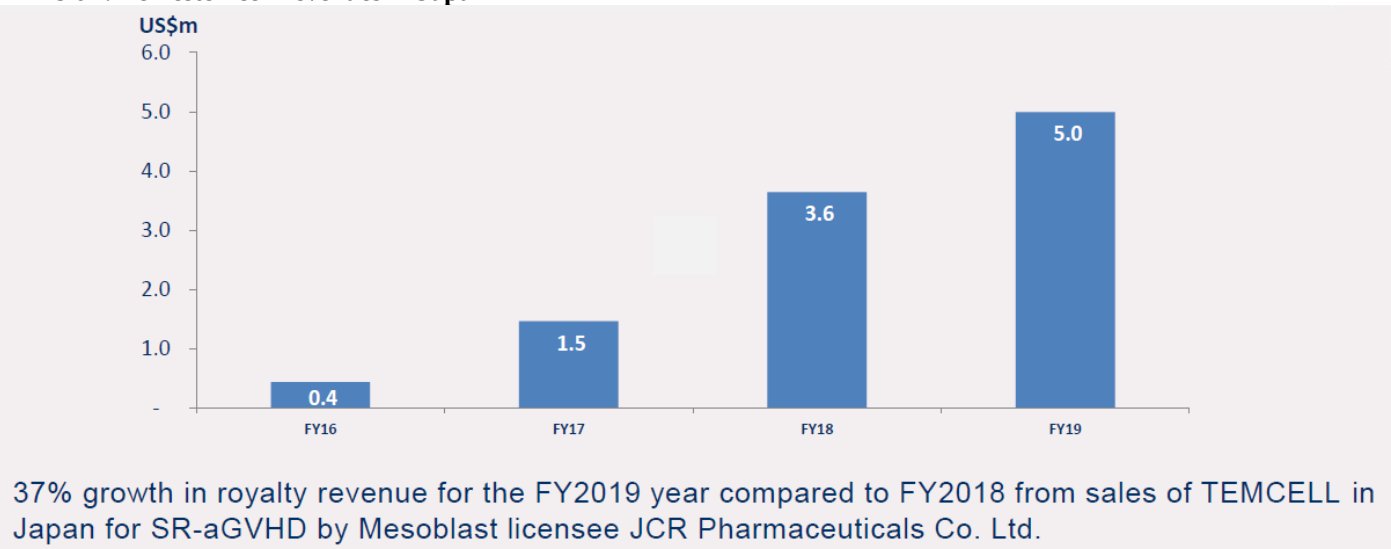
Exhibit 6. Layout of Phase 3 Pediatric Trail for Patients who Failed Steroids



Source: Mesoblast Presentation

Mesoblast Strategies for Remestemcel-L Development. Mesoblast is hopeful for commercialization due to investment in manufacturing as well as an efficient sales forces with the help of TEMCELL HS. Receiving the Fast Track designation will give the company a priority review by the FDA and speed up the approval process. They also anticipate a pre-BLA (Biologics License Applications) meeting with the FDA within the next few months. Their target audience for commercialization will be pediatric patients with SR-aGvHD due to the strength and legitimacy of the data received during their Phase 3 trial. Next, high-risk adult patients will be targeted.

Exhibit 7. Remestemcel Revenues in Japan



Source: Mesoblast Presentation

Modeling Assumptions for GVHD (Remestemcel-L)

1. We assume a 2% annual market size growth for all patients with GvHD.
2. We assume the cost of therapy for GvHD is $250,000 in the U.S. and will decrease to $212,200 by 2030.
3. We assume the cost of therapy for GvHD is $230,000 in the E.U. and will decrease to $195,224 by 2030.
4. We assume the cost of therapy for GvHD in Japan will decrease to $125,000 by 2030.
5. We assume market share penetration for pediatric GvHD in the U.S. will be 3% in 2019 and increase to 85% by 2030.
6. We assume market share penetration for adult GvHD in the U.S. will be 25% beginning in 2022 and will increase to 85% by 2030.
7. We assume market share penetration for pediatric GvHD in the EU will be 3% in 2019 and increase to 85% by 2030.
8. We assume market share penetration for adult GvHD in the EU will be 25% beginning in 2022 and increase to 85% by 2030.
9. We assume market share penetration for GvHD in Japan to be 30% by 2030.
10. We assume the probability of success for all GvHD patients is 70%.

Exhibit 8. GvHD Model(s)

Pediatric GvHD - USA	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Allogenic Stem Cell Transplants	16000	16320	16647	16980	17319	17666	18019	18379	18747	19122	19504
Market Size Growth (Annual)	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Ped. & Adult Acute GvHD (grades II-IV)	8679	8853	9030	9210	9394	9582	9774	9969	10169	10372	10580
Pediatric Steroid Refractory Acute GvHD (Grades II-IV)	672	686	699	713	728	742	757	772	787	803	819
Market Share Penetration	0.0%	25.0%	50.0%	75.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Number of Patients Procedures	0	171	350	535	618	631	643	656	669	683	696
Cost of Therapy	$ 250,000	$ 250,000	$ 250,000	$ 247,500	$ 235,125	$ 223,369	$ 212,200	$ 212,200	$ 212,200	$ 212,200	$ 212,200
Price Change	0%	0%	0%	-1%	-5%	-5%	-5%	0%	0%	0%	0%
Probability of Success	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Pediatric Acute GvHD Grades II-IV Revenues (M)	$ -	$ 30	$ 61	$ 93	$ 102	$ 99	$ 96	$ 97	$ 99	$ 101	$ 103

Adult GvHD - USA	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Allogenic Stem Cell Transplants	16000	16320	16647	16980	17319	17666	18019	18379	18747	19122	19504
Market Size Growth (Annual)	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Ped. & Adult Acute GvHD (grades II-IV)	8679	8853	9030	9210	9394	9582	9774	9969	10169	10372	10580
Adult Steroid Refractory (liver involvement / high risk, Grades II-IV)	1605	1637	1670	1704	1738	1772	1808	1844	1881	1919	1957
Market Share Penetration	0.0%	0.0%	25.0%	50.0%	75.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Number of Patients Procedures	0	0	418	852	1,303	1,507	1,537	1,567	1,599	1,631	1,663
Cost of Therapy	$ 250,000	$ 250,000	$ 250,000	$ 247,500	$ 235,125	$ 223,369	$ 212,200	$ 212,200	$ 212,200	$ 212,200	$ 212,200
Price Change	0%	0%	0%	-1%	-5%	-5%	-5%	0%	0%	0%	0%
Probability of Success	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Adult Acute GvHD Revenues (M)	$ -	$ -	$ 73	$ 148	$ 214	$ 236	$ 228	$ 233	$ 237	$ 242	$ 247

Pediatric GvHD - EU	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Allogenic Stem Cell Transplants	20233	20637	21050	21471	21900	22338	22785	23241	23706	24180	24663
Market Size Growth (Annual)	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Ped. & Adult Acute GvHD (grades II-IV)	10723	10938	11157	11380	11607	11840	12076	12318	12564	12815	13072
Pediatric Steroid Refractory Acute GvHD (Grades II-IV)	555	566	577	588	600	612	624	637	650	663	676
Market Share Penetration	0.0%	25.0%	50.0%	75.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Number of Patients Procedures	0	141	288	441	510	520	531	541	552	563	575
Cost of Therapy	$ 230,000	$ 230,000	$ 230,000	$ 227,700	$ 216,315	$ 205,499	$ 195,224	$ 195,224	$ 195,224	$ 195,224	$ 195,224
Price Change	0%	0%	0%	-1%	-5%	-5%	-5%	0%	0%	0%	0%
Probability of Success	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Pediatric Acute GvHD Grades II-IV Revenues (M)	$ -	$ 23	$ 46	$ 70	$ 77	$ 75	$ 73	$ 74	$ 75	$ 77	$ 79

Adult GvHD - EU	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Allogenic Stem Cell Transplants	20233	20637	21050	21471	21900	22338	22785	23241	23706	24180	24663
Market Size Growth (Annual)	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Ped. & Adult Acute GvHD (grades II-IV)	10723	10938	11157	11380	11607	11840	12076	12318	12564	12815	13072
Adult Steroid Refractory (liver involvement / high risk, Grades II-IV)	2094	2136	2179	2223	2267	2312	2359	2406	2454	2503	2553
Market Share Penetration	0.0%	0.0%	25.0%	50.0%	75.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Number of Patients Procedures	0	0	545	1,111	1,700	1,965	2,005	2,045	2,086	2,127	2,170
Cost of Therapy	$ 230,000	$ 230,000	$ 230,000	$ 227,700	$ 216,315	$ 205,499	$ 195,224	$ 195,224	$ 195,224	$ 195,224	$ 195,224
Price Change	0%	0%	0%	-1%	-5%	-5%	-5%	0%	0%	0%	0%
Probability of Success	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Adult Acute GvHD Revenues (M)	$ -	$ -	$ 88	$ 177	$ 257	$ 283	$ 274	$ 279	$ 285	$ 291	$ 297

GvHD - Japan	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Allogenic Stem Cell Transplants	4085	4167	4250	4335	4422	4510	4600	4692	4786	4882	4980
Market Size Growth (Annual)	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Ped. & Adult Acute GvHD (grades II-IV)	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%
Number of Patients Procedures	1,430	1,458	1,488	1,517	1,548	1,579	1,610	1,642	1,675	1,709	1,743
Market Share Penetration	14.0%	16.0%	20.0%	24.0%	30.0%	34.0%	36.0%	38.0%	40.0%	42.0%	44.0%
Number of Patients Procedures	200	233	298	364	464	537	580	624	670	718	767
Cost of Therapy	$ 170,000	$ 150,000	$ 150,000	$ 150,000	$ 125,000	$ 125,000	$ 125,000	$ 125,000	$ 125,000	$ 125,000	$ 125,000
Revenues	$ 34	$ 35	$ 45	$ 55	$ 58	$ 67	$ 72	$ 78	$ 84	$ 90	$ 96
Japan Annual Royalty/Revenues to Mesoblast: 20%	$ 6.8	$ 7.0	$ 8.9	$ 10.9	$ 11.6	$ 13.4	$ 14.5	$ 15.6	$ 16.8	$ 17.9	$ 19.2
% Growth (qtrly)	376%	3%	28%	22%	6%	16%	8%	8%	7%	7%	7%

Source: Dawson James Estimates

Advanced and End-Stage Heart Failure will have affected approximately 8 million patients by 2030 in the U.S. alone (currently affecting 2% of adults in the U.S). This is just a fraction of the 80 million Americans who have one of many cardiovascular conditions. Those suffering from this condition are found to have weakened heart muscles that fail to effectively pump blood in and out of the heart. Most of those suffering from advanced heart failure die within five years, while 17-45% die within one year of hospitalization. More than 1.3 million patients in the U.S. alone live with NYHA class III-IV chronic heart failure.

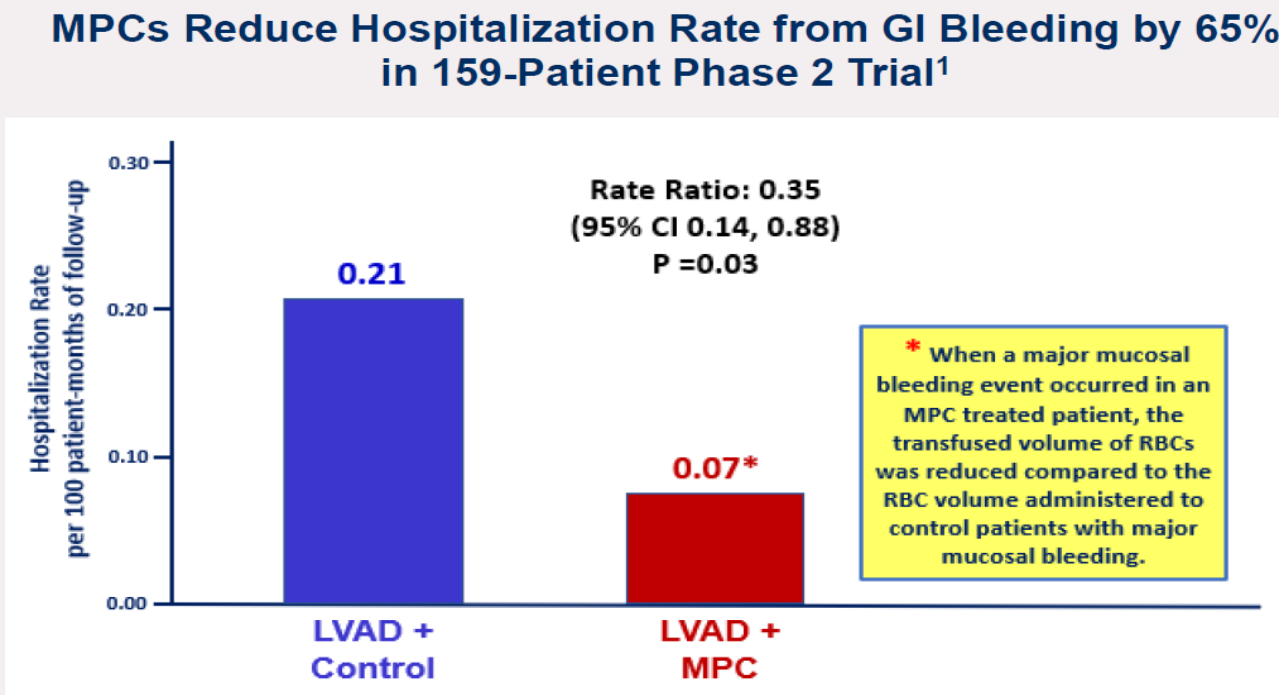
Unmet Need: Currently, there are an estimated 300,000 patients who suffer from advanced systolic heart failure, despite ongoing treatments (excluding assist devices). Current options right now include cardiac resynchronization therapy, LVADs, implantable cardioverter-defibrillators, and heart transplants. These patients have a one year expected mortality rate of 25%, even reaching 50% in more advanced cases. The greatest unmet medical need is within the NYHA class III-IV where new therapies are required to reduce hospitalizations and mortality for those who have failed other therapies. Yearly US healthcare costs for NYHA class II-IV are estimated to be a $115B market, which comprises 69% of this due to hospital expenditures. While assistive devices, such as LVADs, have improved survival, these devices also have major adverse side effects that cost an average of $46,500 per hospitalization.

Revascor is a mesenchymal precursor cell (MPC) based drug developed in order to treat advanced and end-stage heart failure (CHF) after failing to respond to other therapies. It's administered through direct injection into the heart of those suffering from this condition. The drug reduces inflammation, cardiac scarring, and repairs the vascular network by strengthening damaged tissue. Recently, Revascor has received Regenerative Medicine Advanced Therapies (RMAT) designation for the use in end-stage heart failure patients with LVADs. This gives them potential eligibility for priority review, accelerated approval, as well as other possible benefits.

Phase 3 Trial: Advanced Heart Failure. This trial has completed enrollment of 566 patients suffering from advanced heart failure. This will be used to evaluable Revascor in patients with moderate-to-severe advanced chronic heart failure. This is following the success of the pre-specified futility analysis of the primary efficacy endpoints of the Phase 3 trial in April 2017 (utilizing 270 patients).

Phase 2 Trial: End-Stage Heart Failure. The Phase 2 trial was sponsored by the United States National Institutes of Health (NIH). Using 159 patients, they tested the efficacy of Revascor in patients with LVAD (left ventricular assist device) implantations by direct injection of the drug into the heart. Results displaced a 76% reduction of GI bleeding and a 65% reduction in associated hospitalizations. This is the most common non-surgical complication of LVAD patients (up to 40% of patients) and has been acknowledged as a meaningful outcome by the FDA. Revascor Reduced Hospitalization rate from GI bleeding in the Phase 2 trial.

Exhibit 9. Results of LVAD Trial



Source: Mesoblast

End-Stage Heart Failure patients have the option of receiving a heart transplant. The extremely limited availability of donor's hearts leaves patients with one option, which is assistive cardiac devices. LVADs are one example of these devices, with 4,500-5,500 implantations annually (in the U.S. alone). These solutions fall short and lead to more than three hospitalizations per year in relation to GI bleeding and infections caused by the devices.

Is Bigger Better? Adapting statistical measures to rapidly changing therapeutic landscapes- Case Study in Heart Failure. Clinical trials in heart failure (and other indications), historically, have required larger numbers of patients. The question now is bigger, really mean better? Many, in our view, continue to believe that the larger a pivotal Phase 3 study is, the higher the probability of demonstrating a statistically significant difference (hitting a P-value) between active and control. However, the rationale supporting the need for large clinical studies, particularly in heart failure, is based on expected outcomes for patients over 30 years ago and not representative of expected outcomes today. We also must take into consideration the special dynamics today that surround the use of stem cells. Stem cells, in the context of heart failure (autologous or allogeneic), have typically shown themselves to be extremely safe. As such, one of the typical reasons behind large trials, to detect an off-target drug-related adverse event, is unlikely and, for the most part, just not required. Historically in heart failure (in the mid-'80s), patients who were admitted to a hospital (for heart failure) and subsequently released had a median life expectancy of fewer than two years. During this period, therapeutic interventions were limited. Clinical trials were designed then based on all-cause mortality as the likelihood of a heart failure patient dying from a non-cardiac event was significantly low, and a statistically significant improvement in patient outcome could be achieved with a new drug in development.

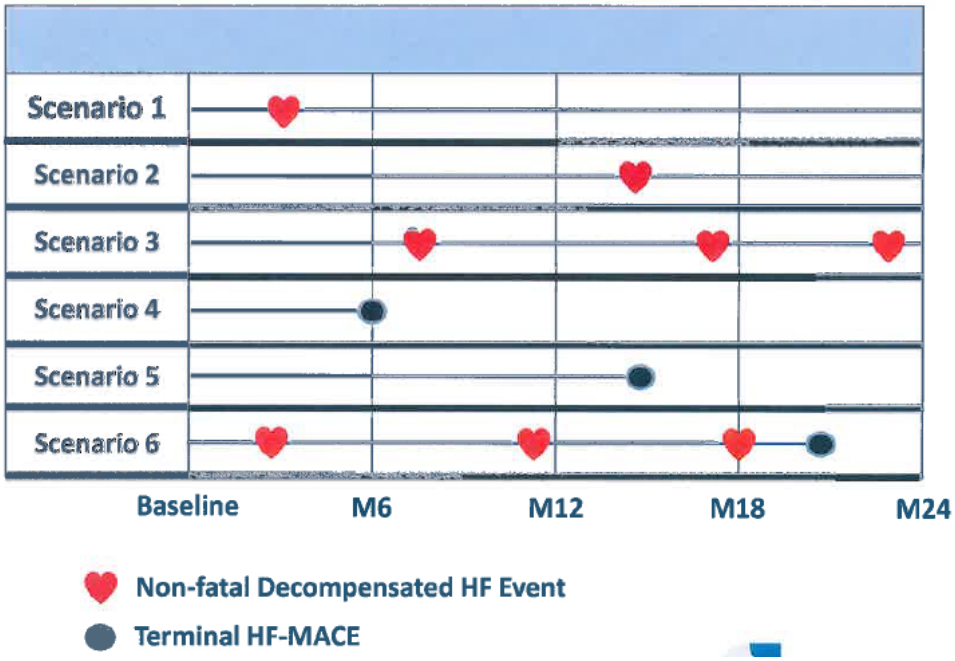
Over the next 20 years, therapeutics, including implantable defibrillators, ACE inhibitors, and beta-blockers, transformed the cardiac therapeutic landscape and greatly extended the life expectancy of a patient with heart failure. However, while patients have a longer life expectancy, they are still suffering from heart failure and a condition that was once viewed as "acute" with relatively rapid time to death (which was the "first event"), became a "chronic" condition with a patient suffering both cardiac and non-cardiac events over time and eventually death from either cardiac or non-cardiac causes. What hadn't changed was clinical trial design. Clinical studies had not moved away from using all-cause mortality, or time to the first event, as a primary endpoint. With patients living much longer and experiencing multiple events, and death from non-cardiac causes, novel therapeutics in clinical development can no longer rise above the "noise" level and show a P-value unless the trial size was remarkably large. Even more important is that many events in the studies were missed since the only measure was time to the first event, thus the therapeutic effect of a new therapy that changes the course of the disease could not be observed with statistical significance. Novel therapeutics in development today, particularly in the cell therapy space, are altering the course of the disease or shifting the disease trajectory over time. As such, how that therapeutic benefit is captured statistically requires significant changes to clinical trial design.

Case study: Mesoblast's Study in Heart Failure. Mesoblast's Revascor (allogeneic) is currently in a Phase 3 study for congestive heart failure. The study was designed to enroll 1,100 patients but was subsequently reduced to 600. Why? It's all in the statistics and a trial that is designed to move away from traditional "time to the first event." With many patients experiencing multiple events over time, the use of time to the first event ignored repeat events, and thus the true burden of disease and how Revascor could impact the overall burden of disease could not be measured appropriately. For example, if patient "A" died at month three after treatment and Patient "B" died at month 18 but had four events (hospitalizations) along the way with the first event at month 3, the time to first event endpoint would stop at month three and ignore all the other events as well patient B's death. Then how could we know if Revascor really changed the disease burden? What if patient B's first event at three months was non-cardiac? The potential treatment effect and all of the other data is not captured in the statistical analysis. What Mesoblast did then was to evaluate three statistical models to determine which was best suited to analyze recurrent events to better understand the overall impact of Revascor cell therapy in HF patients…The Poisson Model, The Negative Binomial Model, and the Joint Frailty Model. Mesoblast moved forward using a Joint Frailty Model in the Phase 3 study. Still, it's important to understand why the Poisson and Negative Binomial models won't work and why Mesoblast's approach to a phase III study can utilize a smaller patient population to demonstrate a statistically significant treatment effect.

Mesoblast: A Trial Evaluating Congestive Heart Failure. Heart failure in the recent past was considered essentially a fatal disease with a median survival of fewer than 1.25 years after discharge (1980's). Patients with a reduced ejection fraction (HF-REF) died either from progressive pump failure or suddenly, mainly due to ventricular arrhythmias. This picture has been transformed in the past two decades. Angiotensin-converting enzyme (ACE) inhibitors, beta-blockers, mineralocorticoid receptor antagonists, and devices (implanted cardioverter defibrillators and cardiac resynchronization therapy) have completely changed the prognosis for patients with HF-REF. Systolic heart failure has been converted from a relatively short-term and quickly fatal condition to a chronic disease characterized by recurrent non-fatal events (hospital admissions) and delayed death that is now nearly as often due to a non-cardiovascular as a cardiovascular cause.

The design of clinical trials and the choice of endpoints have to reflect this changing pattern of disease. All-cause mortality is no longer considered an appropriate or practical endpoint for clinical trials in heart failure. First, the mortality rate in heart failure has decreased so dramatically that trials using death from any cause as the primary outcome have become unfeasibly large. Secondly, non-cardiovascular deaths now account for a substantial proportion of deaths in heart failure. As they are unlikely to be reduced by a therapy for heart failure, their inclusion in a primary endpoint obscures the effect of treatment on the disease in question by adding 'noise.' Thirdly, and most importantly, all-cause mortality does not fully reflect the current burden of disease, i.e., it neglects hospital admission.

Exhibit 10. Examples of the timing of Potential Primary Endpoints Events.



Source: Mesoblast

Poisson Model. The Poisson model was used by Vericel to evaluate their HF cell therapy (ixmeyelocel-T stem cells) in a phase II study in end-stage heart failure patients. Vericel was attempting to capture all of the events experienced by a patient over a period of time. In fact, the Poisson model is based on the probability of a number of events occurring over a fixed period of time, like a hazard ratio (HR, risk of death per unit time per treatment group). In terms of heart failure, all hospitalizations, emergency room visits, and heart-related mortalities are captured though independent of which type of event. Thus, two emergency room visits for any cause and two hospitalizations are equally weighted, as is a patient death from any cause. This approach provides the investigator, in this case, Vericel, with a hazard ratio comparison. Though it was a small study (N=107, placebo-controlled), Vericel demonstrated a 37% reduction in events in the ixmeyelocel-T treated group. However, were the results clinically meaningful? The Poisson approach cannot tell us that as all events are equally weighted…a death = an ER visit for some cause and also = a hospitalization for some cause. The FDA likely would not except this statistical approach for approval, where a therapeutic effect is measured using equal weight of any event. This introduces potential bias, as well as a lack of censuring (non-cardiac ER visits, hospitalization, etc.) or appropriate weighting of critical events.

Negative Binomial Model, an extension of the Poisson Model. As described above, the Poisson Model captures the probability of "X" events occurring over some specific period of time. For Vericel, this allowed for the generation of a Hazard Ratio comparison in their HF study. However, the Poisson model cannot account for an important factor, the "randomness" of event distribution among different patients in the population. In other words, there is a "proneness" of some patients to have more events or more cardiac-related events over some period of time than for other patients. The question is, what happens if the variability in number events for some patients over a specified period of time exceeds the mean number of events in the study population. This is called "overdispersion." In heart failure, overdispersion is the norm. Another question is, how related are the recurring events in a patient to the patient's terminal event? What the Negative Binomial Model is attempting to capture are all the events but correcting for the tremendous variability and heterogeneity in the heart failure population. This approach is a "simplified" or "generalized" version of the Poisson Model. The challenge is that if recurrent HF-related events are even moderately correlated to terminal events, then the negative binomial model injects significant unfavorable bias in the hazard ration analysis. The opposite is also true. If the terminal events are unrelated or minimally related to the recurring events in a patient, the bias is minimized, and the Negative Binomial Model could provide reliable estimates of a treatment effect.

The Joint Frailty Model and the Mesoblast approach. The Joint Frailty Model is more likely to show a significant treatment effect for a cell therapy like Revascor and be an acceptable statistical approach for regulators. Recall that the Poisson Model treats deaths and HF events the same and as such cannot account for differences between recurrent HF events (time, type, etc.) or recurrent events and a terminal event. The Negative Binomial Model, like the Poisson Model, treats all events the same (death and HF events) but corrects for patient variability. This model can show a difference between recurrent HF events but cannot differentiate between HF events and death; thus, like the Poisson Model, it's of limited use in an HF trial. The Joint Frailty model is ideal for a chronic disease such as HF. In HF, recurring events can be interrupted by death. Thus any subsequent events for that patient would be lost information, skewing the results and potentially causing investigators to miss observation of a significant treatment effect. What the Joint Frailty model does is show the relationship and time dependence of recurring HF events to a death event. The heterogeneity or variability from patient to patient is accounted for with a random-effects approach. Meaning, the model induces dependence among the recurring event times. This model also assumes the risk of death for each patient. As opposed to censoring patients following death, the model counts HF events like hospitalizations that would have occurred if the patient remained alive. This otherwise lost information is then used in the estimation of underlying events and whether or not changes in the events or time of events is due to a true treatment effect. The combination of relating all possible events, time of events, death provides enough information to allow for the design of clinical trials with fewer patients. Thus, Mesoblast is able to reduce the trial size from 1,100 to 600 and still have enough data points and power to achieve statistical significance (hitting P values).

Exhibit 11. Summary Comparison of Statistical Models for Evaluation of Recurrent Events.

	Types of Events Assessed in the Model	Takes into Account Correlation	
		Between Recurrent HF Events	Between Recurrent HF and Terminal Events
Poisson Model	Treats terminal and recurrent HF events similarly	No	No
Negative Binomial Model	Treats all events similarly but accounts for different patient-specific event rates	Yes	No
Joint Frailty Model	Treats terminal and recurrent HF events differently	Yes	Yes

Source: Mesoblast

Modeling Assumptions for Heart Failure (Revascor)

1. We assume the probability of success for all other Heart Failure patients to be 50%.
2. We assume market share penetration for Class IV Heart Failure with LVAD to be 50% in 2020 and increase to 85% by 2030.
3. We assume market share penetration for Heart Failure in the US to be 2% in 2024 and increase to 20% by 2030.
4. We assume market share penetration for Heart Failure in the EU to be 6% in 2026 and increase to 14% by 2030.
5. We assume the cost of therapy to be $50,000 in the U.S. and increase by 0.2% annually.
6. We assume the cost of therapy to be $30,000 in the E.U. and increase by 0.2% annually.
7. We assume the manufacturing costs for Revascor is $1,000.
8. We assume the cost of therapy for Heart Failure for class IV patients with LVADs is $50,000 in 2019 and will increase by 0.2% annually.
9. We assume the market size for Heart Failure patients of class IV with LVADs will grow 2% annually.
10. We assume the probability of success for Heart Failure patients of class IV with LVADs is 35%.
11. We assume the probability of success for all other Heart Failure patients to be 50%.
12. We assume the probability of success for all other Heart Failure patients to be 50%.

Exhibit 12. HF Model & LVAD Models

Heart Failure	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalance CHF	5,000,000	5,005,000	5,010,005	5,015,015	5,020,030	5,025,050	5,030,075	5,035,105	5,040,140	5,045,180	5,050,226	5,055,276	5,060,331
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	500,000	500,500	501,001	501,502	502,003	502,505	503,008	503,511	504,014	504,518	505,023	505,528	506,033
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%	20.0%	20.0%	20.0%
Number of Patients Procedures	0	0	0	0	0	0	10,060	25,176	50,401	75,678	101,005	101,106	101,207
Cost of Therapy	$ 50,000	$ 50,100	$ 50,200	$ 50,301	$ 50,401	$ 50,502	$ 50,603	$ 50,704	$ 50,806	$ 50,907	$ 51,009	$ 51,111	$ 51,213
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
U.S. Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ -	$ 127	$ 319	$ 640	$ 963	$ 1,288	$ 1,292	$ 1,296

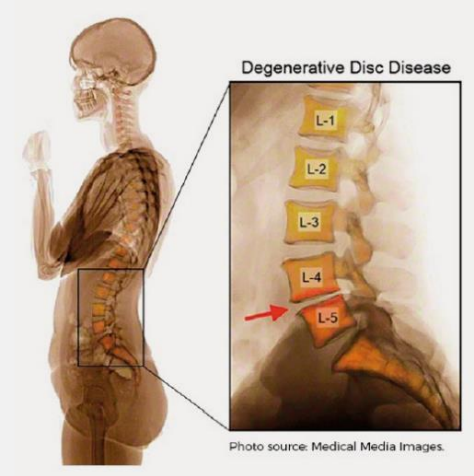
Heart Failure	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
E.U. Prevalance CHF	9,000,000	9,009,000	9,018,009	9,027,027	9,036,054	9,045,090	9,054,135	9,063,189	9,072,253	9,081,325	9,090,406	9,099,496	9,108,596
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	900,000	900,900	901,801	902,703	903,605	904,509	905,414	906,319	907,225	908,132	909,041	909,950	910,860
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.0%	10.0%	14.0%	14.0%	14.0%
Number of Patients Procedures	0	0	0	0	0	0	0	0	54,434	90,813	127,266	127,393	127,520
Cost of Therapy	$ 30,000	$ 30,060	$ 30,120	$ 30,180	$ 30,241	$ 30,301	$ 30,362	$ 30,423	$ 30,483	$ 30,544	$ 30,605	$ 30,667	$ 30,728
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
U.S. Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 415	$ 693	$ 974	$ 977	$ 980

Heart Failure Class IV with LVAD	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Prevalance U.S. NYHA Class IV	275,000	275,275	275,550	275,826	276,102	276,378	276,654	276,931	277,208	277,485	277,762	278,040	278,318
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
% of Patients with LVAD (rising)	2.0%	2.1%	2.2%	2.3%	2.4%	2.5%	2.6%	2.7%	2.8%	2.9%	3.0%	3.0%	3.0%
Candidates (Class IV) for Therapy	5,500	5,781	6,062	6,344	6,626	6,909	7,193	7,477	7,762	8,047	8,333	8,341	8,350
Market Share Penetration	0.0%	0.0%	50.0%	60.0%	70.0%	80.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Number of Patients Procedures	0	0	3,031	3,806	4,639	5,528	6,114	6,356	6,598	6,840	7,083	7,090	7,097
Cost of Therapy	$ 50,000	$ 50,100	$ 50,200	$ 50,301	$ 50,401	$ 50,502	$ 50,603	$ 50,704	$ 50,806	$ 50,907	$ 51,009	$ 51,111	$ 51,213
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
U.S. Annual Sales (M)	$ -	$ -	$ 38	$ 48	$ 58	$ 70	$ 77	$ 81	$ 84	$ 87	$ 90	$ 91	$ 91

Source: Dawson James Estimates

Chronic Lower Back Pain (CLBP) is most commonly caused by disruption to the discs found in between vertebrae. These fluids filled discs give people movement and stability in their everyday lives. When the nerves surrounding these discs are damaged, causing an inflammatory response, it causes chronic pain and functional disability. This damage can be caused by trauma, genetic predisposition, or aging, and affects more than 3.2 million people in the United States alone.

Exhibit 13. The Effect of Degenerative Disc Disease on Spinal Vertebrae



The Current Standard of Care for CLBP focuses on masking the pain rather than treating the problem at its core. All treatment options provide patients with short term solutions to their pain with the intention of temporarily minimizing it. Ibuprofen is a common relief to this problem, with more extreme solutions being major back surgery for long term management. Opioids are commonly prescribed in order to relieve the pain associated with degenerative disc disease. In fact, more than half of the prescriptions for opioids are for people with this condition. Opioids have recently been declared a public health emergency due to their addictive qualities, leading to the need for a non-addictive solution.

MPC-06-ID is a Phase 3 drug intended for the treatment of CLBP due to disc degeneration. The product will be injected directly into the patient's damaged disc, using only 6 MPCs. MPC-06-ID will act as an anti-inflammatory, triggering the creation of new proteoglycan and collagen in order to regenerate the disc. Therefore, this drug does not aim to simply cover the pain, but rather strengthen the disc in order to resolve the problem at its core.

Phase 3 Trial. Mesoblast has recently completed enrollment for its Phase 3 trial, including 404 patients with CLBP due to disc degeneration. The primary endpoints would be pain relief as well as a 50% reduction in lower back pain. While seemingly subjective, these factors would be measured using Visual Analog Score and a 15-point improvement in the Oswestry Disability Index, ensuring the objective nature of the data. Overall Treatment Success Composites will be measured both at 12 months and 24 months, with no additional treatments over the course of time. Safety and efficacy tests at the 12-month mark for all patients are expected to be completed in the first half of 2019.

Phase 2 Trial. The Phase 2 trial of MPC-06-ID had several primary endpoints: efficacy, medication usage, and quality of life improvement measures. There were 100 patients enrolled; each suffered from CLBP due to disc degeneration for at least sixth months prior to the trial. After the injection of MPC-06-ID, patients saw statistically significant improvements in pain and function up to three years after.

Modeling Assumptions for Degenerative Disc Disease (DDD)

1. We assume market share penetration for Back Pain & Related Disc Repair to be 5% in 2023 and increase to 24% in 2030.
2. We assume that the market size will increase by 0.5% annually.
3. We assume the probability of success for all CLBP patients to be 50%.
4. We assume the cost of therapy to be $10,040 in 2018 and grow 0.2% each year to reach $10,284 in 2030.

Back Pain & Related Disc Repair	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Back Pain Prevalance	30,452,254	30,604,515	30,757,538	30,911,325	31,065,882	31,221,211	31,377,317	31,534,204	31,691,875	31,850,334	32,009,586	32,169,634	32,330,482
Market Size Growth (Annual)	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%
5% Patients Considered Candidates for Therapy	1,522,613	1,530,226	1,537,877	1,545,566	1,553,294	1,561,061	1,568,866	1,576,710	1,584,594	1,592,517	1,600,479	1,608,482	1,616,524
Patients which qualify	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Target Market	380,653	382,556	384,469	386,392	388,324	390,265	392,216	394,178	396,148	398,129	400,120	402,120	404,131
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	5.0%	10.0%	15.0%	20.0%	22.0%	24.0%	24.0%	24.0%
Number of Patients Procedures	0	0	0	0	0	19,513	39,222	59,127	79,230	87,588	96,029	96,509	96,991
Cost of Therapy	$ 10,040	$ 10,060	$ 10,080	$ 10,100	$ 10,121	$ 10,141	$ 10,161	$ 10,181	$ 10,202	$ 10,222	$ 10,243	$ 10,263	$ 10,284
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
U.S. Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ 99	$ 199	$ 301	$ 404	$ 448	$ 492	$ 495	$ 499

Valuation: Our valuation methodology begins with our projected revenues from our product models. We apply assumptions for the timing of approval, launch dates, and product attributes to estimate revenues. These estimates feed into our income statement through the year 2030. The result of these projections is then fed into our income statement projections. Our price target is derived from an equal-weighted average of free cash flow to the firm (FCFF), discounted EPS (EPS), and sum-of-the-parts (SOP) models. A 30% discount is then applied and rounded to the nearest whole number to derive our price target. A higher risk rate of 30% is applied (vs. 15% or 10%) since Mesoblast is a microcap company with drug candidates in clinical trials that have yet to gain FDA approval.

Exhibit 14. Free Cash Flow Model

Average	$	14

Price Target	$	13
Year		2020

DCF Valuation Using FCF (mln):

units (millions - $)	2018A	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(66)	(105)	(74)	(96)	(58)	71	367	757	1,680	2,363	3,038	3,685	4,334
Tax Rate	0%	0%	3%	0%	0%	15%	25%	30%	35%	36%	36%	36%	36%
EBIT(1-t)	(66)	(105)	(72)	(96)	(58)	60	275	530	1,092	1,512	1,945	2,358	2,774
CapEx													
Depreciation													
Change in NWC													
FCF	(66)	(105)	(72)	(96)	(58)	60	275	530	1,092	1,512	1,945	2,358	2,774
PV of FCF	(111)	(137)	(72)	(74)	(34)	27	96	143	226	241	238	222	201
Discount Rate	30%												
Long Term Growth Rate	1%												
Free Cash Flow	9,661												
Terminal Value YE 2030	701												
NPV	1,917												
NPV-Debt	84												
Shares out (M)	144	2030E											
NPV Per Share	$ 13												

Source: Dawson James

Exhibit 15. Discounted-EPS Model

		2020
Year of EPS		2030
Earnings Multiple		10
Discount Factor		30%
Selected Year EPS	$	19.21
NPV	$	14

		Discount Rate and Earnings Multiple Varies, Year is Constant 2030 EPS					
		10%	15%	20%	25%	30%	35%
Earnings Multiple	1	$7.41	$4.75	$3.10	$2.06	$1.39	$ 0.96
	5	$37.03	$23.74	$15.51	$10.31	$6.97	$ 4.78
	10	$74.06	$47.48	$31.02	$20.62	$13.93	$ 9.55
	15	$111.08	$71.22	$46.53	$30.94	$20.90	$ 14.33
	20	$148.11	$94.96	$62.04	$41.25	$27.87	$ 19.11
	25	$185.14	$118.70	$77.55	$51.56	$34.83	$ 23.88
	30	$222.17	$142.44	$93.07	$61.87	$41.80	$ 28.66
	35	$259.19	$166.18	$108.58	$72.19	$48.77	$ 33.44

Source: Dawson James

Exhibit 16. Sum-of-the-Parts Model

Mesoblast Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MM's	NPV
Revascor - CHF (Class II - III) U.S.	1%	30%	5	25%	$5,152	$17,766
NPV						$4.14
Revascor - CHF - LVAD: Class IV	1%	30%	2	25%	$319	$1,099
NPV						$0.56
Revascor - CHF (Class II - III) EU	1%	30%	6	25%	$4,173	$14,390
NPV						$2.58
Acute Pediatric GvHD - U.S.	1%	30%	1	70%	$142	$490
NPV						$0.91
Acute Adult GvHD U.S.	1%	30%	3	70%	$319	$1,101
NPV						$1.21
Acute Pediatric GvHD - E.U.	1%	30%	2	70%	$108	$372
NPV						$0.53
Acute Adult GvHD E.U.	1%	30%	3	70%	$383	$1,322
NPV						$1.46
CLBD-DDD U.S.	1%	30%	2	30%	$984	$3,392
NPV						$2.08
TEMCELL	1%	10%	0	75%	$20	$222
NPV						$0.58
Other Indications	1%	30%	5	30%	$0	$0
NPV						$0.00
Net Margin						50%
MM Shrs OS					2030E	144
Total						$14

Source: Dawson James

Exhibit 17. Income Statement

Mesoblast, Inc. Income Statement (M)		Sept.	Dec.	March	June											
Mesoblast: YE June 30	**2019A**	**1Q20A**	**2Q20**	**3Q20**	**4Q20**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**
Milestone / Partnership Revenues	14	15														
% Sequential Growth																
Revasco in CHF U.S.		-	-	-	-	-	-	-	-	127	319	640	963	1,288	1,615	1,944
% Sequential Growth																
Revascor in CHF; EU	-	-	-	-	-	-	-	-	-	-	-	415	693	1,043	1,395	1,749
% Sequential Growth																
Discogenic Disc Chronic Lower Back (U.S.)							-	-	99	199	301	404	448	492	516	540
% Sequential Growth																
Remestemcel-L GvHD - USA - Pediatric	1		-	-	-	-	30	61	93	102	99	96	97	99	101	103
% Sequential Growth																
Remestemcel-L GvHD - USA - Acute Adult	-	-	-	-	-	-	-	-	-	71	139	201	219	224	228	233
% Sequential Growth																
Remestemcel-L GvHD - EU Pediatric	-		-	-	-	-	-	19	47	77	75	73	74	75	77	77
% Sequential Growth																
Remestemcel-L GvHD - EU Acute Adult	-	-	-	-	-	-	-	-	-	-	83	161	247	268	274	279
% Sequential Growth																
Product Revenues	**15**	**15**	**-**	**-**	**-**	**15**	**30**	**80**	**239**	**577**	**1,015**	**1,990**	**2,741**	**3,490**	**4,206**	**4,925**
TemCell GvHD - Japan Adult & Pediatric	1	2	2	2	2	7	7	9	11	12	13	14	16	17	18	19
Product & Royalty Revnues	**17**	**17**	**2**	**2**	**2**	**22**	**37**	**89**	**249**	**589**	**1,029**	**2,004**	**2,757**	**3,507**	**4,224**	**4,944**
Expenses																
MesoBlast COGS	-					-	9	16	48	87	142	199	274	349	421	493
COGS % Sales	0%	0%	0%	0%	0%	0%	30%	-20%	-20%	-15%	-14%	-10%	-10%	-10%	-10%	-10%
R&D	60	13	15	16	19	63	66	69	73	76	73	69	65	66	67	67
Manufacturing & Commercialization	15	3	4	4	6	16	32	26	21	20	19	18	18	17	16	16
Management & Adminastration	22	5	3	3	1	13	25	36	37	39	38	38	37	36	35	35
Total expenses	**97**	**21**	**22**	**23**	**26**	**92**	**133**	**147**	**178**	**222**	**272**	**324**	**394**	**468**	**539**	**610**
Oper. Inc. (Loss)	(80)	(4)	(20)	(21)	(24)	(70)	(96)	(58)	71	367	757	1,680	2,363	3,038	3,685	4,334
Oper Margin																
Fair Value Remeasurement (contingent consideration)	(6)	0														
Finance Cost/Interest Expense		0														
Changes in the fair value of available-for-sale financial assets																
Exchange differences on translation of foreign operations	(1)															
Interest Payments	(11)	3	-	-	-	3	-			-	-	-	-	-	-	-
Other comprehensive loss/income for the period, net of tax																
Total other income	(20)	4	-	-	-	4	-	-	-	-	-	-	-	-	-	-
Pre-tax income	**(105)**	**(8)**	**(20)**	**(21)**	**(24)**	**(74)**	**(96)**	**(58)**	**71**	**367**	**757**	**1,680**	**2,363**	**3,038**	**3,685**	**4,334**
Pretax Margin																
Tax benefit (or expense)	9	2	-	-	-	2	-	-	(11)	(92)	(227)	(588)	(851)	(1,094)	(1,327)	(1,560)
Tax Rate		0%	0%	0%	0%	3%	0%	0%	15%	25%	30%	35%	36%	36%	36%	36%
Net Income	**(97)**	**(6)**	**(20)**	**(21)**	**(24)**	**(72)**	**(96)**	**(58)**	**60**	**275**	**530**	**1,092**	**1,512**	**1,945**	**2,358**	**2,774**
Net Margin																
EPS	**$ (0.72)**	**$ (0.06)**	**$ (0.17)**	**$ (0.18)**	**$ (0.20)**	**$ (0.61)**	**$ (0.69)**	**$ (0.41)**	**$ 0.43**	**$ 1.95**	**$ 3.74**	**$ 7.69**	**$ 10.60**	**$ 13.57**	**$ 16.40**	**$ 19.21**
Non GAAP EPS (dil)																
Wgtd Avg Shrs (Bas) - '000s	106	106	119	119	119	116	139	140	140	141	142	142	143	143	144	144
Wgtd Avg Shrs (Dil) - '000s	106	106	119	119	119	116	139	140	140	141	142	142	143	143	144	144

Source: Dawson James

Risk Analysis
In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to Mesoblast are as follows:

Clinical and regulatory risk. Lead products must start and complete clinical trials. Trials may not produce results sufficient for regulatory approval.

Commercial risk. There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

Employee risk. Mesoblast. has an experienced and dedicated management team, many of whom have been with the company since its founding. The company plans to bring its proposed products to market in the next two years, and as such, transitioning from a clinical to a commercial team will be a critical success factor. The success of the business may depend on the experience, abilities, and continued services of its senior officers, sales staff, and key scientific personnel.

Financial risk. The company may need to raise capital in the marketplace in order to support operations. There are no assurances that the company will be able to successfully raise capital and or do so on favorable terms.

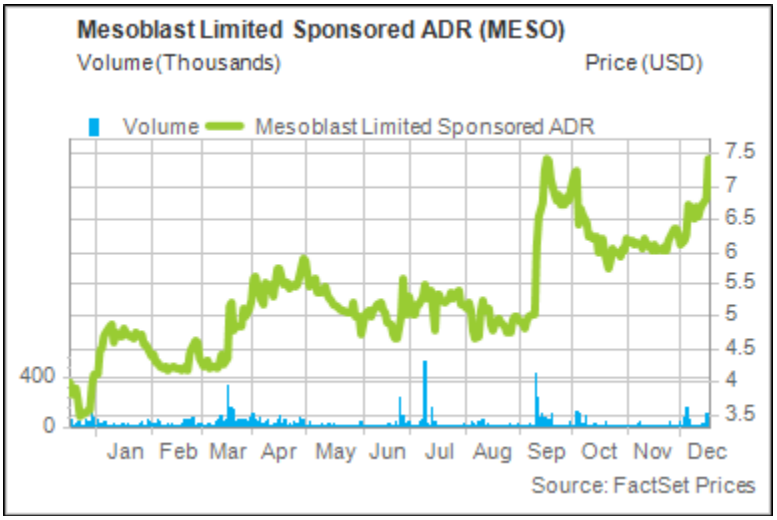
Legal and intellectual property risk. The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the company may infringe on third party's patents.

Partnership risk. Mesoblast may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the company will be able to secure a favorable partnership.

Important Disclosures:

Companies Mentioned int his report includes the list below. None of these companies are rated.
BlueBird
Celgene
Cephalon
Grunethal
JCR Pharma
Juno
Kite
Lonza
Osiris
Takeda (which acquired Tigenix)
Teva
Tasly
Vericel

Price Chart:



Price target and rating changes over the past three years:
Initiated – Buy – December 19, 2019 – Price Target $14.00

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1) **Buy**: The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
2) **Neutra**l: The analyst believes the price of the stock is fairly valued for the next 12-18 months;
3) **Sel**l: The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	26	90%	3	12%
Market Perform (Neutral)	3	10%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	3	10%

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