NOTICE OF FILING

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Registrar

Important Information

This Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

The date of the filing of the document is determined pursuant to the Court's Rules.

No. VID 268 of 2022

Federal Court of Australia

District Registry: Victoria

Division: General

PAUL TIBOR HORSKY

First Applicant

OIL SURVEILLANCE AUSTRALIA PTY LTD (ACN 092 979 498) ATF D.A LYNCH SUPERFUND

Second Applicant

MESOBLAST LIMITED (ACN 109 431 870)

Respondent

AMENDED CONSOLIDATED STATEMENT OF CLAIM

Filed on behalf of	Paul Tibor Horsky, First Applicant Oil Surveillance Australia Pty Ltd (ACN 092 979 498) ATF D.A Lynch Superfund, Second Applicant
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A. PARTIES

A.1. The Applicants and the Group Members

1. The First Applicant and Second Applicant (the **Applicants**) bring this proceeding as a representative proceeding pursuant to Part IVA of the *Federal Court of Australia Act 1976* (Cth) (**FCAA**).

2. This proceeding is commenced by the Applicants on their own behalves and on behalf of all persons who:

   (a) during the period from 22 February 2018 until the close of trading on 17 December 2020 inclusive (**Claim Period**) acquired:

      (i) an interest in fully paid ordinary shares (**MSB Shares**) in the Respondent (**Mesoblast**) listed as "MSB" on the Australian Securities Exchange (**ASX**);

      (ii) an interest in American Depository Receipts traded on the NASDAQ exchange under the symbol "MESO" (**MESO ADRs**);

      (iii) an interest in securities traded over the counter in the United States with the symbol "MEOBF" (**MEOBF OTCs**); and/or

      (iv) long exposure to MSB Shares by entering into equity swap confirmations in respect of MSB Shares (**MSB Equity Swaps**),

      (together, **Mesoblast Securities**);

   (b) suffered loss and damage by or resulting from the alleged contravening conduct of the Respondent as described in this Amended Consolidated Statement of Claim (other than those who have only suffered Excluded ADR Loss); and

   (c) are not or were not during the Claim Period:

      (i) a director or an officer or a close associate (as defined in s 9 of the *Corporations Act 2001* (Cth) (**Corporations Act**)) of Mesoblast; or

(ii) a related party (as defined in s 228 of the Corporations Act) of Mesoblast; or

(iii) a related body corporate (as defined in s 50 of the Corporations Act) of Mesoblast; or

(iv) an associated entity (as defined in s 50AAA of the Corporations Act) of Mesoblast; or

(v) a Chief Justice, Justice, Registrar, District Registrar, or Deputy District Registrar of the High Court of Australia or the Federal Court of Australia; or

(vi) an officer, employee, or legal practitioner engaged by either William Roberts Lawyers or Phi Finney McDonald in relation to the class action; or

(d) an expert or consultant engaged in relation to the class action,

(**Group Members**).

Particulars

1. Excluded ADR Loss is defined at paragraph [158].

3. As at the date of the commencement of this proceeding, there are seven or more persons who have claims against Mesoblast.

4. Each Applicant acquired an interest in MSB Shares in the Claim Period.

Particulars

1. The First Applicant's interests were acquired as set out in the table below:

DATE	ACCOUNT NAME	NUMBER OF SHARES	PRICE PER SHARE	COST (INCLUDING BROKERAGE AND GST WHERE APPLICABLE)

9 March 2020	PTH INVEST	5,000	$1.93	$9,650.00
2 October 2020	PTH	3,000	$3.05	$9,150.00
8 October 2020	PTH INVEST	15,000	$3.39	$50,850.00
20 November 2020	PTH INVEST	3,000	$3.62	$10,860.00

2. The Second Applicant acquired 3,996 MSB Shares on 24 September 2020 at an execution price of $5.0031 per share.

A2. The Respondent

5. Mesoblast is and at all material times during the Claim Period was:

(a) a corporation registered pursuant to the Corporations Act and capable of being sued;

(b) listed on the ASX:

(i) which is and was at all material times a "listing market" within the meaning of s 674 of the Corporations Act;

(ii) of which Australian Securities Exchange Limited is and was at all material times the "market operator" within the meaning of s 674 of the Corporations Act;

(c) a "person" within the meaning of s 1041H of the Corporations Act;

(d) a "person" within the meaning of s 12DA of the *Australian Securities and Investments Commission Act 2001* (Cth) (**ASIC Act**);

(e) a "person" within the meaning of s 18 of the *Australian Consumer Law* set out in Schedule 2 of the *Competition and Consumer Act 2010* (Cth), as applicable pursuant to:

(i) s 7 of the *Fair Trading (Australian Consumer Law) Act 1992* (ACT);

(ii) s 28 of the *Fair Trading Act 1987* (NSW);

(iii) s 12 of the *Australian Consumer Law and Fair Trading Act 2012* (Vic);

(iv) s 16 of the *Fair Trading Act 1989* (Qld);

(v) s 6 of the *Australian Consumer Law (Tasmania) Act 2010* (Tas);

(vi) s 19 of the *Fair Trading Act 2010* (WA);

(vii) s 14 of the *Fair Trading Act 1987* (SA); and/or

(viii) s 27 of the *Consumer Affairs and Fair Trading Act* (NT),

(severally, or together, the **ACL**);

(f) a "public company" within the meaning of s 9 of the Corporations Act; and

(g) a "listed disclosing entity" within the meaning of s 111AL(1) of the Corporations Act.

6. At all material times during the Claim Period, MSB Shares were:

(a) "ED securities" within the meaning of s 111AE of the Corporations Act;

(b) "quoted ED securities" within the meaning of s 111AM of the Corporations Act;

(c) "financial products" within the meaning of ss 763A, 764A and 1041H of the Corporations Act;

(d) "financial products" and "financial services" within the meaning of ss 12BAA, 12BAB and 12DA of the ASIC Act; and

(e) able to be purchased and sold by investors on the ASX using the ASX code or designation "MSB".

7. Consequent upon the foregoing, Mesoblast was at all material times during the Claim Period:

(a) subject to and bound by the ASX Listing Rules, which are and at all material times were "listing rules" within the meaning of s 674 of the Corporations Act;

(b) obliged (unless any of the exceptions in ASX Listing Rule 3.1A were applicable) to immediately inform the ASX of any information concerning Mesoblast upon becoming aware of that information if the information was not generally available and:

(i) at all material times up to 26 May 2020, a reasonable person would expect the information, if it were generally available, to have a material effect on the price or value of MSB Shares; and

(ii) on and from 26 May 2020 through to the end of the Claim Period, Mesoblast knew, or was reckless or negligent with respect to whether, the information would, if it were generally available, have a material effect on the price or value of MSB Shares,

(**Continuous Disclosure Obligations**); and

(c) prohibited pursuant to:

(i) s 1041H of the Corporations Act, from engaging in conduct in relation to MSB Shares;

(ii) s 12DA of the ASIC Act, from engaging in conduct in trade or commerce in relation to MSB Shares; and

(iii) s 18 of the ACL, from engaging in conduct in trade or commerce,

that was misleading or deceptive or likely to mislead or deceive (**Misleading Conduct Obligations**).

8. At all material times during the Claim Period:

(a) MESO ADRs were able to be purchased and sold by investors on the NASDAQ exchange using the code or designation "MESO";

(b) each MESO ADR represented 5 MSB Shares and the price at which MESO ADRs traded on the NASDAQ exchange reflected (i) the price of 5 MSB Shares and (ii) the exchange rate between Australian dollars and United States of America dollars;

(c) MEOBF OTCs were able to be purchased and sold by investors over the counter in the United States using the code or designation "MEOBF"; and

(d) each MEOBF OTC represented 1 MSB Share purchased with United States of America dollars.

B. MESOBLAST'S BUSINESS

B.1 Introduction

B.1.1. History

9. Mesoblast is, and was at all material times during the Claim Period, an Australian biopharmaceutical company with the purpose of developing and commercialising allogenic cellular medicines.

10. Mesoblast's proprietary regenerative medicine technology platform is based on specialised cells known as "mesenchymal stem cells" or "mesenchymal stromal cells" (**MSCs**).

11. In or around October 2013, Mesoblast acquired the entire culture-expanded MSC business of Osiris Therapeutics, Inc. (**Osiris**).

12. The acquisition pleaded in paragraph 11 included MSC-100-IV (remestemcel-L) (**R-L**) (subsequently registered in the United States, Canada and Australia with the trade-mark **RYONCIL**, and also known as Prochymal).

13. R-L was and is an investigational therapy comprising MSCs derived from the bone marrow of a donor unrelated to the recipient.

14. During the Claim Period, Mesoblast identified R-L as a potential treatment for:

    (a) paediatric patients suffering steroid refractory acute Graft Versus Host Disease (**SR-aGVHD**) (the **SR-aGVHD Application**); and

    (b) patients with acute respiratory distress syndrome caused by COVID-19 (**COVID-19 ARDS**) (the **COVID-19 ARDS Application**).

15. During the Claim Period, the United States Food and Drug Administration (**FDA**) needed to provide approval (**FDA Marketing Approval**) before R-L could be used to treat either SR-aGVHD or COVID-19 ARDS in the United States of America (which was a major potential market for Mesoblast).

B.1.2 Acute Graft Versus Host Disease

16. Acute graft versus host disease (**aGVHD**) is a life-threatening condition that can occur following a stem cell transplant.

17. aGVHD occurs when donor cells attack the organs and tissue of the patient who has received them.

18. The incidence of aGVHD in patients following a stem cell transplant is approximately 30-50%.

19. Approximately 50% of the patients who suffer from aGVHD will not respond to treatment by steroids (that is, they suffer from SR-aGVHD).

20. Prior to May 2019, there was no treatment approved in the United States by the FDA for patients who suffer from SR-aGVHD.

21. In May 2019, the FDA approved the drug ruxolitinib to treat patients 12 years of age and over who suffer from SR-aGVHD.

22. There was and is no FDA approved treatment for patients under the age of twelve years who suffer from SR-aGVHD.

B.1.3. Applications to the FDA for R-L to treat aGVHD

23. In 1998, Osiris submitted an investigational new drug application to the FDA for R-L for the treatment of aGVHD.

24. On or about 20 January 2009, Osiris submitted a biologics license application (**BLA**) to the FDA for R-L to treat aGVHD.

25. On or about 5 March 2010, Osiris withdrew its BLA for R-L after the FDA had recommended that additional prospective trials be conducted.

26. In or about 2015, Protocol MSB-GVHD001 (**Study 001**, described in further detail in paragraphs [55] and [56] below) was commenced to assess the impact of R-L on paediatric patients with SR-aGVHD.

27. On or about 7 March 2017, the FDA granted Mesoblast fast track designation for the use of R-L to achieve improved overall response rates in children with SR-aGVHD.

28. On or about 31 January 2020, Mesoblast submitted BLA 1256706 to the FDA for R-L for treatment of SR-aGVHD in paediatric patients with the results of Study 001 being relied upon as the sole basis of efficacy.

B.1.4. COVID-19

29. Severe Acute Respiratory Syndrome Coronavirus 2 or SARS-CoV-2 was and is a virus that causes the respiratory disease 2019-nCoV which is commonly referred to as COVID-19.

30. COVID-19 was and is an infectious and contagious human disease that can cause severe illness, including acute respiratory distress syndrome (**ARDS**) and death.

31. During the Claim Period, the FDA had not approved a vaccine for the treatment of COVID-19 and has only approved one antiviral drug, Veklury (remdesivir), for the treatment of COVID-19.

B.2. Governance of Mesoblast

B.2.1. Mesoblast Governance Protocols

32. At all material times during the Claim Period, Mesoblast had a Materials Review Committee (renamed the External Communications Review Committee from April 2020) which, acting in conjunction with the Chief Executive Officer, was responsible for overseeing disclosure of information to the ASX.

Particulars

1. Mesoblast's Corporate Governance Statements 2018-2020, p. 6.
2. Mesoblast's Market Communications and Disclosure Controls Policy, September 2016.
3. Mesoblast's Financial Market Communications and Disclosure Policy, April 2020.
4. Further particulars, including as to the composition of the Materials Review Committee may be provided following discovery and/or the service of evidence.

B.2.2. Chief Executive Officer

33. Dr Silviu Itescu (**Itescu**):

(a) was Mesoblast's Chief Executive Officer (**CEO**) and Managing Director from 2011 to the present and has been on the Board of Directors since Mesoblast's incorporation in 2004; and

(b) was at all material times an "officer" of Mesoblast within the meaning of s 9 of the Corporations Act and ASX Listing Rule 19.12.

Particulars

1. FY2018 Annual Report, pp. 92, 96.
2. FY2019 Annual Report, pp. 94, 98.
3. FY2020 Annual Report, pp. 97, 101.

B.2.3. Chief Medical Officer

34. Dr Donna Skerret (**Skerret**):

(a) was Mesoblast's Chief Medical Officer (**CMO**) from 2011 through to 19 August 2019 and previously held roles at Mesoblast in Clinical and Regulatory Affairs since 2004; and

(b) was at all material times until 19 August 2019, an "officer" of Mesoblast within the meaning of s 9 of the Corporations Act and ASX Listing Rule 19.12.

Particulars

1. FY2018 Annual Report, p. 97.
2. FY2019 Annual Report, p. 100.
3. FY2020 Annual Report, p. 103.

35. Dr Fred Grossman (**Grossman**):

(a) was Mesoblast's CMO from 19 August 2019 through to the present; and

(b) was at all material times from 19 August 2019 onwards an "officer" of Mesoblast within the meaning of s 9 of the Corporations Act. and ASX Listing Rule 19.12.

Particulars

1. FY2019 Annual Report, pp. 99-100.
2. FY2020 Annual Report, p. 103.
3. ASX Announcement: 'Mesoblast Appoints Leading Pharmaceutical Industry Executive as Chief Medical Officer', 12 August 2019 (**12 August 2019 Announcement**).

B.2.4. Chief Financial Officer

36. Mr Paul Hodgkinson (**Hodgkinson**):

(a) was from June 2014 through to 31 May 2018 the Chief Financial Officer (**CFO**) of Mesoblast; and

(b) was at all material times from June 2014 through to 31 May 2018 an "officer" of Mesoblast within the meaning of s 9 of the Corporations Act and ASX Listing Rule 19.12.

Particulars

1. FY2018 Annual Report, pp. 92, 96.

37. Mr Josh Muntner (**Muntner**):

(a) was Mesoblast's CFO from 28 May 2018 through to the end of the Claim Period; and

(b) was at all material times during his employment with Mesoblast an "officer" of Mesoblast within the meaning of s 9 of the Corporations Act and ASX Listing Rule 19.12.

Particulars

1. FY2018 Annual Report, pp. 92, 97.
2. FY2019 Annual Report, pp. 94, 98.
3. FY2020 Annual Report, pp. 97, 101.

B.2.5. Chief Operating Officer

38. Ms Dagmar Rosa-Bjorkeson (**Rosa-Bjorkeson**):

(a) was Mesoblast's Chief Operating Officer (**COO**) from July 2020 through to the end of the Claim Period; and

(b) was at all material times during her employment with Mesoblast an "officer" of Mesoblast within the meaning of s 9 of the Corporations Act and ASX Listing Rule 19.12.

Particulars

1. FY2020 Annual Report, p. 101.

B.2.6. General Counsel

39. Mr Peter Howard (**Howard**):

(a) was Mesoblast's General Counsel and Corporate Executive from July 2011 through to the end of the Claim Period; and

(b) was at all material times during his employment with Mesoblast an "officer" of Mesoblast within the meaning of s 9 of the Corporations Act and ASX Listing Rule 19.12.

Particulars

1. FY2018 Annual Report, p. 97.
2. FY2019 Annual Report, p. 98.
3. FY2020 Annual Report, p. 101.

B.2.7. Head of Regulatory Affairs and Quality Management

40. Ms Geraldine Storton (**Storton**):

(a) was from December 2015 to the present Mesoblast's Head of Regulatory Affairs and Quality Management; and

(b) was at all material times during her employment with Mesoblast an "officer" of Mesoblast within the meaning of s 9 of the Corporations Act and ASX Listing Rule 19.12.

Particulars

1. FY2018 Annual Report, p. 98.
2. FY2019 Annual Report, p. 99.
3. FY2020 Annual Report, p. 102.

B.2.8. Head of Research and New Product Development

41. Dr Paul Simmons (**Simmons**):

(a) was from 2011 to the present Mesoblast's Head of Research and New Product Development; and

(b) was at all material times during his employment with Mesoblast an "officer" of Mesoblast within the meaning of s 9 of the Corporations Act and ASX Listing Rule 19.12.

Particulars

1. FY2018 Annual Report, p. 97.
2. FY2019 Annual Report, p. 98.
3. FY2020 Annual Report, p. 102.

B.2.9. The knowledge of Mesoblast Officers is knowledge of Mesoblast

42. Any information which came into possession of:

(a) any of the persons referred to in paragraphs [33] to [41] above; or

(b) any member of the board of directors of Mesoblast from time to time,

(each being **Mesoblast Officers**), or which ought reasonably to have come into their possession, in the course of the performance of their respective duties as an officer of Mesoblast, was information of which Mesoblast was aware (within the meaning of Rule 3.1 and Rule 19.12 of the ASX Listing Rules).

C. RELEVANT INFORMATION AND MESOBLAST'S KNOWLEDGE

C.1. Information concerning trials related to the SR-aGVHD Application

C.1.1. Protocol 280 and Protocol 280 Information

43. Protocol 280, conducted from 17 August 2006 to 28 May 2009, was a Phase 3 randomised, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of R-L in patients with SR-aGVHD grades B-D (**Protocol 280**).

44. Protocol 280 consisted of 260 participants aged 6 months to 60 years.

45. Of the 260 participants in Protocol 280, 232 were adults and 28 were children.

46. In relation to Protocol 280:

(a) patients were randomised (1:1) to R-L or placebo added to institutional standard second-line therapy (rather than with R-L alone);

(b) the primary efficacy endpoint was durable complete response (**DCR**), defined as achieving a complete response (**CR**) (complete resolution of symptoms in all organs) of at least 28 days duration within 100 days after starting the study drug;

(c) DCR was not significantly improved compared to the control group (35% vs. 30%);

(d) on re-evaluation by the FDA using the current recommended endpoint of Day 28 overall response rate (**ORR**) (referring to CR plus partial response (**PR**) (organ improvement of at least one stage without worsening of any other organ)), there was no significant difference between the R-L and placebo study arms.

Particulars

1. FDA Briefing Document ODAC Meeting, Session on Clinical Evidence (PM Session) BLA 125706 (13 August 2020) (**FDA Clinical Evidence Briefing Document**), pp. 21-23.

2. Mesoblast Briefing Information, Meeting of the Oncologic Drugs Advisory Committee (Combined AM-PM Session) (13 August 2020) (**Mesoblast ODAC Briefing Submission**), p. 52.

47. Protocol 280:

(a) did not meet its primary endpoint (it was a negative trial);

(b) did not improve response rates versus placebo (when adding R-L to standard of care);

(c) could not be relied upon for subgroup analysis to support FDA approval for Mesoblast's BLA;

(d) did not provide confirmatory evidence of the efficacy of R-L when used in patients with SR-aGVHD to support FDA Marketing Approval,

(the **Protocol 280 Information**).

Particulars

1. With respect to subparagraph (c), refer to:

    a. FDA Clinical Evidence Briefing Document, p. 10;

    b. FDA, Guidance for Industry: Choice of Control Group and Related Issues in Clinical Trials (ICH E10), (May 2001) (**ICH E10 Guidance**), pp. 3, 4, 26-29; and

    c. FDA, ICH Harmonised Tripartite Guideline, Statistical Principles for Clinical Trials (E9), (February 1998) (**ICH E9 Guidance**), pp. 3, 4, 33, 34, 39.

2. With respect to subparagraph (d), Protocol 280 did not provide substantial evidence of effectiveness as required by the FDA regulatory regime. Biological products are licensed based on a demonstration of safety, purity and potency (s 351(a)(2)(C) of the Public Health Service Act, 42 United States Code (**U.S.C.**) § 262(a)(2)(C)). Potency has long been interpreted to include effectiveness (21 Code of Federal Regulations (**C.F.R.**) § 600.3(s) (**Effectiveness Requirement**).

3. Further particulars may be provided following discovery and/or the service of evidence (including expert evidence).

C.1.2. Protocol 265 and Protocol 265 Information

48. Protocol 265, conducted from 31 January 2008 to 20 May 2010, was a Phase 3 randomised, double-blind, placebo-controlled clinical trial to investigate the safety and efficacy of R-L (then known as Prochymal) versus placebo in combination with corticosteroids as initial therapy for aGVHD (**Protocol 265**).

49. Protocol 265 consisted of 192 participants aged 18-70 years.

50. In relation to Protocol 265:

(a) the primary endpoint was CR of at least 28 days;

(b) Protocol 265 showed no benefit of adding R-L to corticosteroids versus corticosteroids alone;

(c) on re-evaluation by the FDA using the recommended endpoint of Day 28 ORR, there was no significant difference between the R-L and placebo study arms.

Particulars

1. FDA Clinical Evidence Briefing Document, p. 21.
2. Mesoblast ODAC Briefing Submission, p. 52.

51. Protocol 265:

(a) was a trial in respect of adults only;

(b) did not meet its primary endpoint (it was a negative trial);

(c) did not improve response rates versus placebo (when adding R-L to standard of care);

(d) did not provide confirmatory evidence of the efficacy of R-L to support FDA Marketing Approval,

(the **Protocol 265 Information**).

Particulars

1. With respect to subparagraph (d), refer to the Effectiveness Requirement in particular 2 to paragraph [47] above.
2. Further particulars may be provided following discovery and/or the service of evidence (including expert evidence).

C.1.3. EAP 275 and EAP 275 Information

52. Expanded Access Protocol 275, conducted from 2007 to 2015, consisted of a group of 241 paediatric patients with SR-aGVHD who had failed to respond to systemic corticosteroids and who were given R-L as a rescue or salvage therapy (**EAP 275**).

Particulars

1. FDA Clinical Evidence Briefing Document, pp. 9-11.
2. Mesoblast ODAC Briefing Submission, pp. 52, 83-92.

53. Expanded access protocols (**EAP**), sometimes referred to as "compassionate use", are:

(a) a way for patients to gain access to an investigational medical product through treatment outside of clinical trials; and

(b) are not designed to meet the Effectiveness Requirement.

54. EAP 275:

(a) was comprised of patients who had additional aGVHD therapy before and concomitant with R-L, at the discretion of their treating physician, and accordingly, consisted of a pre-treated patient population;

(b) did not meet the criteria for an adequate and well controlled trial for the purposes of the FDA regulatory regime;

(c) did not provide confirmatory evidence of efficacy of R-L to support FDA Marketing Approval,

(the **EAP 275 Information**).

Particulars

1. With respect to subparagraph (b), refer to:
    a. 21 C.F.R. § 314.126;
    b. 21 U.S.C. § 355(d).
2. With respect to subparagraph (c), refer to the Effectiveness Requirement in particular 2 to paragraph [47] above.
3. Further particulars may be provided following discovery and/or the service of evidence (including expert evidence).

C.1.4. Study 001 and Study 001 Information

55. Study 001, conducted from 2015 to 2018, was a prospective, multicentre, single arm, open-label trial for 55 paediatric patients with SR-aGVHD grades B-D (excluding grade B skin alone).

56. In relation to Study 001:

(a) the primary endpoint of the trial was the proportion of patients in the full analysis set with ORR at 28 days after initiation of therapy;

(b) the trial was designed to determine if the Day 28 ORR exceeded 45% (i.e. 45% was the null hypothesis);

(c) the Day-28 ORR in the full analysis set was 69.1%; and

(d) the trial met the primary objective to exceed a 45% ORR.

Particulars

1. FDA Clinical Evidence Briefing Document, pp. 12-15.
2. Mesoblast ODAC Briefing Submission, p. 53-56.

57. While Study 001 met its endpoint as against its stipulated null hypothesis, the study:

(a) was not a randomised, controlled study;

(b) did not meet the criteria for an adequate and well controlled trial for the purposes of the FDA regulatory regime;

(c) did not adequately take into account FDA guidance on external controls;

(d) did not adequately address the risks of drawing inappropriate conclusions due to bias in externally controlled studies;

(e) did not follow the advice provided by the FDA in calculating duration of response; and

(f) did not have an appropriate null hypothesis,

(the **Study 001 Information**).

Particulars

1. See FDA Clinical Evidence Briefing Document, pp. 13, 18-20.

2. With respect to subparagraph (b), refer to:

    a. 21 C.F.R. § 314.126;

    b. 21 U.S.C. § 355(d);

    ~~b.~~c. Pre-BLA Meeting held between the FDA and Mesoblast on 5 April 2019 and communications between FDA and Mesoblast in respect thereof (**5 April 2019 Pre-BLA Meeting Information**).

3. With respect to subparagraph (c), ICH E10 Guidance.

4. With respect to subparagraph (d), refer to:

    a. ICH E9 Guidance; and

    b. ICH E10 Guidance.

5. With respect to subparagraph (e), refer to FDA Clinical Evidence Briefing Document, pp. 13, 18-20.

6. With respect to subparagraph (f), refer to:

    a. FDA Clinical Evidence Briefing Document, pp. 11, 13-15;

    ~~a.~~b. 5 April 2019 Pre-BLA Meeting Information.

~~6.~~7. Further particulars may be provided following discovery and/or the service of evidence (including expert evidence).

C.1.5. MAGIC Database and MAGIC Comparison Data Information

58. The Mount Sinai Acute GVHD International Consortium (**MAGIC**) Database and Biorepository is the continuation of a database/biorepository originally created by the University of Michigan in 2001 to develop a curated and clinically annotated biorepository of blood research specimens obtained from allogenic bone marrow transplant recipients in order to study GVHD.

59. To provide additional support for Study 001's assumed 45% null hypothesis, a cohort of paediatric patients from the MAGIC database with SR-aGVHD was identified and analysed by Mesoblast in 2020 for Day 28 ORR and survival, prior to the final submission of its BLA to the FDA (**MAGIC Comparison Data**).

60. The MAGIC Comparison Data:

(a) was not part of the original Statistical Analysis Plan (**SAP**) for Study 001 and there was no *a priori* specified hypothesis for the utility of the data;

(b) did not have an independent SAP or disclose the raw data for FDA review;

(c) did not involve patients that were matched;

(d) did not follow FDA guidance on external controls; and

(e) did not "demonstrate the effectiveness", alternatively, provide confirmatory evidence of the efficacy of R-L in the relevant patient population for Study 001,

(the **MAGIC Comparison Data Information**).

Particulars

1. FDA Clinical Evidence Briefing Document, pp. 17-18.
2. With respect to subparagraph (d), refer to ICH E10 Guidance, pp. 27-28.
3. With respect to subparagraphs (e), refer to the Effectiveness Requirement in particular 2 to paragraph [47] above.
4. Further particulars may be provided following discovery and/or the service of evidence (including expert evidence).

C.2. Information concerning the SR-aGVHD Application

C.2.1 Unproved Consistency in Manufactured Product Information

61. At all material times in the Claim Period up until 11 August 2020:

(a) R-L did not have a demonstrated relationship to the clinical performance of specific drug product lots and its proposed immunomodulatory mechanism of action had not been demonstrated in vivo in study subjects receiving R-L; and

(b) it could not be assured that control of the defined critical quality attributes of R-L were sufficient to ensure the manufacturing process produced R-L lots of acceptable quality on a consistent basis,

(the **Unproved Consistency in Manufactured Product Information**).

Particulars

1. "FDA Briefing Document, Oncologic Drugs Advisory Committee (**ODAC**) Meeting, Session on Product Characterisation (AM Session) August 13, 2020, BLA 125706" (**FDA Product Characterisation Briefing Document**), pp. 4, 6-7.

2. FDA Advice in response to 20 August 2018 Meeting Package for CMC Meeting with FDA.

3. 2 October 2018 Type C Meeting between Mesoblast and the FDA regarding Chemistry, Manufacturing and Controls for R-L.

4. 1 June 2020 Mid-Cycle Communication Teleconference between Mesoblast and the FDA.

~~2.~~5. Further particulars may be provided following discovery and/or the service of evidence (including expert evidence).

C.2.2. Differences in aGVHD Studies Information

62. In comparison to Study 001, there were substantial differences in patient populations, trial design, study conduct and primary endpoint evaluations in EAP 275, Protocol 280, and Protocol 265 (the **Differences in aGVHD Studies Information**).

Particulars

1. The differences included:

    a. differences in primary endpoints (CR sustained for greater than 28 days versus ORR at Day 28);

    b. differences in populations with respect to:

i. ages (paediatric versus adult subjects);

ii. disease state (newly diagnosed aGVHD versus SR-aGVHD);

iii. disease stage (allowing grade B skin only disease);

c. differences in treatment regimes;

d. the impact of concomitant medications (positively or negatively) on efficacy outcomes in Protocol 280 and EAP 275, particularly in light of the unknown mechanism of action of R-L; and

e. limitations in reporting of duration of response and variability in duration of follow-up (Day 180 versus Day 90).

2. FDA Clinical Evidence Briefing Document, pp. 20-24.

C.2.3. Non-compliance with FDA Advice Regarding SR-aGVHD Information

63. The FDA met with Mesoblast on six occasions between 2009 and when Mesoblast filed its marketing application for R-L in relation to the SR-aGVHD Application, and gave Mesoblast the following advice on the clinical development program for the treatment of aGVHD:

(a) a single-arm trial that is designed to provide a quantitative evaluation of outcomes in the face of heterogeneity in the patient population may fulfill the regulatory requirements. Case-control studies or modelling from historical controls are two potential methods to achieve this when the eligible population is exceedingly small. Such a study would need to be designed and reviewed prior to its conduct.

(b) EAP 275 is not an adequate and well-controlled trial and does not provide confirmatory evidence of efficacy to support a license application.

(c) Protocol 280 is a negative trial, so subgroup analyses would not be sufficient to support a marketing application.

(d) The results of EAP 275 and Protocol 280 may inform a hypothesis for design of a prospective trial. The sponsor should consider conducting a randomised clinical trial to provide confirmatory evidence of the efficacy of the study agent in the treatment of aGVHD.

(e) The FDA recommended a new randomised trial of R-L versus standard of care for treatment of SR-aGVHD, indicating that such a study would likely be feasible in the adult population. A randomised, controlled study in the adult population could potentially also confirm clinical benefit in the paediatric population, depending on the results.

(f) Study 001, a single-arm trial in paediatric patients permitted use of other agents, such as those used in prophylaxis, that may affect efficacy outcomes. This confounds the interpretation of the treatment effect of R-L. In the absence of an appropriate or historical control, the treatment effect of R-L will be difficult to discern.

(g) The null hypothesis for Study 001 is not based on data from a historical control population. In the absence of data from appropriate historical controls, the FDA is unable to agree that the proposed null hypothesis is acceptable.

(h) Given the absence of appropriate concurrent or historical controls, Study 001 does not appear to be an adequate and well-controlled study. The trial as designed ~~may not be~~ appears to be insufficient to provide primary evidence of effectiveness to support a marketing application.

(i) Any claim of efficacy based on Study 001 needs to take into account all studies of R-L for treatment of aGVHD, including the failed trials,

(severally and cumulatively, on and from the dates conveyed to Mesoblast, the **FDA Information and Advice Regarding SR-aGVHD Application**).

Particulars

1. FDA Clinical Evidence Briefing Document, p. 10.

2. With respect to subparagraph (b) only, it is further particularised that Mesoblast met with the FDA in 2014 to discuss EAP 275, and the FDA identified that a number of confounding factors, including previous and concomitant treatment standard of care therapies, made it difficult to assess the contribution of R-L to the benefit seen in EAP 275 (the **2014 FDA Meeting Information**): Mesoblast ODAC Briefing Submission, p. 51.

3. 5 April 2019 Pre-BLA Meeting Information.

~~3.~~4. Further particulars with respect to the timing of Mesoblast's receipt of the above information may be provided following discovery and/or the service of evidence.

64. Study 001 and Mesoblast's BLA for the treatment of SR-aGVHD in paediatric patients did not comply with the FDA Information and Advice Regarding SR-aGVHD Application (**Non-compliance with FDA Advice regarding a-GVHD Information**).

Particulars

1. FDA Clinical Evidence Briefing Document, p. 10.

2. Further particulars with respect to the above information may be provided following discovery and/or the service of evidence.

C.2.4. Inadequately Designed Trial for a-GVHD Information

65. Study 001 was inadequately designed, alternatively was likely to be inadequately designed, to achieve approval from the FDA for R-L to treat SR-aGVHD in paediatric patients (**Inadequately Designed Trial for a-GVHD Information**).

Particulars

1. The Applicants refer to and repeat the Study 001 Information from paragraph [57] above.

2. Study 001 was a single-arm trial when there was a history of multiple negative clinical trials for the treatment of aGVHD which included randomised controlled trials.

    a. The Applicants refer to the Effectiveness Requirement in particular 2 to paragraph [47] above and FDA Clinical Evidence Briefing Document, pp. 7, 24 and 32.

    b. Mesoblast's BLA did not involve submission of a SAP for FDA review in relation to the post hoc comparative analysis used to support the Day-28 ORR results: refer to FDA Guidance Document on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics Guidance for Industry - December 2018, (**Biologics Clinical Trial Endpoints Guidance**), p. 14.

    c. The additional materials submitted with and for the BLA, including: (a) the analysis of 309 children with SR-aGVHD who had received R-L across three separate studies; and (b) the MAGIC Comparison Data, were insufficient to address the deficiencies in the design of Study 001.

3. Further and alternatively, the Applicants refer to the FDA Information and Advice Regarding SR-aGVHD Application and the Non-compliance with FDA Advice regarding a-GVHD Information.

4. Further particulars may be provided following discovery and the service of the Applicants' evidence.

C.2.5. Unlikely to be Approved by FDA Information

66. At all material times during the period from 22 February 2018, it was unlikely that Mesoblast's BLA for the treatment of SR-aGVHD in paediatric patients would be approved based on the information that Mesoblast had provided the FDA (**Unlikely to be Approved by FDA for SR-aGVHD Information**).

Particulars

1. This was unlikely by reason of one or more or a combination of the matters pleaded in paragraphs [61] to [65] above, which are repeated.

C.3. Information concerning trials related to the COVID-19 ARDS Application

C.3.1. Study 001 No Support for ARDS Treatment Information

67. The results of Study 001 did not provide support for, or improve the likelihood of, R-L being effective to treat COVID-19 ARDS (**Study 001 No Support for ARDS Treatment Information**).

Particulars

1. The results did not provide support by reason of one or more or a combination of the matters pleaded in paragraphs [61] to [65] above, which are repeated.

C.3.2. Pilot Study and Pilot Study Information

68. During the months of April and May 2020, 12 patients with moderate/severe COVID-19 ARDS at New York City's Mount Sinai Hospital were treated with two infusions of R-L within the first five days under an emergency EAP or Investigational New Drug Application (**Pilot Study**).

69. In the Pilot Study, 75% (9/12) of patients successfully came off ventilator support within a median of 10 days.

Particulars

1. ASX Announcement: "83% Survival In COVID-19 Patients With Moderate/Severe Acute Respiratory Distress Syndrome Treated In New York With Mesoblast's cell therapy remestemcel-L", 24 April 2020 (**24 April 2020 Announcement**), p. 1.

70. The Pilot Study:

(a) was comprised primarily of patients who were younger than 65;

(b) did not meet the criteria for an adequate and well controlled trial for the purposes of the FDA regulatory regime; and

(c) did not provide confirmatory evidence of the efficacy, alternatively was likely to be inadequate evidence of the efficacy, of R-L when used in patients with COVID-19 ARDS to support FDA Marketing Approval,

(the **Pilot Study Information**).

Particulars

1. With respect to subparagraph (b), refer to 21 C.F.R. § 314.126 and paragraph [54(b)] above.
2. With respect to subparagraph (c), refer to the Effectiveness Requirement in particular 2 to paragraph [47] above.
3. Further particulars may be provided following discovery and/or the service of evidence (including expert evidence).

C.3.3. COVID-19 Trial and COVID-19 Trial Information

71. From 1 May 2020 until around 18 December 2020, Mesoblast conducted a randomised, placebo-controlled Phase 2/3 trial to assess the effect of R-L in patients with moderate to severe COVID-19 ARDS (**COVID-19 Trial)**.

72. The COVID-19 Trial was initially scoped to enrol up to 300 ventilator dependent patients in intensive care units to be given either R-L or placebo (1:1) on top of maximal care.

Particulars

1. See:

    a. ASX Announcement: "First patients dosed in phase 2/3 randomised controlled trial in Mesoblast's remestemcel-L for COVID 19 acute respiratory distress syndrome", 6 May 2020 (**6 May 2020 Announcement**);

    b. ASX Announcement: "Mesoblast reports strong financial position and substantial operational progress for the period ended March 31, 2020", 28 May 2020 (**28 May 2020 Announcement**), p. 4.

73. The COVID-19 Trial had a primary endpoint of 43% reduction in mortality at 30 days (**COVID-19 Trial Primary Endpoint)**, which:

(a) had a projected mortality reduction based on pilot data observed, and the maximal care provided to COVID-19 patients, during the initial stages of the pandemic;

(b) was considered by Mesoblast to be a "very high bar".

Particulars

1. As to (a) see:

    a. 6 May 2020 Announcement;

    b. 28 May 2020 Announcement, p. 4.

    c. ASX Announcement: "Mesoblast update on COVID-19 ARDS trial", 18 December 2020 (**18 December 2020 Announcement**), p. 1.

2. As to (b) see: 18 December 2020 Transcript of Earnings Call, p. 4

74. The COVID-19 Trial included three interim analyses for stopping accrual early for efficacy or futility when 30%, 45%, and 60% of the total target of randomised patients reached the endpoint of assessment.

Particulars

1. See ASX Announcement: "Data safety monitoring board recommends continuation of remestemcel-L Phase 3 trial in COVID-19 patients with acute respiratory distress syndrome", 4 September 2020 (**4 September 2020 Announcement**), p. 1.

75. The COVID-19 Trial ultimately enrolled 223 patients after the Data Safety Monitoring Board (**DSMB**) performed the third interim analysis on the first 180 patients.

Particulars

1. 18 December 2020 Announcement, p. 1.

76. At all material times after the Pilot Study was conducted in March/April 2020, changes in the treatment regimens for COVID-19 patients occurred, including both prior to and while on mechanical ventilation, which:

(a) caused the nature of maximal care received by the patients in the COVID-19 Trial to evolve from that received by the patients in the Pilot Study, and continue to evolve during the COVID-19 Trial; and/or

(b) reduced overall mortality rates of the patients who had not received treatment of R-L in the COVID-19 Trial compared with the patients in the Pilot Study, and continued to reduce such mortality rates during the COVID-19 Trial.

Particulars

1. 18 December 2020 Announcement, third paragraph.
2. 18 December 2020 Transcript of Earnings Call, p. 4.
3. Further particulars may be provided following discovery and the service of the Applicants' evidence.

77. During the first half of the enrolment in the COVID-19 Trial, patients had a mean age of less than 50, whereas in the second half of enrolment in that trial, patients had a mean age of more than 60, approaching 70.

Particulars

1. 18 December 2020 Announcement, third paragraph.

2. 18 December 2020 Transcript of Earnings Call, p. 4.

3. Further particulars may be provided following discovery and the service of the Applicants' evidence.

78. At all material times by reason of one or more of the matters pleaded in [76] and [77] above:

(a) it was more difficult to achieve improved reduction in mortality rates via R-L on top of maximal care during the COVID-19 Trial than it had been during the Pilot Study; and

(b) that difficulty increased as the COVID-19 Trial progressed,

(the **Difficulty With Primary Endpoint Information**).

79. The COVID-19 Trial design:

(a) was based on overstated mortality rates of patients receiving standard care;

(b) did not take into account the age of participants in setting the COVID-19 Trial Primary Endpoint against which the treatment effect of R-L and the success of the trial was to be evaluated; and

(c) did not account for the possibility that treatment or care of COVID-19 ARDS would improve over time,

(the **COVID-19 Trial Information**).

Particulars

1. With respect to subparagraph (a), refer to the comparison data referenced by Mesoblast in discussing the Pilot Study results, at paragraph [103], particular 1 below (defined therein as the COVID-19 Comparative Study Data Information).

2. The remaining information is evident by the announcements made by Mesoblast in respect of the COVID-19 Trial, including those referred to in the particulars to paragraph [72] above.

3. Further particulars may be provided following discovery and/or the service of evidence (including expert evidence).

C.3.4. Actual COVID-19 Trial Results Information

80. By 4 September 2020, the actual reduction in mortality rates in the first 90 patients enrolled caused by treatment using R-L was materially lower than both the Pilot Study results and the COVID-19 Trial Primary Endpoint.

Particulars

1. This may be inferred from all or any of the matters pleaded in paragraphs [68] to [79], and/or the fact that as per the 18 December 2020 Announcement, the COVID-19 Trial was abandoned after an interim analysis on the trial's first 180 patients was completed, following a report from DSMB that the trial was not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment.

2. Further particulars may be provided following discovery and the service of the Applicants' evidence.

81. By 11 November 2020, the actual reduction in mortality rates in the first 135 patients enrolled caused by treatment using R-L was materially lower than both the Pilot Study results and the COVID-19 Trial Primary Endpoint.

Particulars

1. This may be inferred from all or any of the matters pleaded in paragraphs [68] to [79], and/or the fact that as per the 18 December 2020 Announcement, the COVID-19 Trial was abandoned after an interim analysis on the trial's first 180 patients was completed, following a report from DSMB that the trial was not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment.

2. Further particulars may be provided following discovery and the service of the Applicants' evidence.

82. The materially lower reduction in mortality rates of patients enrolled in the COVID-19 Trial identified in paragraphs [80] and [81] is referred to (as and from 4 September 2020 and 11 November 2020 cumulatively) as the **Actual COVID-19 Trial Results Information**.

C.3.5. Low Likelihood of COVID-19 Trial Success Information

83. At all material times, the likelihood of the COVID-19 Trial meeting the COVID-19 Primary Endpoint was low (**Low Likelihood of COVID-19 Trial Success Information**).

Particulars

1. The likelihood was low by reason of the COVID-19 Trial Information and/or one or more or a combination of the matters pleaded in paragraphs [68] to [79] and/or [80] and [81], above, which are repeated.

C.4. Mesoblast's knowledge of information

C.4.1 Mesoblast's knowledge of SR-aGVHD Trial Deficiencies Information

84. By a date presently unknown, but by no later than 22 February 2018, alternatively by 5 April 2019, Mesoblast was aware (within the meaning of ASX Listing Rule 19.12) of:

(a) the Protocol 280 Information, Protocol 265 Information and the EAP 275 Information;

(b) the Study 001 Information;

(c) the Differences in aGVHD Studies Information;

(d) the Inadequately Designed Trial for a-GVHD Information; and

(e) to the extent the FDA Information and Advice Regarding SR-aGVHD Application had been received, the Non-compliance with FDA Advice regarding a-GVHD Information;

(severally and cumulatively, to the extent proved, the **SR-aGVHD Trial Deficiencies Information**).

Particulars

1. Mesoblast's knowledge of the matters in subparagraphs (a) and (c) above is to be inferred from the following:

a. At the time Mesoblast acquired Osiris, Protocol 280 and Protocol 265 had concluded. It is to be inferred Mesoblast Officers conducted, caused to be conducted and/or reviewed significant due diligence in respect of R-L and Protocol 280 and Protocol 265, and were aware of the Protocol 280 Information and Protocol 265 Information.

b. At the time Mesoblast acquired Osiris, EAP 275 was ongoing. It is to be inferred that EAP 275 and Study 001 took place under the control and direction of Mesoblast.

c. Mesoblast relied upon an analysis of Protocol 280 and EAP 275 in formulating Study 001: Mesoblast ODAC Briefing Submission, p. 49.

2. Mesoblast's knowledge of the Study 001 Information is to be inferred from the following matters:

    a. that Mesoblast Officers had experience and know-how in clinical trial design, and interpretation of statistics and results; and the regulatory regime applicable to obtaining FDA Marketing Approval, by reason of which they knew, or ought reasonably to have known, of the Effectiveness Requirement, the criteria for an adequate and well controlled trial for the purposes of the FDA regulatory regime (21 C.F.R. § 314.126, 21 U.S.C. § 355(d)), and the FDA guidance on external controls (ICH E10 Guidance), and that they consequently knew, or ought reasonably to have known, that EAP 275 and Study 001 did not satisfy the relevant criteria and guidance. The experience is to be inferred from FY2018 Annual Report, pp. 91-98, FY2019 Annual Report, pp. 93-100, FY2020 Annual Report, pp. 97-103 and the 12 August 2019 Announcement; and

    b. that certain aspects of the SR-aGVHD Trial Deficiencies Information were specifically communicated to Mesoblast by way of the FDA Information and Advice Regarding SR-aGVHD Application (the extent of the advice provided prior to 22 February 2018 not being a matter presently known to the Applicants and to be clarified following discovery).

3. Mesoblast's knowledge of the Inadequately Designed Trial for a-GVHD Information ought reasonably to have been known by Mesoblast Officers by reason of:

    a. that Mesoblast Officers had experience and know-how in clinical trial design, and interpretation of statistics and results; and the regulatory regime applicable to obtaining FDA Marketing Approval, which experience is to be inferred from FY2018 Annual Report, pp. 91-98, FY2019 Annual Report, pp. 93-100,

FY2020 Annual Report, pp. 97-103 and the 12 August 2019 Announcement;

b. Mesoblast's knowledge of the Study 001 Information and Differences in aGVHD Studies Information, as detailed in particulars 1 and 2 above, which are repeated;

c. R-L received fast track designation from the FDA on or about 7 March 2017, permitting "more frequent meetings with FDA to discuss the drug's development plan and ensure appropriate collection of appropriate data needed to support drug approval" and "more frequent written communications from FDA about such things as the design proposed clinical trials and use of biomarkers: (www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track); and

d. to the extent the FDA Information and Advice Regarding SR-aGVHD Application had been received, that information.

Further or in the alternative, by reason of the above matters it can also be inferred that Mesoblast Officers had actual knowledge of the Inadequately Designed Trial for a-GVHD Information.

4. Mesoblast's knowledge of the FDA Information and Advice Regarding SR-aGVHD Application and the Non-compliance with FDA Advice regarding a-GVHD Information ought reasonably to have been known by Mesoblast Officers by reason of:

a. FDA Clinical Evidence Briefing Document, p. 10.

b. the roles of Mesoblast Officers detailed at paragraphs [33] to [41] above;

~~b.~~c. 5 April 2019 Pre-BLA Meeting Information; and

~~c.~~d. particular 3(a) to paragraph [84] above is repeated.

Further or in the alternative, by reason of the above matters it can also be inferred that Mesoblast Officers had actual knowledge of the FDA Information and Advice Regarding SR-aGVHD Application and the Non-compliance with FDA Advice regarding a-GVHD Information.

5. Further particulars may be provided following discovery and/or the service of evidence (including expert evidence).

C.4.2. Mesoblast's knowledge of the SR-aGVHD Approval Application Deficiencies Information

85. By a date presently unknown, but by no later than 22~~8~~ February 2018, alternatively from various dates between 22~~8~~ February 2018 and 31 January 2020 when the final module of the rolling BLA was filed with the FDA (identified in the particulars to the defined terms below), Mesoblast was aware (within the meaning of ASX Listing Rule 19.12) of:

(a) the Unproved Consistency in Manufactured Product Information;

(b) the FDA Information and Advice Regarding SR-aGVHD Application and Non-compliance with FDA Advice regarding a-GVHD Information;

(c) the MAGIC Comparison Data Information; and

(d) the Unlikely to be Approved by FDA Information,

(severally and cumulatively, to the extent proved, the **SR-aGVHD Approval Application Deficiencies Information**).

Particulars

1. Mesoblast Officers ought reasonably to have known of the Unproved Consistency in Manufactured Product Information by reason of:

    a. their roles as Mesoblast Officers as detailed at paragraphs [33] to [41] above;

    b. particular 3(a) to paragraph [84] above is repeated;

    c. particular 3(c) to paragraph [84] above is repeated;

    d. various communications took place between Mesoblast and the FDA before and during the period from 22 February 2018 to 11 August 2020 in respect of the development and production of R-L to treat SR-aGVHD (see ASX announcements made by Mesoblast on 22 February 2018, 20 September 2018, 13 December 2018, 16 April 2019, and 30 May 2019; see also communications associated with Type C CMC Meeting on 2 October 2018 and Mid-Cycle Communication Teleconference on 1 June 2020).

Further or in the alternative, by reason of those matters it can also be inferred that Mesoblast Officers had actual knowledge of the Unproved Consistency in Manufactured Product Information.

2. With respect to the FDA Information and Advice Regarding SR-aGVHD Application and Non-compliance with FDA Advice regarding a-GVHD Information, the Applicants' refer to and repeat the particulars from particular 4 to paragraph [84](d) above.

3. Mesoblast Officers ought reasonably to have known of the MAGIC Comparison Data Information by reason of:

    a. their roles as Mesoblast Officers as detailed at paragraphs [33] to [41] above;

    b. particular 3(a) to paragraph [84] above is repeated;

    c. consequent upon (a) and (b), their knowledge of the Effectiveness Requirement, the criteria for an adequate and well controlled trial for the purposes of the FDA regulatory regime (21 C.F.R. § 314.126, 21 U.S.C. § 355(d)) and the FDA guidance on external controls (ICH E10 Guidance); and

    d. the matters pleaded in paragraph [59] above.

    Further or in the alternative, by reason of those matters it can also be inferred that Mesoblast Officers had actual knowledge of the MAGIC Comparison Data Information.

4. Mesoblast Officers ought reasonably to have known of the Unlikely to be Approved by FDA Information by reason of their knowledge of one or more or a combination of the matters identified in particulars 1 through 3 above. Further or in the alternative, by reason of those matters it can also be inferred that Mesoblast Officers had actual knowledge of the Unlikely to be Approved by FDA Information.

5. Further particulars may be provided following discovery and/or the service of evidence (including expert evidence).

C.4.3. Mesoblast's knowledge of Study 001 No Support for ARDS Treatment Information

86. During the period from 6 April 2020 to 11 August 2020, Mesoblast was aware (within the meaning of ASX Listing Rule 19.12) of the No Support for ARDS Treatment Information.

Particulars

1. The Study 001 No Support for ARDS Treatment Information ought reasonably to have been known, alternatively was known, to Mesoblast Officers by reason of:

    a. their roles as Mesoblast Officers as detailed at paragraphs [33] to [41] above;

    b. particular 3(a) to paragraph [84] above is repeated; and

    c. their knowledge of one or more or a combination of the matters pleaded at paragraphs [84] and [85] above.

2. Further particulars may be provided following discovery and the service of the Applicants' evidence.

C.4.4. Mesoblast's knowledge of COVID-19 Trial Deficiencies Information

87. From 24 April 2020 until 17 December 2020, Mesoblast was aware (within the meaning of ASX Listing Rule 19.12) of:

(a) the COVID-19 Comparative Study Data Information (as defined at paragraph [103], particular 1(b) below);

(b) the COVID-19 Trial Information;

(c) the Difficulty with Primary Endpoint Information; and

(d) the Low Likelihood of COVID-19 Trial Success Information,

(severally and cumulatively, to the extent proved, the **COVID-19 Trial Deficiencies Information**).

Particulars

1. As regards the COVID-19 Comparative Study Data Information in subparagraph (a), it is to be inferred that Mesoblast Officers, would have carefully reviewed the studies underpinning the COVID-19 Comparative Study Data Information, referred to in the 24 April 2020 Announcement (including the Richardson Study and Petrilli Study and the studies referred to in those studies) and that given the fact that Mesoblast Officers had experience and know-how in clinical trial design, and interpretation of statistics and results, and the regulatory regime applicable to obtaining FDA Marketing Approval, which experience is to be inferred from FY2018

Annual Report, pp. 91-98, FY2019 Annual Report, pp. 93-100, FY2020 Annual Report, pp. 97-103 and the 12 August 2019 Announcement, such information would have been readily apparent to Mesoblast Officers from that review.

2. It is to be inferred that Mesoblast Officers knew, or ought reasonably to have known of the COVID-19 Trial Information by reason of:

    a. their roles as Mesoblast Officers as detailed at paragraphs [33] to [41] above and their involvement in the COVID-19 Trial design;

    b. particular 3(a) to paragraph [84] above is repeated;

    c. their knowledge of the COVID-19 Comparative Study Data Information, as detailed in particular 1 above; and

    d. their awareness that age was a determining factor in respect of mortality rates and comorbidities based on both the Pilot Study and the COVID-19 Comparative Study Data Information.

3. As regards the Difficulty with Primary Endpoint Information in subparagraph (c):

    a. at all material times, Mesoblast considered the primary endpoint of 43% to be a 'very high bar': Transcript of Earnings Call of 18 December 2020, p. 4; and

    b. the matters in particulars 1 and 2 above are repeated.

4. As regards the Low Likelihood of COVID-19 Trial Success Information in subparagraph (d), it is to be inferred that Mesoblast Officers knew, or ought reasonably to have known this information from:

    a. scientific studies and other information available to Mesoblast Officers about improvements in standard of care and changes of age cohorts and other patient attributes in relation to COVID-19 ARDS patients in intensive care; and

    b. the matters in particular 3 above, which are repeated.

5. Further particulars may be provided following discovery and/or the service of evidence (including expert evidence).

C.4.5. Mesoblast's knowledge of the Actual COVID-19 Trial Results Information

88. By 4 September 2020, alternatively 11 November 2020, Mesoblast was aware (within the meaning of ASX Listing Rule 19.12) of the Actual COVID-19 Trial Results Information.

Particulars

1. The matters pleaded in paragraph [88] ought reasonably to have been known by Mesoblast Officers by reason of their roles as Mesoblast Officers as detailed at paragraphs [33] to [41] above.

D. MISLEADING OR DECEPTIVE CONDUCT

D.1. Representations made by Mesoblast

89. During the Claim Period, materials published by Mesoblast to the ASX were available to the market of investors and potential investors in Mesoblast Securities (the **Affected Market**), including during:

(a) the period from 22 February 2018 until the close of trading on 10 August 2020 (the **SR-aGVHD Claim Period**); and

(b) the period from 6 April 2020 until the close of trading on 17 December 2020 (the **COVID-19 ARDS Claim Period**).

D.1.1. The 22 February 2018 Representations

90. On and from 22 February 2018, Mesoblast represented to the Affected Market that:

(a) the use of 45% as the historical control rate for the primary endpoint for Study 001 was appropriate (the **Historical Control Rate Representation**);

(b) the safety and efficacy results of Study 001 could be meaningfully compared with the use of R-L to treat children under EAP 275 (**EAP 275 Comparison Representation**);

(c) the FDA had not raised critical issues with respect to the design of Study 001 (the **Study 001 FDA Interactions Representation**);

(d) the results from Study 001 would or were likely to form the basis for a successful application for approval by the FDA to treat paediatric patients with SR-aGVHD with R-L (**Study 001 Outcome Future Representation**, and together with the representations at (a) through (c) above, the **22 February 2018 Representations**); and

(e) Mesoblast had a reasonable basis for making the 22 February 2018 Representations (**22 February 2018 Basis Representation**).

Particulars

1. The representation in subparagraph (a) was part express and part implied:

    a. To the extent it was express, refer to ASX Announcement: "Primary Endpoint Successfully Achieved In Mesoblast's Phase 3 Cell Therapy Trial For Acute Graft Versus Host Disease" 22 February 2018 (**22 February 2018 Announcement**), p. 1.

    b. To the extent it was implied, it was implied from the statement in particular 1(a) above, coupled with the failure to modify or qualify that statement, in the circumstances of, severally or in combination:

        i. the Differences in aGVHD Studies Information; and

        ii. the FDA Information and Advice Regarding SR-aGVHD Application (to the extent applicable to the historical control rate).

2. The representation in subparagraphs (b) was part express and part implied:

    a. To the extent it was express, refer to 22 February 2018 Announcement, p. 1, and the statement that the safety and efficacy results of Study 001 were "consistent with" Mesoblast's prior experience using R-L in 241 children treated under an expanded access protocol (being EAP 275).

    b. To the extent they were implied, they were implied from the statement in particular 3(a) above, coupled with the failure to modify or qualify that statement in the circumstances of, severally or in combination:

        i. the EAP 275 Information;

        ii. the 2014 FDA Meeting Information;

iii. the Differences in aGVHD Studies Information (to the extent applicable to EAP 275 and Study 001); and

iv. the FDA Information and Advice Regarding SR-aGVHD Application (to the extent applicable to EAP 275 and Study 001); and

v. the Non-compliance with FDA Advice regarding a-GVHD Information.

3. The representation in subparagraph (c) was part express and part implied:

   a. To the extent it was express, refer to 22 February 2018 Announcement, p. 1, and the statement commencing "based on interactions with the FDA…".

   b. To the extent it was implied, it was implied from the statement in particular 4(a) above, coupled with the failure to modify or qualify that statement in the circumstances of Mesoblast's receipt of the FDA Information and Advice Regarding SR-aGVHD Application.

4. The representation in subparagraph (d) was part express and part implied:

   a. To the extent it was express, refer to 22 February 2018 Announcement.

   b. To the extent it was implied, it was implied from the 22 February 2018 Announcement, coupled with the failure to modify or qualify that statement in the circumstances of, severally or in combination:

      i. the Study 001 Information; and

      ii. the FDA Information and Advice Regarding SR-aGVHD Application; and/or

      iii. the Non-compliance with FDA Advice regarding a-GVHD Information.

   c. The Study 001 Outcome Future Representation is a representation as to a future matter and s 12BB of the ASIC Act, s 769C of the Corporations Act and/or s 4 of the ACL are relied upon.

5. The representation in subparagraph (e) was implied by the conduct of making the 22 February 2018 Announcement in the circumstances described in particulars 1 through 4 above.

91. Mesoblast repeated the EAP 275 Comparison Representation to the Affected Market on:

(a) 30 May 2019;

(b) 30 August 2019; and

(c) 2 January 2020.

Particulars

1. With respect to subparagraph (a), the representation was part express and part implied:

    a. To the extent it was express, refer to ASX Announcement: "Mesoblast Initiates Rolling Submission Of Biologics Licence Application (BLA) to U.S. FDA For Remestemcel-L In The Treatment of Acute Graft Versus Host Disease", 30 May 2019 (**30 May 2019 Announcement**), p. 1.

    b. To the extent it was implied, it was implied from the statement in particular 1(a) above, coupled with the failure to modify or qualify that statement in the circumstances of, severally or in combination, the matters referred to at paragraph [90], particular (3)(b).

2. With respect to subparagraph (b), the representation was part express and part implied:

    a. To the extent it was express, refer to ASX Announcement: "Mesoblast Reports 2019 Full Year Results", 30 August 2019, pp. 1-2.

    b. To the extent it was implied, it was implied from the statement in particular 2(a) above, coupled with the failure to modify or qualify that statement in the circumstances of, severally or in combination, the matters referred to at paragraph [90], particular (3)(b).

3. With respect to subparagraph (c), the representation was part express and part implied:

    a. To the extent it was express, refer to ASX Announcement: "Mesoblast submits clinical efficacy and safety data to FDA in rolling biologics license application for remestemcel-L", 2 January 2020 (**2 January 2020 Announcement**), p. 1, third paragraph and sentence commencing "These conclusions are

supported by prior results from an Expanded Access Program in 241 children where remestemcel-L was used…".

b. To the extent it was implied, it was implied from the statement in particular 3(a) above, coupled with the failure to modify or qualify that statement in the circumstances of, severally or in combination, the matters referred to at paragraph [90], particular (3)(b).

92. Mesoblast repeated the Study 001 FDA Interactions Representation to the Affected Market on:

(a) 20 September 2018; and

(b) 13 December 2018.

Particulars

1. With respect to subparagraph (a), the Study 001 FDA Interactions Representation was part express and part implied:

    a. To the extent it was express, refer to ASX Announcement: "Children treated with remestemcel-L continue to have strong survival outcomes at six months in Mesoblast's phase 3 trial for acute graft versus host disease", 20 September 2020 (**20 September 2018 Announcement**), p. 1, fifth paragraph commencing "In discussions with the Company…".

    b. To the extent it was implied, it was implied from the statement in particular 1(a) above, coupled with the failure to modify or qualify that statement in the circumstances of Mesoblast's receipt of the FDA Information and Advice Regarding SR-aGVHD Application.

2. With respect to subparagraph (b), the Study 001 FDA Interactions Representation was part express and part implied:

    a. To the extent it was express, refer to ASX Announcement: "Meetings held with the FDA Support Mesoblast's Planned Regulatory Filing For Commercialisation of Remestemcel-L in Acute GVHD", 13 December 2018 (**13 December 2018 Announcement**), p. 1, first sentence of first paragraph.

    b. To the extent it was implied, it was implied from the statement in particular 2(a) above, coupled with the failure to modify or qualify that statement in the circumstances of, either severally or in combination:

i. the Study 001 Information; and

ii. Mesoblast's receipt of the FDA Information and Advice Regarding SR-aGVHD Application.

D.1.2. 20 September 2018 Representations

93. On and from 20 September 2018, Mesoblast represented to the Affected Market:

(a) that its proprietary processes for the production of R-L were such that they could produce doses of R-L that were of consistent and acceptable quality (**R-L Quality Representation**); and

(b) that Mesoblast had a reasonable basis for making the R-L Quality Representation (**20 September 2018 Basis Representation**).

Particulars

1. The R-L Quality Representation was part express and part implied:

   a. To the extent it was express, refer to 20 September 2018 Announcement, p. 2.

   b. To the extent it was implied, it was implied from the statement in particular 1(a) above, coupled with the failure to modify or qualify that statement in the circumstances of the Unproved Consistency in Manufactured Product Information.

2. With respect to subparagraph (b), the 20 September Basis Representation was implied, by the conduct of making the 20 September 2018 Announcement in the circumstances described in particular 1 above.

D.1.3. 13 December 2018 Representations

94. On and from 13 December 2018, Mesoblast represented to the Affected Market that:

(a) the guidance provided to Mesoblast by the FDA in respect of the presentation of data from EAP 275 supported Mesoblast relying upon such data for the purposes of FDA Marketing Approval (the **EAP 275 Reliance Representation**);

(b) the FDA agreed with Mesoblast's proposed chemistry and manufacturing for commercialisation of R-L in paediatric patients with SR-aGVHD (the **R-L Manufacturing Representation**); and

(c) represented to the Affected Market that Mesoblast had a reasonable basis for making the representations in subparagraphs (a) and (b) above (**13 December 2018 Basis Representation**).

Particulars

1. With respect to subparagraph (a), the EAP 275 Reliance Representation was part express and part implied:

    a. To the extent it was express, refer to 13 December 2018 Announcement, p. 1, and the statement that the FDA provided "guidance" on the 241 patient EAP to be included in the filing for the proposed indication, coupled with the introductory remarks that recent meetings support its planned regulatory filing for commercialisation of R-L.

    b. To the extent it was implied, it was implied from the statements identified in particular 1(a) above, coupled with the failure to modify or qualify that statement in the circumstances of, severally or in combination:

        i. the EAP 275 Information;

        ii. the 2014 FDA Meeting Information; and

        iii. Mesoblast's receipt of the FDA Information and Advice Regarding SR-aGVHD Application (to the extent applicable to EAP 275).

2. With respect to subparagraph (b), the R-L Manufacturing Representation was part express and part implied:

    a. To the extent it was express, refer to 13 December 2018 Announcement, p. 1, first sentence of second paragraph.

    b. To the extent it was implied, it was implied from the statements identified in particular 2(a) above, coupled with the failure to modify or qualify that statement or to disclose the Unproved Consistency in Manufactured Product Information**.**

3. With respect to subparagraph (c), the 13 December 2018 Basis Representation was implied by the conduct of making the 13 December 2018 Announcement in the circumstances described in particulars 1 and 2 above.

D.1.4. 20 February 2019 Representations

95. On and from 20 February 2019, Mesoblast represented to the Affected Market that:

(a) Mesoblast had adequately addressed key questions on clinical matters raised by the FDA in connection with the marketing application for R-L (**FDA Issues Addressed Representation**); and

(b) Mesoblast had a reasonable basis for making the FDA Issues Addressed Representation (**20 February 2019 Basis Representation**).

Particulars

1. With respect to subparagraph (a), the FDA Issues Addressed Representation was partly express and partly implied:

    a. To the extent it was express, reference is made to the Half Year 2019 Earnings Call with investors (**20 February 2019 Earnings Call**) transcript, where the analyst from H.C. Wainright, Swyampakula Ramakanth said to CEO Itescu: "*On the remestemcel-L filing for steroid-refractory GVHD, you stated that you're planning to meet with the FDA in April of 2019. So what sort of clarifications are you trying to seek in that particular meeting? And what would be the time line for filing the BLA post that?*"

    b. In response, Itescu stated: "*Look, this is very much an administrative meeting. The key meetings were held in November. We had 2 Type C meetings, 1 on manufacturing and 1 on clinical. So I think the key questions were addressed during those meetings. This is very much administrative and I expect shortly thereafter we'll be filing.*"

    c. To the extent it was implied, it was implied from the statements identified in particular 1(a) above, coupled with the failure by CEO Itescu to modify or qualify that statement in the circumstances of, severally or in combination:

        i. Mesoblast's receipt of the FDA Information and Advice Regarding SR-aGVHD Application; and

        ii. the Non-compliance with FDA Advice regarding a-GVHD Information.

2. With respect to subparagraph (b), the 20 February 2019 Basis Representation was implied by the conduct of making the 20 February 2019 Earnings Call in the circumstances described in particular 1 above.

D.1.4A. 16 April 2019 Address Substantial Matters Future Representation

95A. On 16 April 2019, Mesoblast represented to the Affected Market that Mesoblast expected it could adequately address any "substantial matters raised" by the FDA during the rolling basis process of submitting its BLA (**16 April 2019 Address Substantial Matters Future Representation**).

Particulars

1. The 16 April 2019 Address Substantial Matters Future Representation was an express representation made in ASX Announcement: "FDA agrees to rolling review of Mesoblast's biologic licence application for its cell therapy in children with steroid refractory acute graft versus host disease", 16 April 2019, (**16 April 2019 Announcement**), p. 1, second paragraph.

2. The 16 April 2019 Address Substantial Matters Future Representation is a representation as to a future matter and s 12BB of the ASIC Act, s 769C of the Corporations Act and/or s 4 of the ACL are relied upon.

D.1.5. 2 January 2020 Representations

96. On 2 January 2020, Mesoblast represented to the Affected Market that:

(a) it was relying upon the results of the data from the use of R-L in 309 children across three separate studies as the basis for the BLA seeking FDA Marketing Approval (the **Three Studies Reliance Representation**);

(b) the MAGIC Comparison Data was a legitimate source of comparison data to demonstrate the effectiveness of R-L in the Study 001 patient population for the purposes of obtaining FDA Marketing Approval for R-L (**MAGIC Comparison**

Data Representation, and together with the representations identified at paragraphs (a) and (b) above, the **2 January 2020 Representations**); and

(c) Mesoblast had a reasonable basis for making the 2 January 2020 Representations (**2 January 2020 Basis Representation**).

Particulars

1. In respect of subparagraph (a) above, the Three Studies Reliance Representation was part express and part implied:

    a. To the extent it was express, reference is made to the 2 January 2020 Announcement, p. 1, second paragraph, and the reference to the analysis of 309 children who received R-L across three separate studies.

    b. To the extent it was implied, it was implied from the statements identified in particular 1(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination:

        i. the EAP 275 Information;

        ii. the 2014 FDA Meeting Information;

        iii. the Protocol 280 Information; and

        iv. Mesoblast's receipt of the FDA Information and Advice Regarding SR-aGVHD Application (to the extent applicable to the EAP 275 Information and Protocol 280 Information).

2. In respect of paragraph (b) above, the MAGIC Comparison Data Representation was part express and part implied:

    a. To the extent it was express, reference is made to the second, third and fifth paragraphs of the 2 January 2020 Announcement.

    b. To the extent it was implied, it was implied from the statements identified in particular 2(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of the MAGIC Comparison Data Information.

3. In respect of paragraph (c) above, the 2 January 2020 Basis Representation was implied by the conduct of making the 2 January 2020 Announcement in the circumstances described in particulars 1 and 2 above.

97. Mesoblast repeated the Three Studies Reliance Representation to the Affected Market on:

(a) 3 February 2020;

(b) 25 May 2020; and

(c) 27 May 2020.

Particulars

1. As to subparagraph (a), the Three Studies Reliance Representation was part express and part implied:

    a. To the extent it was express, reference is made to ASX Announcement: "Mesoblast submits completed Biologics Licence", 3 February 2020, (**3 February 2020 Announcement**), p. 1, and the statement in the second paragraph that Mesoblast had filed the final module of the rolling BLA submission with the FDA on 31 January 2020, and the first statement in the fifth paragraph that RYONCIL had been used on 309 children across three separate studies;

    b. To the extent it was implied, it was implied from the statements identified in particular 1(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination:

        i. the matters referred to at paragraph [96], particular (1)(b)(i)-(iv); and

        ii. that on 31 January 2020, Mesoblast submitted its final module of the BLA to the FDA with the results of Study 001 as the sole basis of efficacy.

2. As to subparagraph (b), the Three Studies Reliance Representation was part express and part implied:

    a. To the extent it was express, reference is made to ASX Announcement: "Clinical outcomes using Ryoncil (remestemcel-L) in children and adults with severe inflammatory graft versus host disease published in three articles in Biology of Blood and Marrow Transplantation", 25 May 2020 (**25 May 2020 Announcement**), p. 1, and the first three bullet points under the "key points" heading;

b. To the extent it was implied, it was implied from the statements identified in particular 2(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination:

i. the matters referred to at paragraph [96], particular (1)(b)(i)-(iv); and

ii. on 31 January 2020, Mesoblast submitted its final module of the BLA to the FDA with the results of Study 001 as the sole basis of efficacy.

3. As to subparagraph (c), the Three Studies Reliance Representation was part express and part implied:

a. To the extent it was express, reference is made to Thomson Reuters, Q3 2020 Mesoblast Ltd Earnings Call, 27 May 2020 (**27 May 2020 Earnings Call**), Transcript p. 4;

b. To the extent it was implied, it was implied from the statement identified in particular 3(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination:

i. the matters referred to at paragraph [96], particular (1)(b)(i)-(iv);

ii. Mesoblast's receipt of the FDA Information and Advice Regarding SR-aGVHD Application; and

iii. on 31 January 2020, Mesoblast submitted the final module of the BLA to the FDA with the results of Study 001 as the sole basis of efficacy.

D.1.6. Three Studies Confirmatory Evidence Representations

98. On 24 February 2020, Mesoblast

(a) represented to the Affected Market that the results of 309 children treated with R-L in EAP 275, Protocol 280 and Study 001:

(i) were comparable successful studies or trials for the purpose of FDA Marketing Approval; and/or

(ii) that EAP 275 and Protocol 280 provided confirmatory evidence of the efficacy of R-L that, together with Study 001 supported FDA Marketing Approval,

(together and severally, the **Three Studies Confirmatory Evidence Representations**); and

(b) represented to the Affected Market that Mesoblast had a reasonable basis for making the Three Studies Confirmatory Evidence Representations (**24 February 2020 Basis Representation**).

Particulars

1. The Three Studies Confirmatory Evidence Representations were part express and part implied:

    a. To the extent they were express, reference is made to the document published and lodged by Mesoblast with the ASX titled "Consistent outcomes using Ryoncil as first-line treatment or salvage therapy in 309 children with steroid-refractory acute GVHD" on 24 February 2020 (**24 February 2020 Announcement**), p. 1, opening paragraph, key points and quote from Mesoblast CMO Grossman.

    b. To the extent they were implied, it is from the statements identified in particular 1(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination:

        i. the EAP 275 Information, the Protocol 280 Information, the Study 001 Information;

        ii. the Differences in aGVHD Studies Information;

        iii. Mesoblast's receipt of the FDA Information and Advice Regarding SR-aGVHD Application; and

        iv. that Mesoblast submitted its final module of the BLA to the FDA with the results of Study 001 as the sole basis of efficacy.

2. The 24 February 2020 Basis Representation was implied by the conduct of making the 24 February 2020 Announcement in the circumstances described in particular 1 above.

99. Mesoblast repeated the Three Studies Confirmatory Evidence Representations to the Affected Market on:

(a) 25 May 2020;

(b) 27 May 2020; and

(c) 28 May 2020.

Particulars

1. As to subparagraph (a), the Three Studies Confirmatory Evidence Representations were part express and part implied:

    a. To the extent they were express, reference is made to the 25 May 2020 Announcement, p. 1, first three bullet points under "key points" heading, quote from CMO Grossman, and description of three studies on pp. 1 and 2.

    b. To the extent they were implied, they were implied from the statements identified in particular 1(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination, the matters referred to at paragraph [98], particulars (1)(b)(i) - (iv).

2. As to subparagraph (b), the Three Studies Confirmatory Evidence Representations were part express and part implied:

    a. To the extent they were express, reference is made to the 27 May 2020 Earnings Call and CEO Itescu's comments, after referring to the result from Study 001, Protocol 280 and EAP 275 that "all 3 studies provide the support to the BLA that has been filed for RYONCIL with the FDA…".

    b. To the extent they were implied, they were implied from the statement identified in particular 2(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination, the matters referred to at paragraph [98], particulars (1)(b)(i) - (iv).

3. As to paragraph (c), the Three Studies Confirmatory Evidence Representations were part express and part implied:

    a. To the extent they were express, reference is made to the 28 May 2020 Announcement, p. 4, bullet points two and three.

b. To the extent they were implied, they were implied from the statements identified in particular 3(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination, the matters referred to at paragraph [98], particulars (1)(b)(i) - (iv).

D.1.7. Study 001 Support for R-L Use in COVID-19 Patients Future Representation

100. On 6 April 2020, Mesoblast represented to the Affected Market that the results of Study 001 provided support for, or improved the likelihood of, R-L being effective to treat COVID-19 ARDS patients (**Study 001 Support for R-L Use in COVID-19 Patients Future Representation**).

Particulars

1. In respect of subparagraph (a) above, the Study 001 Support for R-L Use in COVID-19 Patients Future Representation was part express and part implied:

    a. To the extent it was express, reference is made to ASX Announcement: "FDA clears investigational new drug application for Mesoblast to use remestemcel-L in patients with acute respiratory disease syndrome caused by COVID-19", 6 April 2020 (**6 April 2020 Announcement**), p. 1, paragraphs 3 and 4.

    b. To the extent it was implied, it was implied from the statements identified in particular 1(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination:

        i. the EAP 275 Information;

        ii. the Protocol 280 Information;

        iii. the Protocol 265 Information;

        iv. the Study 001 Information;

        v. the FDA Information and Advice Regarding SR-aGVHD Application and/or the Non-compliance with FDA Advice regarding a-GVHD Information; and

        vi. that Mesoblast had not established the efficacy of R-L in SR-aGVHD to the satisfaction of the FDA.

2. The Study 001 Support for R-L Use in COVID-19 Patients Future Representation is a representation as to a future matter and s 12BB of the ASIC Act, s 769C of the Corporations Act and/or s 4 of the ACL are relied upon.

D.1.8. R-L Efficacy Representation

101. On 9 April 2020, Mesoblast represented to the Affected Market that:

(a) R-L had demonstrated safety, efficacy and significant survival benefit for aGVHD patients (**R-L Efficacy Representation**); and

(b) Mesoblast had a reasonable basis for making the R-L Efficacy Representation (**9 April 2020 Basis Representation**).

Particulars

1. The R-L Efficacy Representation was part express and part implied:

a. To the extent it was express, reference is made to ASX Announcement: "Mesoblast Partners With The Cardiothoracic Surgical Trials Network Established By The U.S. National Institutes Of Health's National Heart, Lung And Blood Institute To Conduct Randomized Controlled Trial Of Remestemcel-L For Patients With Acute Respiratory Distress Syndrome Due To COVID-19", 9 April 2020 (**9 April 2020 Announcement**), p. 1:

i. Penultimate paragraph, describing R-L as "successful" in a Phase 3 trial for SR-aGVHD and that a post hoc analysis of a randomised placebo-controlled study in 60 patients with COPD demonstrated that R-L significantly improved respiratory function; and

ii. Final paragraph, where Grossman is quoted as stating that "Remestemcel-L has demonstrated safety, efficacy and significant survival benefit in aGVHD….".

b. To the extent it was implied, it was implied from the statement identified in particular 1(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination:

i. the EAP 275 Information;

ii. the Protocol 280 Information;

iii. the Protocol 265 Information;

iv. the Study 001 Information; and

v. the FDA Information and Advice Regarding SR-aGVHD Application.

2. The 9 April 2020 Basis Representation was implied by the conduct of making the 9 April 2020 Announcement in the circumstances described in particular 1 above.

102. Mesoblast repeated the R-L Efficacy Representation to the Affected Market on:

(a) 28 May 2020; and

(b) 6 July 2020.

Particulars

1. As to subparagraph (a), the R-L Efficacy Representation was part express and part implied:

    a. To the extent it was express, reference is made to the 28 May 2020 Announcement, p. 2, fifth bullet point commencing "Based on the extensive safety and efficacy data for remestemcel-L in SR-aGVHD…" and p. 4, third bullet point "Results from these three trials show a consistent pattern of safety and efficacy for RYONCIL…".

    b. To the extent it was implied, it was implied from the statement identified in particular 1(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination, the matters referred to at paragraph [101] particulars (1)(b)(i) - (v).

2. As to subparagraph (b), the R-L Efficacy Representation was part express and part implied:

    a. To the extent it was express, reference is made to ASX Announcement: "Expanded Access Protocol initiated for compassionate use of remestemcel-L in children with multisystem inflammatory syndrome associated with COVID-19", 6 July 2020 (**6 July 2020 Announcement**), p. 1, fourth paragraph where Grossman is quoted as stating that "The extensive body of safety and efficacy data generated to date using remestemcel-L in children with graft versus host disease…".

b. To the extent it was implied, it is from the statement identified in particular 2(a) above, coupled with the failure by Mesoblast to modify or qualify that statement in the circumstances of, severally or in combination, the matters referred to at paragraph [101] particulars (1)(b)(i) - (v).

D.1.9. 24 April 2020 Representations

103. On 24 April 2020, Mesoblast represented to the Affected Market that:

(a) survival outcomes for COVID-19 patients treated with R-L in the Pilot Study were 83% compared to a 12% survival rate for patients at two major referral hospital networks in New York not treated with R-L during the same time period (**Comparative Survival Representation**);

(b) the COVID-19 Trial met the criteria for an adequate and well controlled trial for the purposes of the FDA regulatory regime (**Adequate and Well Designed COVID-19 Trial Representation**, and together with the representations in subparagraphs (a) and (b) above, the **24 April 2020 Representations**); and

(c) Mesoblast had a reasonable basis for making the 24 April 2020 Representations (**24 April 2020 Basis Representation**).

Particulars

1. As to subparagraph (a), the Comparative Survival Representation was part express and part implied:

   a. To the extent it was express, reference is made to the 24 April 2020 Announcement, p. 1:

      i. first three bullet points under 'key points' heading; and

      ii. first two substantive paragraphs following date of announcement.

   b. To the extent it was implied, it was implied from the statements identified in particular 1(a) above, coupled with the failure by Mesoblast to modify or qualify that statement or to disclose with the 24 April 2020 Announcement, severally or in combination:

i. that the comparison survival figure referenced in the announcement regarding the Richardson Study was not directly comparable with the "83% survival" figure;

ii. that the referenced "88% mortality" and "12% survival" rates in the announcement regarding the Richardson Study did not take into account those patients who were still alive at the end of the study and in hospital;

iii. that the approach to reporting the comparative data biased mortality rates higher by including more patients who died early during the course of hospitalisation; and

iv. that 75% of patients in the Richardson Study and 64% of patients in the Petrilli Study were still alive at the endpoint of those studies,

(together and severally, the **COVID-19 Comparative Study Data Information**).

2. As to subparagraph (b), the Adequate and Well Designed COVID-19 Trial Representation was part express and part implied:

    a. To the extent it was express, reference is made to the 24 April 2020 Announcement, p. 1:

        i. penultimate paragraph, final sentence; and

        ii. final paragraph, second sentence of quote from Grossman.

    b. To the extent it was implied, it was implied from the statements identified in particular 2(a) above, coupled with the failure by Mesoblast to disclose with the 24 April 2020 Announcement the COVID-19 Trial Information.

3. As to subparagraph (c), the 24 April 2020 Basis Representation was implied by the conduct of making the 24 April 2020 Announcement in the circumstances described in particulars 1 through 3 above.

D.1.10. Pilot Study Future Representation

104. On 30 April 2020, Mesoblast represented to the Affected Market that the results of the Pilot Study meant that it was likely the COVID-19 Trial would establish the

effectiveness of R-L in COVID-19 ARDS patients (**Pilot Study Future Representation**).

Particulars

1. The Pilot Study Future Representation was part express and part implied:

    a. To the extent it was express, reference is made to ASX Announcement: "Phase 2/3 randomised controlled trial of remestemcel-L in 300 patients with COVID-19 acute respiratory distress syndrome begins enrollment", 30 April 2020 (the **30 April 2020 Announcement**), p. 1.

    b. To the extent it was implied, it was implied from the statements identified in particular 1(a) above, and the absence of anything to modify, qualify or contradict those statements.

2. The Pilot Study Future Representation is a representation as to a future matter and s 12BB of the ASIC Act, s 769C of the Corporations Act and/or s 4 of the ACL are relied upon.

D.1.11. Cleansing Notice Representation

105. On 11 May 2020, MSB Shares were placed in a trading halt.

106. On or around 13 May 2020, Mesoblast completed a capital raising of AUD$138 million via a placement of 43 million fully paid ordinary shares issued at an issue price of AUD$3.20 per share to sophisticated and professional investors (**May Capital Raising).**

107. On 18 May 2020, Mesoblast represented to the Affected Market that:

    (a) in respect of the May Capital Raising, Mesoblast was not relying on an exception to disclosure under the ASX Listing Rules (relevantly, Rule 3.1A) with respect to information that investors would reasonably require to make an informed assessment of the value of Mesoblast Securities (the **Cleansing Notice Representation**); and

    (b) Mesoblast had a reasonable basis for making the Cleansing Notice Representation (**18 May 2020 Basis Representation**).

Particulars

1. The Cleansing Notice Representation was part express and part implied by the making of the ASX Announcement titled "Cleansing Notice", 18 May 2020 (**Cleansing Notice**) and the absence of any relevant qualification thereto.

2. The 18 May 2020 Basis Representation was implied by the conduct of publishing the Cleansing Notice in the circumstances described in particular 1.

D.1.12. 30 July Representations

108. On 30 July 2020, Mesoblast represented to the Affected Market that:

(a) the COVID-19 Trial was designed in a way which meant the Pilot Study results were likely to be informative of the COVID-19 Trial results (**30 July 2020 Representation**); and

(b) Mesoblast had a reasonable basis for making the 30 July 2020 Representation (**30 July 2020 Basis Representation**).

Particulars

1. The 30 July 2020 Representation was partly expressed and partly implied.

    a. To the extent it was express, reference is made to ASX Announcement: "Mesoblast provides remestemcel-L update and quarterly activity report", 30 July 2020 (the **30 July 2020 Announcement**), p. 1.

    b. To the extent it was implied, it was implied from the 30 July 2020 Announcement and the absence of anything to modify, qualify or contradict those statements.

2. The 30 July 2020 Basis Representation was implied by the conduct of making the 30 July 2020 Announcement in the circumstances described in particular 1 above.

D.1.13. COVID-19 Trial Primary Endpoint Representation

109. On 4 September 2020, Mesoblast represented to the Affected Market that Mesoblast:

(a) had no reason to doubt that the results of the COVID-19 Trial to date showed a reduction in mortality rate caused by R-L treatment which was not materially

lower than the Pilot Study or the COVID-19 Trial Primary Endpoint (**COVID-19 Trial Primary Endpoint Representation**); and

(b) Mesoblast had a reasonable basis for making the COVID-19 Trial Primary Endpoint Representation (**4 September 2020 Basis Representation**).

Particulars

1. The COVID-19 Trial Primary Endpoint Representation was partly expressed and partly implied.

    a. To the extent that they were express, reference is made to the 4 September 2020 Announcement, p. 1.

    b. To the extent it was implied, it was implied from the 4 September 2020 Announcement and the absence of anything to modify, qualify or contradict those statements.

2. The 4 September 2020 Basis Representation was implied by the conduct of making the 4 September 2020 Announcement in the circumstances described in particular 1 above.

110. Mesoblast repeated the COVID-19 Trial Primary Endpoint Representation to the Affected Market on:

(a) 13 October 2020; and

(b) 11 November 2020.

Particulars

1. As to subparagraph (a), the COVID-19 Trial Primary Endpoint Representation was part express and part implied:

    a. To the extent it was express, reference is made to the 13 October 2020 Announcement, p. 1.

    b. To the extent it was implied, it was implied from the 13 October 2020 Announcement, and the absence of anything to modify, qualify or contradict those statements.

2. As to subparagraph (b), the COVID-19 Trial Primary Endpoint Representation was part express and part implied:

    a. To the extent it was express, reference is made to ASX Announcement: "Second Interim Analysis of Clinical Outcomes

after 135 Patients Results in Recommendation to Continue Remestemcel-L Phase 3 Trial in COVID-19 ARDS", 11 November 2020 (the **11 November 2020 Announcement**), p. 1.

b. To the extent it was implied, it was implied from the statements made in the 11 November 2020 Announcement, and the absence of anything to modify, qualify or contradict those statements.

D.2. SR-aGVHD Application Related Misleading Conduct

D.2.1. Conduct in trade or commerce

111. The conduct of Mesoblast in making, and failing to correct and/or qualify, each of the:

(a) representations made on and from 22 February 2018, namely:

(i) Historical Control Rate Representation;

(ii) EAP 275 Comparison Representation;

(iii) Study 001 FDA Interactions Representation;

(iv) Study 001 Outcome Future Representation; and

(v) 22 February 2018 Basis Representation;

(b) representations made on and from 20 September 2018, namely:

(i) R-L Quality Representation; and

(ii) 20 September 2018 Basis Representation;

(c) representations made on and from 13 December 2018, namely:

(i) EAP 275 Reliance Representation;

(ii) R-L Manufacturing Representation; and

(iii) 13 December 2018 Basis Representation;

(d) representations made on and from 20 February 2019, namely:

(i) FDA Issues Addressed Representation; and

(ii) 20 February 2019 Basis Representation;

(d1) 16 April 2019 Address Substantial Matters Future Representation;

(e) representations made on and from 2 January 2020, namely:

(i) Three Studies Reliance Representation;

(ii) MAGIC Comparison Data Representation; and

(iii) 2 January 2020 Basis Representation;

(f) representations made on and from 24 February 2020, namely:

(i) Three Studies Confirmatory Evidence Representations; and

(ii) 24 February 2020 Basis Representation;

(g) representations made on and from 9 April 2020, namely:

(i) R-L Efficacy Representation; and

(ii) 9 April 2020 Basis Representation;

(severally and cumulatively, to the extent proved, the **SR-aGVHD Representations**), was conduct engaged in by Mesoblast:

(a) in trade or commerce, within the meaning of s 18 of the ACL; and/or

(b) in trade or commerce, and in relation to financial services (being MSB Shares), within the meaning of s 12DA of the ASIC Act; and/or

(c) in relation to a financial product or financial service (being MSB Shares), within the meaning of s 1041H of the Corporations Act.

D.2.2. Continuing conduct

112. At no time during the SR-aGVHD Claim Period did Mesoblast withdraw or qualify the SR-aGVHD Representations such that they were continuing representations throughout the SR-aGVHD Claim Period from the time at which they were made.

Particulars

1. In the case of the 22 February 2018 Representations and the 22 February 2018 Basis Representation, the Applicants refer to the express repetition of certain of those representations (as pleaded in paragraphs [91] and [92]), and Mesoblast's failure to correct or qualify those representations after 22 February 2018.

2. In the case of the R-L Quality Representation and the 20 September 2018 Basis Representation, the Applicants refer to Mesoblast's failure to correct or qualify those representations after 20 September 2018.

3. In the case of the EAP 275 Reliance Representation, R-L Manufacturing Representation and 13 December 2018 Basis Representation, the Applicants refer to Mesoblast's failure to correct or qualify those representations after 13 December 2018.

4. In the case of the FDA Issues Addressed Representation and 20 February 2019 Basis Representation, the Applicants refer to Mesoblast's failure to correct or qualify those representations after 20 February 2019.

5. In the case of the 2 January 2020 Representations and the 2 January 2020 Basis Representation, the Applicants refer to the express repetition of certain of those representations (as pleaded in paragraph [97]), and Mesoblast's failure to correct or qualify those representations after 2 January 2020.

6. In the case of the Three Studies Confirmatory Evidence Representations and the 24 February 2020 Basis Representation, the Applicants refer to the express repetition of certain of those representations (as pleaded in paragraph [99]), and Mesoblast's failure to correct or qualify those representations after 24 February 2020.

7. In the case of the R-L Efficacy Representation and 9 April 2020 Basis Representation, the Applicants refer to the express repetition of certain of those representations (as pleaded in paragraph [102]), and Mesoblast's failure to correct or qualify those representations after 9 April 2020.

D.2.3. Conduct was misleading

113. By reason of (severally and cumulatively, to the extent proved):

(a) the Study 001 Information;

(b) the Differences in aGVHD Studies Information; and

(c) the FDA Information and Advice Regarding SR-aGVHD Application,

Mesoblast's conduct in making and failing to correct and/or qualify the Historical Control Rate Representation was misleading or deceptive (or likely to mislead or deceive):

(d) when made on 22 February 2018;

(e) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period.

114. By reason of (severally and cumulatively, to the extent proved):

(a) the EAP 275 Information;

(b) the 2014 FDA Meeting Information;

(c) the Effectiveness Requirement and the Adequate and Well Controlled Trial Criteria; and

(d) the FDA Information and Advice Regarding SR-aGVHD Application,

Mesoblast's conduct in making and failing to correct and/or qualify the EAP 275 Comparison Representation was misleading or deceptive (or likely to mislead or deceive):

(e) when made on 22 February 2018;

(f) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period.

115. By reason of the FDA Information and Advice Regarding SR-aGVHD Application (to the extent received by 22 February 2018, alternatively by 5 April 2019), the Study 001

FDA Interactions Representation was misleading or deceptive (or likely to mislead or deceive):

(a) when made on 22 February 2018;

(b) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period.

116. By reason of (severally and cumulatively, to the extent proved):

(a) the Study 001 Information;

(b) the Differences in aGVHD Studies Information;

(c) the Effectiveness Requirement and the Adequate and Well Controlled Trial Criteria;

(d) the FDA Information and Advice Regarding SR-aGVHD Application;

(e) the Inadequately Designed Trial for a-GVHD Information;

(f) the Non-compliance with FDA Advice regarding a-GVHD Information; and

(g) the Unlikely to be Approved by FDA Information,

Mesoblast did not have reasonable grounds to make the Study 001 Outcome Future Representation, and Mesoblast's conduct in making and failing to correct and/or qualify the representation was misleading or deceptive (or likely to mislead or deceive):

(h) when made on 22 February 2018;

(i) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period.

117. By reason of the matters pleaded in paragraphs [113] to [116] above, the 22 February 2018 Basis Representation was misleading or deceptive (or likely to mislead or deceive):

(a) when made on 22 February 2018;

(b) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period.

118. By reason of the Unproved Consistency in Manufactured Product Information, Mesoblast's conduct in making and failing to correct and/or qualify the R-L Quality Representation and 20 September 2018 Basis Representation was misleading or deceptive (or likely to mislead or deceive):

(a) when made on 20 September 2018 and continuing thereafter throughout the SR-aGVHD Claim Period;

(b) further or alternatively from 31 January 2020 and continuing thereafter throughout the SR-aGVHD Claim Period.

119. By reason of (severally and cumulatively, to the extent proved):

(a) the EAP Information;

(b) the 2014 FDA Meeting Information;

(c) the Effectiveness Requirement and the Adequate and Well Controlled Trial Criteria; and

(d) the FDA Information and Advice Regarding SR-aGVHD Application,

Mesoblast's conduct in making and failing to correct and/or qualify the EAP 275 Reliance Representation was misleading or deceptive (or likely to mislead or deceive):

(e) when made on 13 December 2018;

(f) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period by Mesoblast maintaining and/or failing to correct or qualify the EAP 275 Reliance Representation.

120. By reason of the Unproved Consistency in Manufactured Product Information, Mesoblast's conduct in making and failing to correct and/or qualify the R-L Manufacturing Representation was misleading or deceptive (or likely to mislead or deceive):

(a) when made on 13 December 2018 and continuing thereafter throughout the SR-aGVHD Claim Period;

(b) further or alternatively from 31 January 2020 and continuing thereafter throughout the SR-aGVHD Claim Period.

121. By reason of the matters pleaded in paragraphs [119] and [120] above, Mesoblast's conduct in making and failing to correct and/or qualify the 13 December 2018 Basis Representation was misleading or deceptive (or likely to mislead or deceive):

(a) when made on 13 December 2018;

(b) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period.

122. By reason of (severally and cumulatively, to the extent proved):

(a) the Study 001 Information;

(b) the 2014 FDA Meeting Information; and

(c) the FDA Information and Advice Regarding SR-aGVHD Application;

Mesoblast's conduct in making and failing to correct and/or qualify the FDA Issues Addressed Representation and 20 February 2019 Basis Representation was misleading or deceptive (or likely to mislead or deceive):

(d) when made on 20 February 2019;

(e) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period.

123. By reason of (severally and cumulatively, to the extent proved):

(a) the EAP 275 Information;

(b) the Protocol 280 Information;

(c) the Study 001 Information;

(d) the Differences in aGVHD Studies Information;

(e) the 2014 FDA Meeting Information; and

(f) the FDA Information and Advice Regarding SR-aGVHD Application,

Mesoblast's conduct in making and failing to correct and/or qualify the Three Studies Reliance Representation was misleading or deceptive (or likely to mislead or deceive):

(g) when made on 2 January 2020;

(h) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period; or

(i) alternatively, on and from 31 January 2020 throughout the SR-aGVHD Claim Period, by reason of the fact that on that date Mesoblast submitted its final module of the BLA to the FDA with the results of Study 001 as the sole basis for efficacy.

123A. By reason of (severally and cumulatively, to the extent proved):

(a) 5 April 2019 Pre-BLA Meeting Information;

(b) the Study 001 Information;

(c) the FDA Information and Advice Regarding SR-aGVHD Application,

Mesoblast's conduct in making and failing to correct and/or qualify the 16 April 2019 Address Substantial Matters Future Representation was misleading or deceptive (or likely to mislead or deceive):

(d) when made on 16 April 2019;

(e) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period.

124. By reason of (severally and cumulatively, to the extent proved):

(a) the Study 001 Information; and

(b) the MAGIC Comparison Data Information,

Mesoblast's conduct in making and failing to correct and/or qualify the MAGIC Comparison Data Representation was misleading or deceptive (or likely to mislead or deceive):

(c) when made on 2 January 2020;

(d) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period.

125. By reason of the matters pleaded in paragraphs [123] and [124] above, Mesoblast's conduct in making and failing to correct and/or qualify the 2 January 2020 Basis Representation was misleading or deceptive (or likely to mislead or deceive):

(a) when made on 2 January 2020;

(b) further or alternatively continuing thereafter from the date they were made throughout the SR-aGVHD Claim Period.

126. By reason of (severally and cumulatively, to the extent proved):

(a) the EAP 275 Information;

(b) the Protocol 280 Information;

(c) the Study 001 Information;

(d) the Differences in aGVHD Studies Information;

(e) the 2014 FDA Meeting Information;

(f) the FDA Information and Advice Regarding SR-aGVHD Application; and

(g) the fact that on 31 January 2020 Mesoblast submitted its final module of the BLA to the FDA with the results of Study 001 as the sole basis for efficacy,

Mesoblast's conduct in making and failing to correct and/or qualify the Three Studies Confirmatory Evidence Representations and 24 February Basis Representation was misleading or deceptive (or likely to mislead or deceive):

(h) when made on 24 February 2020;

(i) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period.

127. By reason of (severally and cumulatively, to the extent proved):

(a) the Protocol 280 Information, the Protocol 265 Information, the EAP 275 Information, and the Study 001 Information;

(b) the 2014 FDA Meeting Information;

(c) the Differences in aGVHD Studies Information;

(d) the Effectiveness Requirement, the Adequate and Well Controlled Trial Criteria, the FDA guidance on external controls (ICH E10 Guidance) and the risks of drawing inappropriate conclusions due to bias in externally controlled studies (ICH E9 Guidance and ICH E10 Guidance);

(e) the Inadequately Designed Trial for a-GVHD Information;

(f) the FDA Information and Advice Regarding SR-aGVHD Application;

(g) the Non-compliance with FDA Advice regarding a-GVHD Information; and

(h) the Unlikely to be Approved by FDA Information,

Mesoblast's conduct in making and failing to correct and/or qualify the R-L Efficacy Representation and 9 April 2020 Basis Representation was misleading or deceptive (or likely to mislead or deceive):

(i) when made on 9 April 2020;

(j) further or alternatively continuing thereafter throughout the SR-aGVHD Claim Period.

D.3. COVID-19 Misleading Conduct

D.3.1. Conduct in trade or commerce

128. Mesoblast's conduct in making and failing to correct and/or qualify each of the:

(a) Study 001 Support for R-L Use in COVID-19 Patients Future Representation;

(b) Comparative Survival Representation;

(c) Adequate and Well Designed COVID-19 Trial Representation;

(d) 24 April 2020 Basis Representation;

(e) Pilot Study Future Representation;

(f) 30 July 2020 Representation;

(g) 30 July 2020 Basis Representation;

(h) COVID-19 Trial Primary Endpoint Representation; and

(i) 4 September 2020 Basis Representation;

(severally and cumulatively, to the extent proved, the **COVID-19 ARDS Representations**) was conduct engaged in by Mesoblast:

(j) in trade or commerce, within the meaning of s 18 of the ACL; and/or

(k) in trade or commerce, and in relation to financial services (being Mesoblast Securities), within the meaning of s 12DA of the ASIC Act; and/or

(l) in relation to a financial product or financial service (being Mesoblast Securities), within the meaning of s 1041H of the Corporations Act.

D.3.2. Continuing conduct

129. At no time during the COVID-19 ARDS Claim Period did Mesoblast withdraw or qualify the COVID-19 ARDS Representations (or any of them) such that they were continuing representations throughout the COVID-19 ARDS Claim Period from the time at which they were made.

Particulars

1. In the case of the Study 001 Support for R-L Use in COVID-19 Patients Future Representation, the Applicants refer to Mesoblast's failure to correct or qualify those representations after 6 April 2020.

2. In the case of the 24 April 2020 Representations, the Applicants refer to Mesoblast's failure to correct or qualify those representations after 24 April 2020.

3. In the case of the Pilot Study Representation, the Applicants refer to Mesoblast's failure to correct or qualify those representations after 30 April 2020.

4. In the case of the 30 July 2020 Representation and the 30 July 2020 Basis Representation, the Applicants refer to Mesoblast's failure to correct or qualify those representations after 30 July 2020.

5. In the case of the COVID-19 Primary Endpoint Representation and 4 September 2020 Basis Representation, the Applicants refer to the express repetition of certain of those representations (as pleaded in paragraph [110]), and Mesoblast's failure to correct or qualify those representations after 4 September 2020.

D.3.3 Conduct was misleading

130. By reason of (severally and cumulatively, to the extent proved):

(a) the SR-aGVHD Trial Deficiencies Information, in particular, the Study 001 Information; and

(b) the SR-aGVHD Approval Application Deficiencies Information,

Mesoblast did not have reasonable grounds to make the Study 001 Support for R-L Use in COVID-19 Patients Future Representation, and Mesoblast's conduct in making and failing to correct and/or qualify the representation was misleading or deceptive (or likely to mislead or deceive):

(c) when made on 6 April 2020;

(d) further or alternatively continuing thereafter throughout the COVID-19 ARDS Claim Period.

131. By reason of the COVID-19 Comparative Study Data Information, Mesoblast's conduct in making and failing to correct and/or qualify the Comparative Survival Representation was misleading or deceptive (or likely to mislead or deceive):

(a) when made on 24 April 2020;

(b) further or alternatively continuing thereafter throughout the COVID-19 ARDS Claim Period.

132. By reason of (severally and cumulatively, to the extent proved):

(a) the Pilot Study Information;

(b) the COVID-19 Trial Information;

(c) the COVID-19 Comparative Study Data Information;

(d) the Difficulty with Primary Endpoint Information; and

(e) Low Likelihood of COVID-19 Trial Success Information,

Mesoblast's conduct in making and failing to correct and/or qualify the Adequate and Well Designed Trial Representation was misleading or deceptive (or likely to mislead or deceive):

(f) when made on 24 April 2020;

(g) further or alternatively continuing thereafter throughout the COVID-19 ARDS Claim Period.

133. By reason of the matters pleaded in paragraphs [131] and [132] above, Mesoblast's conduct in making and failing to correct and/or qualify the 24 April 2020 Basis Representation was misleading or deceptive (or likely to mislead or deceive):

(a) when made on 24 April 2020;

(b) further or alternatively continuing thereafter from the date they were made throughout the COVID-19 ARDS Claim Period.

134. By reason of (severally and cumulatively, to the extent proved):

(a) the Pilot Study Information;

(b) the COVID-19 Trial Information; and

(c) the COVID-19 Comparative Study Data Information,

Mesoblast did not have reasonable grounds to make the Pilot Study Future Representation, and Mesoblast's conduct in making and failing to correct and/or qualify the representation was misleading or deceptive (or likely to mislead or deceive):

(d) when made on 30 April 2020;

(e) further or alternatively continuing thereafter throughout the COVID-19 ARDS Claim Period.

135. By reason of (severally and cumulatively, to the extent proved):

(a) the Pilot Study Information; and

(b) the COVID-19 Trial Information;

Mesoblast's conduct in making and failing to correct and/or qualify the 30 July 2020 Representation and the 30 July 2020 Basis Representation representations was misleading or deceptive (or likely to mislead or deceive):

(c) when made on 30 July 2020;

(d) further or alternatively continuing thereafter throughout the COVID-19 ARDS Claim Period.

136. By reason of (severally and cumulatively, to the extent proved):

(a) the Pilot Study Information;

(b) the COVID-19 Trial Information;

(c) the COVID-19 Comparative Study Data Information;

(d) the Difficulty with Primary Endpoint Information;

(e) Low Likelihood of COVID-19 Trial Success Information; and

(f) the Actual COVID-19 Trial Results Information,

Mesoblast's conduct in making and failing to correct and/or qualify the COVID-19 Trial Primary Endpoint Representation and 4 September 2020 Basis Representation was misleading or deceptive (or likely to mislead or deceive):

(g) when made on 4 September 2020;

(h) further or alternatively continuing thereafter throughout the COVID-19 ARDS Claim Period.

D.4. Misleading Conduct Contraventions

137. By reason of the matters pleaded in:

(a) paragraphs [111] to [112] and each of paragraphs [113] to [127];

(b) paragraphs [128] to [129] and each of paragraphs [130] to [136],

Mesoblast contravened s 1041H of the Corporations Act, s 12DA of the ASIC Act and/or s 18 of the ACL (severally and cumulatively, to the extent proved, the **Misleading Conduct Contraventions**).

E. CONTINUOUS DISCLOSURE CONTRAVENTIONS

138. Each of:

(a) the SR-aGVHD Trial Deficiencies Information;

(b) the SR-aGVHD Approval Application Deficiencies Information;

(c) the Study 001 No Support for ARDS Treatment Information;

(d) the COVID-19 Trial Deficiencies Information; and

(e) the Actual COVID-19 Trial Results Information,

(each being **Material Information**), was information:

(f) that, from the dates Mesoblast was aware of it (as pleaded respectively in paragraphs [84] to [88]) until:

(i) 11 August 2020 in respect of the SR-aGVHD Trial Deficiencies Information SR-aGVHD Approval Application Deficiencies Information, and the Study 001 No Support for ARDS Treatment Information; and

(ii) the end of the Claim Period, in respect of the COVID-19 Trial Deficiencies Information and the Actual COVID-19 Trial Results Information,

was information that was not generally available within the meaning of s 674(2)(c)(i) of the Corporations Act; and

(g) that:

(i) at all material times up to 26 May 2020, a reasonable person would expect, if it were generally available, to have a material effect on the price or value of MSB Shares; and

(ii) on and from 26 May 2020 through to the end of the Claim Period, Mesoblast knew, or was reckless or negligent with respect to whether, if it were generally available, would have a material effect on the price or value of MSB Shares,

within the meaning of s 674(2)(c)(ii) of the Corporations Act.

139. Pursuant to ASX Listing Rule 3.1, Mesoblast became obliged to tell the ASX the Material Information on and from the date that Mesoblast had, or obtained, that information, as pleaded in paragraphs [84] to [88].

140. Mesoblast did not communicate any of the Material Information to the ASX, and the Material Information was not generally available before:

(a) 11 August 2020 in respect of the SR-aGVHD Trial Deficiencies Information;

(b) 11 August 2020 in respect of the SR-aGVHD Approval Application Deficiencies Information;

(c) 11 August 2020, in respect of the Study 001 No Support for ARDS Treatment Information;

(d) 18 December 2020, in respect of the COVID-19 Trial Deficiencies Information; and

(e) 18 December 2020, in respect of the Actual COVID-19 Trial Results Information.

141. In the circumstances set out in paragraphs [138] to [140], Mesoblast contravened subsection 674(2) of the Corporations Act (**Continuous Disclosure Contraventions**).

142. Further, Mesoblast's conduct in making and failing to correct and/or qualify each of the:

(a) Cleansing Notice Representation; and

(b) 18 May 2020 Basis Representation,

(the **Cleansing Notice Representations**), was conduct engaged in by Mesoblast:

(c) in trade or commerce, within the meaning of s 18 of the ACL; and/or

(d) in trade or commerce, and in relation to financial services (being MSB Shares), within the meaning of s 12DA of the ASIC Act; and/or

(e) in relation to a financial product or financial service (being MSB Shares), within the meaning of s 1041H of the Corporations Act.

143. By reason of the Continuous Disclosure Contraventions which had commenced and were not corrected by 18 May 2020, Mesoblast's conduct in making and failing to correct and/or qualify the Cleansing Notice Representation and 18 May 2020 Basis Representation was misleading or deceptive (or likely to mislead or deceive) when made on 18 May 2020 (and was a Misleading Conduct Contravention).

144. By reason of the matters pleaded in paragraphs [142] and [143] Mesoblast contravened s 1041H of the Corporations Act, s 12DA of the ASIC Act and/or s 18 of the ACL (this being a Misleading Conduct Contravention).

F. CORRECTIVE DISCLOSURES AND THEIR PRICE IMPACT

F.1. 11 August 2020 Disclosure and Price Fall

145. On 11 August 2020, Mesoblast published and lodged with the ASX a document titled "Update on Scheduled FDA Advisory Committee Meeting" (**11 August 2020 Announcement**) which included a hyperlink to a series of briefing materials, including:

(a) the Mesoblast ODAC Briefing Submission;

(b) the FDA Clinical Evidence Briefing Document; and

(c) FDA Product Characterisation Briefing Document, (together with the FDA Clinical Evidence Briefing Document, the **FDA ODAC Briefing Materials**).

146. Following the release of the FDA ODAC Briefing Materials, the price of Mesoblast Securities fell materially **(**the **August Price Fall)**.

Particulars

1. The price of MSB Shares traded on the ASX fell by 31.01% (AUD$1.51) from a closing price of AUD$4.87 on 10 August 2020 to a closing price of AUD$3.36 on 11 August 2020.

2. The price of MSB Shares traded on the ASX fell by a further 8.63% (AUD$0.29) from a closing price of AUD$3.36 on 11 August 2020 to a closing price of AUD$3.07 on 12 August 2020.

3. The price of MESO ADRs fell by 34.96% (US$6.09) from a closing price of US$17.42 on 10 August 2020 (ET) to a closing price of US$11.33 on 11 August 2020 (ET).

4. Further particulars may be provided following service of the Applicants' expert evidence.

F.2. 18 December 2020 Disclosure and Price Fall

147. On 18 December 2020, Mesoblast published and lodged with the ASX the 18 December 2020 Announcement.

148. Following the 18 December 2020 Announcement, the price of Mesoblast Securities fell materially (the **December Price Fall**).

Particulars

1. The price of MSB Shares traded on the ASX fell by 36.07% (AUD$1.36) from a closing price of $3.77 on 17 December 2020 to a closing price of $2.41 on 18 December 2020.

2. The price of MSB Shares fell by a further 4.56% (AUD$0.11) from a closing price of $2.41 on 18 December 2020 to a closing price of $2.30 on 21 December 2020.

3. The price of MESO ADRs fell by 31.69% (US$4.30) from a closing price of US$13.57 on 17 December 2020 (ET) to a closing price of US$9.27 on 18 December 2020 (ET).

4. The price of MESO ADRs fell by 7.34% (US$0.68) from a closing price of US$9.27 on 18 December 2020 (ET) to a closing price of US$8.59 on 21 December 2020 (ET).

5. Further particulars may be provided following service of the Applicants' expert evidence

G. CONTRAVENING CONDUCT CAUSED GROUP MEMBERS' LOSS

G.1. Market based causation (on market acquisitions)

149. The Applicants and the Group Members acquired their interests in MSB Shares in a market of investors or potential investors in MSB Shares:

(a) operated by the ASX;

(b) regulated by, inter alia, the ASX Listing Rules and s 674(2) of the Corporations Act;

(c) where the price or value of MSB Shares would reasonably be expected to have been informed or affected by information disclosed in accordance with the ASX Listing Rules and s 674(2) of the Corporations Act; and

(d) where Mesoblast had the Continuous Disclosure Obligations and the Misleading Conduct Obligations.

150. During the Claim Period, the market for each of MESO ADRs and MEOBF OTCs were markets that traded on the basis that the market for MSB Shares had the features pleaded at paragraph [149] above.

151. In the Claim Period, each or a combination of the Continuous Disclosure Contraventions and/or the Misleading Conduct Contraventions (together, **Market Contraventions**) caused the market price of MSB Shares, MESO ADRs and MEOBF OTCs to be, or materially contributed to the market price of MSB Shares, MESO ADRs and MEOBF OTCs being, substantially greater than:

(a) their true value; and/or

(b) the market price that would have prevailed but for the Market Contraventions,

from the respective dates that those Market Contraventions commenced, as pleaded in this Consolidated Statement of Claim.

Particulars

1. Particulars will be provided at the time of service of the Applicants' expert evidence in chief.

152. The August Price Fall and the December Price Fall, and any consequential declines in the price of MEOBF OTCs, were caused or materially contributed to by:

(a) the market's reaction to the information released to the ASX:

(i) in the FDA ODAC Briefing Materials hyperlinked to the 11 August 2020 Announcement;

(ii) in the 18 December 2020 Announcement; and

(b) the Market Contraventions.

Particulars

1. Particulars will be provided prior to the trial of the individual claims of Group Members following the determination of the common questions.

153. During the Claim Period, the market for MSB Equity Swaps was a market that traded on the basis that the market for MSB Shares had the features pleaded in paragraph [149] above.

154. By reason of the matters pleaded at [149] to [153] above, at all times during the Claim Period when Group Members who entered into MSB Equity Swaps entered into such MSB Equity Swaps, they did so at a time when:

(a) the market price for MSB Shares was substantially greater than;

(i) their true value; and/or

(ii) the market price that would have prevailed but for the Market Contraventions;

(b) the MSB Equity Swaps had been defined by reference to the price of MSB Shares which had the features described at sub-paragraph (a); and

(c) by reason of the matters pleaded in sub-paragraphs (a) and (b), the value of the future cashflows to be received by the equity amount receiver pursuant to the MSB Equity Swaps by reference to the performance of MSB Shares was diminished and/or the value of the cashflows to be paid by the equity amount received in return was inflated.

Particulars

1. Particulars will be provided prior to the trial of the individual claims of Group Members following the determination of the common questions.

G.2. Market based causation (capital raising acquisition)

155. The May Capital Raising was undertaken:

(a) at an offer price fixed by reference to the market price of MSB Shares, which traded in a market with the features pleaded in paragraph [149];

(b) in circumstances where the Material Information the subject of the Continuous Disclosure Contraventions had not been disclosed; and

(c) in circumstances where the Misleading Conduct Contraventions occurring prior to the May Capital Raising (including the Misleading Conduct Contraventions relating to the making and maintaining of the Cleansing Notice Representations) had occurred and were continuing.

Particulars

1. The extent to which the Market Contraventions caused the offer price for MSB Shares under the Capital Raising to be substantially greater than their true value and/or the price that they would have been offered had they been set by reference to the market price that would otherwise have prevailed (that is, inflated) is a matter for evidence, particulars of which will be

served immediately following the Applicants' filing expert evidence in the proceeding.

G.3. Reliance

156. Further, or in the alternative to paragraphs [149] to [154], and [155] above:

(a) the Applicants and some Group Members would not have entered into the transactions pursuant to which they acquired an interest in Mesoblast Securities if they had known the information the subject of the Continuous Disclosure Contraventions; and/or

(b) the Applicants and some Group Members relied on some or all of the SR-aGVHD Representations and/or the COVID-19 ARDS Representations and/or the Cleansing Notice Representations (and/or Mesoblast's conduct in maintaining and not correcting or qualifying some or all of those representations) in entering into the transactions pursuant to which they acquired an interest in Mesoblast Securities.

Particulars

1. The identities of all those Group Members which or who would not have entered into the transactions pursuant to which they acquired an interest in Mesoblast Securities, had they known of any or all of the information that was the subject of the Continuous Disclosure Contraventions and/or which or who relied on any or all of the SR-aGVHD Representations and/or the COVID-19 ARDS Representations are not within the current state of the Applicants' knowledge and cannot be ascertained unless and until those advising the Applicants take detailed instructions from all Group Members on individual issues relevant to the determination of those individual Group Members' claims; those instructions will be obtained (and particulars of the identity of those Group Members will be provided) following opt out, the determination of the Applicants' claims and identified common issues at an initial trial and if and when it is necessary for a determination to be made of the individual claims of those Group Members.

G.4. Loss or damage suffered by the Applicants and Group Members

157. By reason of the matters pleaded in paragraphs [149] to [155] and/or [156] above, the Applicants and Group Members have suffered loss and damage by and resulting from the Market Contraventions (or any one or combination of them).

Particulars

1. The loss suffered by the Applicants will be calculated by reference to:

    a. the difference between the price at which Mesoblast Securities were acquired by the Applicants during the Claim Period and the true value of that interest; or

    b. alternatively, the difference between the price at which the Applicants acquired Mesoblast Securities and the market price that would have prevailed had the Market Contraventions not occurred; or

    c. alternatively, the days during the Claim Period where the traded price of Mesoblast Securities fell as a result of the disclosure information which had not previously been disclosed because of the Market Contraventions, and the quantum of that fall; or

    d. alternatively, the difference between the price at which Mesoblast Securities were acquired by the Applicants and the price left in hand.

2. Further particulars in relation to each Applicant's loss will be provided after the service of evidence in chief.

3. Particulars of the losses of Group Members are not within the current state of the Applicants' knowledge and cannot be ascertained unless and until those advising the Applicants take detailed instructions from all Group Members on individual issues relevant to the determination of those individual Group Members' claims; those instructions will be obtained (and particulars of the losses of those Group Members will be provided) following opt out, the determination of the Applicants' claims and identified common issues at an initial trial and if and when it is necessary for a determination to be made of the individual claims of those Group Members.

158. By reason of the terms of the Stipulation and Agreement of Settlement dated 28 March 2022 (the **Stipulation**), as approved by the United States District Court for the Southern District of New York by a judgment dated 15 August 2022 in the proceeding *Kristal v Mesoblast Limited, et al.* (**US Judgment**), the Applicants and Group Members do not claim for loss or damage arising from the acquisition of an interest in ADRs traded on the NASDAQ exchange under the symbol "MESO" within the period of 13 December 2018 to 5 April 2020 (inclusive) where the purchaser did not submit a request for exclusion that was accepted by the Court in connection with the US Judgment (**Excluded ADR Loss**).

~~3.~~

AND EACH APPLICANT CLAIMS, for itself and on behalf of the Group Members, the relief set out in the Amended Consolidated Originating Application filed herein.

Date: 20 December 2023~~2~~

Signed by Ding Pan
Joint Lawyer for the Applicants

Signed by Diana Clare Forbes Young
Joint Lawyer for the Applicants

This pleading was prepared by R B Davies of Counsel, and settled by W A D Edwards of King's Counsel.

ANNEXURE A – DEFINITIONS

2 January 2020 Announcement	is defined at paragraph [91], particular 3(a)
2 January 2020 Basis Representations	is defined at paragraph [96](d)
2 January 2020 Representations	is defined at paragraph [96]I
3 February 2020 Announcement	is defined at paragraph [97], particular 1(a)
4 September 2020 Announcement	is defined at paragraph [74](c), particular 3
4 September 2020 Basis Representation	is defined at paragraph [109](b)
5 April 2019 Pre-BLA Meeting Information	is defined at paragraph [57], particular 2(c)
6 April 2020 Announcement	is defined at paragraph [100], particular 1(a)
6 May 2020 Announcement	is defined at paragraph [72], particular 1(a)
6 July 2020 Announcement	is defined at paragraph [2], particular 2(a)
9 April 2020 Announcement	is defined at paragraph [101], particular 1(a)
9 April 2020 Basis Representation	is defined at paragraph [101](b)
11 August 2020 Announcement	is defined at paragraph [145]
11 November 2020 Announcement	is defined at paragraph [110], particular 2
12 August 2019 Announcement	is defined at paragraph [35](b), particular 3
13 December 2018 Announcement	is defined at paragraph [92], particular 2(a)
13 December 2018 Basis Representation	is defined at paragraph [94](c)
13 October 2020 Announcement	is defined at paragraph [2], particular 3(a)
16 April 2019 Announcement	is defined at paragraph [95A], particular 1
16 April 2019 Address Substantial Matters Future Representation	is defined at paragraph [95A]
18 May Basis Representation	is defined at paragraph [107](b)
18 December 2020 Announcement	is defined at paragraph [73], particular 1(c)

20 February 2019 Basis Representation	is defined at paragraph [95](b)
20 February 2019 Earnings Call	is defined at paragraph [95], particular 1(a)
20 September 2018 Announcement	is defined at paragraph [92], particular 1(a)
20 September 2018 Basis Representation	is defined at paragraph [93](b)
22 February 2018 Announcement	is defined at paragraph [90], particular 1(a)
22 February 2018 Basis Representation	is defined at paragraph [90](e)
22 February 2018 Representations	is defined at paragraph [90](d)
24 February 2020 Announcement	is defined at paragraph [98], particular 1(a)
24 February 2020 Basis Representation	is defined at paragraph [98](b)
24 April 2020 Announcement	is defined at paragraph [69], particular 1
24 April 2020 Basis Representations	is defined at paragraph [103](d)
24 April 2020 Representations	is defined at paragraph [103](c)
25 May 2020 Announcement	is defined at paragraph [97], particular 2(a)
27 May 2020 Earnings Call	is defined at paragraph [97], particular 3(a)
28 May 2020 Announcement	is defined at paragraph [72], particular 1(b)
30 April 2020 Announcement	is defined at paragraph [104], particular 1(a)
30 May 2019 Announcement	is defined at paragraph [91], particular 1
30 July 2020 Basis Representation	is defined at paragraph [108](b)
30 July 2020 Representation	is defined at paragraph [108](a)
2014 FDA Meeting Information	is defined at paragraph [63], particular 2
ACL	Australian Consumer Law, being schedule 2 to the *Competition and Consumer Act 2010* (Cth)
Adequate and Well Designed COVID-19 Trial Representation	is defined at paragraph [103](c)
Affected Market	is defined at paragraph [89]
aGVHD	Acute Graft-Versus-Host-Disease
Applicants	is defined at paragraph [1]

ARDS	Acute Respiratory Distress Syndrome
ASIC Act	*Australian Securities and Investments Commission Act 2001* (Cth)
ASX	Australian Securities Exchange
ASX Listing Rules	means the listing rules of the ASX
August Price Fall	is defined at paragraph [146]
Biologics Clinical Trial Endpoints Guidance	FDA Guidance Document on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics Guidance for Industry – December 2018
BLA	Biologics License Application
Board	means the Mesoblast Board of Directors, from time to time
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CFR	Code of Federal Regulations
Claim Period	means the period from 22 February 2018 to 17 December 2020 inclusive
Cleansing Notice	is defined at paragraph [107], particular 1
Cleansing Notice Representation	is defined at paragraph [107]
CMO	Chief Medical Officer
Comparative Survival Representation	is defined at paragraph [103](a)
Continuous Disclosure Obligations	is defined at paragraph [7](b)
Continuous Disclosure Contraventions	is defined at paragraph [141]
COO	Chief Operating Officer
COPD	Chronic Obstructive Pulmonary Disease
Corporations Act	*Corporations Act 2001* (Cth)
COVID-19 ARDS	Acute Respiratory Distress Syndrome caused by COVID-19
COVID-19 ARDS Application	is defined at paragraph [14](b)
COVID-19 ARDS Claim Period	is defined at paragraph [89](c)
COVID-19 ARDS Representations	is defined at paragraph [128]
COVID-19 Comparative Study Data Information	is defined at paragraph [103], particular 1(b)
COVID-19 Trial	is defined at paragraph [71]
COVID-19 Trial Deficiencies Information	is defined at paragraph [87]
COVID-19 Trial Information	is defined at paragraph [79]
COVID-19 Trial Primary Endpoint	is defined at paragraph [73]

COVID-19 Trial Primary Endpoint Representation	is defined at paragraph [109](a)
CR	Complete Response
DCR	Durable Complete Response
December Price Fall	is defined at paragraph [148]
Differences in aGVHD Studies Information	is defined at paragraph [62]
Difficulty with Primary Endpoint Information	is defined at paragraph [78]
DOR	Duration of Response
DSMB	Data Safety Monitoring Board
EAP	Expanded Access Protocol
EAP 275	is defined at paragraph [52]
EAP 275 Comparison Representation	is defined at paragraph [90](b)
EAP 275 Information	is defined at paragraph [54]
EAP 275 Reliance Representation	is defined at paragraph [94](a)
Effectiveness Requirement	is defined at paragraph [47], particular 2
Excluded ADR Loss	is defined at paragraph [158]
FCA Act	*Federal Court of Australia Act 1976* (Cth)
FDA	Food and Drug Administration
FDA Clinical Evidence Briefing Document	FDA Briefing Document ODAC Meeting, Session on Clinical Evidence (PM Session) BLA 125706, Aug. 13, 2020
FDA Information and Advice Regarding SR-aGVHD Application	is defined at paragraph [63]
FDA Issues Addressed Representation	is defined at paragraph [95]
FDA Marketing Approval	is defined at paragraph [15]
FDA ODAC Briefing Materials	is defined at paragraph [145](c)
FDA Product Characterisation Briefing Document	is defined at paragraph [61], particular 1
Grossman	Dr Fred Grossman
Group Members	is defined at paragraph [2]
Historical Control Rate Representation	is defined at paragraph [90](a)
Hodgkinson	Mr Paul Hodgkinson
Howard	Mr Peter Howard
ICH E9 Guidance	FDA, ICH Harmonised Tripartite Guideline, Statistical Principles for Clinical Trials (ICH E9), (February 1998)
ICH E10 Guidance	FDA, Guidance for Industry: Choice of Control Group and Related Issues in Clinical Trials (ICH E10), (May 2001)

Inadequately Designed Trial for a-GVHD Information	is defined at paragraph [65]
Itescu	Dr Silviu Itescu
Low Likelihood of COVID-19 Trial Success Information	is defined at paragraph [83]
MAGIC	Mt. Sinai Acute GVHD International Consortium
MAGIC Comparison Data	is defined at paragraph [59]
MAGIC Comparison Data Information	is defined at paragraph [60]
MAGIC Comparison Data Representation	is defined at paragraph [96](c)
Market Contraventions	is defined at paragraph [151]
Material Information	is defined at paragraph [138]
May Capital Raising	is defined at paragraph [106]
MESO ADRs	is defined at paragraph [2](a)(ii)
MEOBF OTCs	is defined at paragraph [2](a)(iii)
Mesoblast ODAC Briefing Submission	Mesoblast Briefing Information for the August 13, 2020 Meeting of the Oncologic Drugs Advisory Committee (Combined AM-PM Session)
Mesoblast	the Respondent, Mesoblast Limited (ACN 109 431 870)
Mesoblast Officers	is defined at paragraph [42]
Mesoblast Securities	is defined at paragraph [2](a) and includes MSB Shares, MESO ADRs, MEOBF OTC's and MSB Equity Swaps
Misleading Conduct Contraventions	is defined at paragraph [108]
Misleading Conduct Obligations	is defined at paragraph [7](c)
MSB Equity Swaps	is defined at paragraph [2](a)(iv)
MSB ADRs	is defined at paragraph [2](a)(ii)
MSB Shares	is defined at paragraph [2](a)(i)
MSC	Mesenchymal Stem Cell
Muntner	Mr Josh Muntner
NASDAQ	means the Nasdaq Global Select Market
Non-compliance with FDA Advice regarding a-GVHD Information	is defined at paragraph [64]
ODAC	Oncologic Drugs Advisory Committee of the FDA
ORR	overall response rate
Osiris	Osiris Therapeutics Inc.
PHS Act	Public Health Services Act (US)
Pilot Study Information	is defined at paragraph [70]
Pilot Study Future Representation	is defined at paragraph [104]
PR	partial response
Protocol 265	is defined at paragraph [48]

Protocol 265 Information	is defined at paragraph [51]
Protocol 280	is defined at paragraph [43]
Protocol 280 Information	is defined at paragraph [47]
PR	Partial response
R-L	Remestemcel-L
R-L Efficacy Representation	is defined at paragraph [101]
R-L Manufacturing Representation	is defined at paragraph [94](b)
R-L Quality Representation	is defined at paragraph [93]
Rosa-Bjorkeson	Ms Dagmar Rosa-Bjorkeson
RYONCIL	is the trade-mark name registered by Mesoblast for R-L
SAP	Statistical Analysis Plan
Simmons	Dr Paul Simmons
Skerret	Dr Donna Skerret
SR-aGVHD	Steroid Refractory Acute Graft Versus Host Disease
SR-aGVHD Application	is defined at paragraph [14](a)
SR-aGVHD Claim Period	is defined at paragraph [89](a)
SR-aGVHD Representations	is defined at paragraph [111]
SR-aGVHD Trial Deficiencies Information	is defined at paragraph [84]
SR-aGVHD Approval Application Deficiencies Information	is defined at paragraph [85]
Storton	Ms Geraldine Storton
Study 001	is defined at paragraph [55]
Study 001 FDA Interactions Representation	is defined at paragraph [90](c)
Study 001 Information	is defined at paragraph [57]
Study 001 No Support for ARDS Treatment Information	is defined at paragraph [67]
Study 001 Outcome Future Representation	is defined at paragraph [90](d)
Study 001 Support for R-L Use in COVID-19 Patients Future Representation	is defined at paragraph [100]
Substantial Evidence Draft Guidance	FDA, Guidance for Industry: Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products [Draft], (Dec 2019)

Three Studies Confirmatory Evidence Representation	is defined at paragraph [98]
Three Studies Reliance Representation	is defined at paragraph [96](a)
Unlikely to be Approved by FDA Information	is defined at paragraph [66]
Unproved Consistency in Manufactured Product Information	is defined at paragraph [61]
USC	United States Code

Certificate of lawyer

I, Ding Pan, certify to the Court that, in relation to the Amended Consolidated Statement of Claim filed on behalf of the Applicants, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 20 December 2023

Signed by Ding Pan
Joint Lawyer for the Applicants

I, Diana Clare Forbes Young, certify to the Court that, in relation to the Amended Consolidated Statement of Claim filed on behalf of the Applicants, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 20 December 2023

Signed by Diana Clare Forbes Young
Joint Lawyer for the Applicants