



AROA BIOSURGERY DECEMBER 2020 4C – COMMENTARY

HIGHLIGHTS

- Aroa maintains expectation to deliver revenue growth on H2 FY20, equating to more than NZ\$21.0m for FY21 on a constant currency basis (i.e. eliminating impact of exchange rate fluctuations)
 - Cash outflow from operations was modest for the December quarter at NZ\$1.1 million and in line with Aroa's internal budget
 - Cash on hand of NZ\$36.8 million as at 31 December
 - Aroa received regulatory approval for three products from India's Central Drugs Standard Control Organisation (CDSCO)
 - Aroa is targeting distribution of its products in India in H2 CY21 and confirms appointment of an experienced Indian distributor to manage a network of sub-distributors across the subcontinent
 - Aroa gains further validation for Myriad™ with two recent clinical studies published in leading peer reviewed scientific journals
 - Aroa initiates manufacturing expansion to support future anticipated demand across the product portfolio
 - Intellectual property portfolio expands with a new patent application for a treatment system to approximate surgically-created tissue planes. The European Patent Office has notified the Company that a patent for the laminated tissue graft product will be granted.
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Soft tissue regeneration company Aroa Biosurgery Limited (ASX:ARX, 'Aroa' or the 'Company') is pleased to provide an update on its activities for the quarter ended 31 December 2020 and release its Appendix 4C.

Financial commentary

With sales in the June quarter being impacted by the COVID-19 pandemic, Aroa saw an improvement in the September quarter and sales have continued to improve during the December quarter. Aroa maintains its expectation to deliver sales growth on H2 FY20, on a constant currency basis (i.e. when eliminating the impact of exchange rate fluctuations, namely USD vs NZD).

Cash receipts for Q3 FY21 (NZ\$5.9 million) were higher than Q2 (NZ\$4.1 million), reflecting the improvement in sales over the course of the September and December quarters.

Cash outflow from operations for the December quarter remained modest at NZ\$1.1 million and in line with Aroa's internal budget, ending the quarter with cash on hand of NZ\$36.8 million.

In accordance with ASX Listing Rule 4.7C.3, Aroa advises that an aggregate amount of NZ\$105k was paid during the quarter to Aroa's five Non-Executive Directors in payment of their director fees.

Appendix A provides a summary of actual expenditure, compared to the estimated use of funds set out in the Prospectus, in accordance with ASX Listing Rule 4.7C. Cash expenditure is consistent with the use of funds set out in Aroa's IPO Prospectus.

Aroa receives Indian regulatory approval for three products

In December, Aroa received regulatory approval to introduce three products to the Indian market based on its Aroa ECM platform. The three products, Myriad™, Endoform® Natural and Endoform® Antimicrobial, were approved under the 'Medical Device Rules 2017' by the national regulatory authority of India, the Central Drugs Standard Control Organisation (CDSCO).

Estimates of the value of the advanced wound care market in India range from US\$225-485 million in 2020, with compounding growth between 5.5 and 8 percent per year.

Aroa is targeting distribution of its products in India in the second half of the 2021 calendar year and has appointed an

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experienced master distributor to secure and manage a network of sub-distributors across the subcontinent.

Endoform® Natural and Endoform® Antimicrobial both provide a tissue matrix for treating chronic wounds (e.g. diabetic foot ulcers and venous leg ulcers) particularly during the inflammatory phase of healing. Myriad™ is a highly perforated, multi-layered extracellular matrix (ECM) graft engineered to have a high volume and surface area with interstitial spaces that are easily and rapidly accessible to cells.

Aroa has five commercial products approved for sale in the US based on its ECM technology, which has been used in more than four million procedures targeting chronic wounds, hernia and soft tissue. Aroa has regulatory market authorisation in more than 44 countries.

Further validation for Myriad™

Aroa gained further validation for soft tissue reconstruction device Myriad™, with two recent studies published in leading peer reviewed scientific journals.

The first study showed 100% healing when Myriad™ was used in eight surgical reconstructions to address inflammatory skin condition Hidradenitis Suppurativa (HS). No major complications were reported out to three months, or longer.

The paper, titled “*Extracellular Matrix Graft for the Surgical Management of Hurley Stage III Hidradenitis Suppurativa: A Pilot Case Series*” was based on a study undertaken by Dr. Abigail Chaffin (Tulane University, New Orleans) and Dr. Maire-Claire Buckley (University of Minnesota, Minneapolis).

Dr Chaffin, Associate Professor of Surgery and Program Director of the Tulane University Plastic Surgery Residency Program, said the study demonstrated the utility of the Myriad™ device for both implant procedures and dermal reconstruction, with no significant complications reported and offers a potential solution for people suffering the most serious cases of HS.

HS is a skin condition where the tissue becomes highly inflamed, and often involves infected lesions, particularly in the groin and armpit areas. It is estimated to affect around 1% of the adult population¹. Around 4% of HS patients are deemed to be severe cases (known as Stage III)², which are difficult to treat and often require surgical excision; with resulting complications as high as 20% of cases³. The study can be found online at <https://www.magonlinelibrary.com/doi/abs/10.12968/jowc.2020.29.11.624>.

The second study showed 100% healing when Myriad™ was used in six surgical reconstructions of soft tissue defects with exposed vital structures and included a variety of different wound types; e.g. full thickness scalp excision, scar revision surgery, tumor (squamous cell carcinoma) excision, traumatic wound, surgical dehiscence, and fistula.

The paper, titled “*Extracellular Matrix Graft for Reconstruction Over Exposed Structures: A Pilot Case Series*” was based on a study also undertaken by Dr Chaffin in conjunction with Dr Gregory Bohn (Central Michigan School of Medicine).

Soft tissue loss, whether from disease, trauma, injury or surgical intervention often exposes underlying tendon or bone, referred to as ‘vital structures’ and may also include veins, arteries or nerves.

Dr Chaffin said the study showed how the Myriad™ device could be effectively used for both implant procedures and dermal reconstruction across a wide range of different surgical procedures. All patients healed well with no complications and no infections were reported, even when Myriad™ was used in a contaminated field. The study can be found online at <https://www.magonlinelibrary.com/doi/full/10.12968/jowc.2020.29.12.742>.

Both studies are published in the *Journal of Wound Care*, the official journal of both the European Wound Management Association (EWMA) and the World Union of Wound Healing Societies (WUWHS).

¹ <https://onlinelibrary.wiley.com/doi/abs/10.1111/jdv.12966>

² Bouazzzi D, Chafanska L, Saunte DML, Jemec GBE. Systematic Review of 22 Complications and Recurrences After Surgical Interventions in Hidradenitis 23 Suppurativa. *Dermatol Surg.* 2020;46(7):914-921.

³ Ovadja ZN, Jacobs W, Zugaj M, van der Horst C, Lapid O. Recurrence Rates 25 Following Excision of Hidradenitis Suppurativa: A Systematic Review and 26 Metaanalysis. *Dermatol Surg.* 2020.

The findings across these two studies indicate high rates of healing and no major complications or infections even in the presence of contaminated wounds. Importantly, these outcomes are consistent with the potential benefits and outcomes of Endoform® in chronic wounds and Ovitex™ in hernia. The Company is encouraged by these results. As surgical procedure volumes recover in United States as the COVID-19 vaccination gains momentum, Myriad™ will play a central role in Aroa's commercial growth strategy.

Manufacturing Expansion

Aroa expects growing demand in H2 2021 and has initiated expansion of its new facility to ensure that sufficient capacity is in place by the end of 2021 to meet expected demand over the next three years. The expansion will also provide scaled up capacity for new products and additional laboratory space to support development activities.

Intellectual Property

Aroa continues to build out the Company's intellectual property portfolio with a new provisional PCT international filing for a novel treatment system for prevention of seroma and to approximate surgically-created tissue planes. This patent complements existing filings for a fluid drainage and delivery device and negative pressure wound dressing patent families.

The Company has also received notification from the European Patent Office that the laminated tissue graft patent will be granted in the European Union. This follows the grant of a corresponding patent (US 10,548,705) in United States and protects important proprietary engineered design features of both Myriad and Symphony.

Authorised on behalf of the Aroa Biosurgery Board of Directors by Brian Ward, CEO.

About Aroa Biosurgery:

Aroa Biosurgery is a soft-tissue regeneration company that develops, manufactures, sells and distributes medical and surgical products to improve healing in complex wounds and soft tissue reconstruction. Committed to 'unlocking regenerative healing for everybody', its products are developed from the Company's proprietary Endoform® technology platform, a novel extracellular matrix biomaterial derived from ovine (sheep) forestomach. Clinically proven with peer reviewed publications, Aroa's products have been used in more than four million procedures to date, with distribution into its key market of the United States by Appulse and Tela Bio. Founded in 2008, Aroa is headquartered in Auckland, New Zealand and is listed on the Australian Securities Exchange (ASX:ARX). www.aroabio.com/

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In accordance with ASX Listing Rule 4.7C, Aroa provides the following use of funds information:

Use of funds	Prospectus Estimate NZ\$m	Actual Funds Used NZ\$m	Actual as a % of Estimate	Note
Investment in sales and marketing	\$5.0	\$0.6	12%	1
Investment in additional manufacturing capacity, investment in new products, plant and equipment and other general corporate capital expenditure	\$5.0	\$0.3	6%	2
Working capital, other operating costs	\$5.0	\$2.1	42%	3
Repayment of borrowings	\$13.1	\$0.0	0%	4
Offer costs	\$3.8	\$3.9	104%	5
Total	\$31.9	\$6.9	17%	

Notes:

1. Commencement of new sales and marketing initiatives including new hires in Q3 FY21.
2. Preliminary costs of manufacturing expansion in Q3 FY21.
3. Net operating cash outflows for Q2 & Q3 FY21, excluding cash outflows relating to the investment in sales & marketing (\$0.6m).
4. Maturing 31 March 2022. Remains unchanged from Q2 FY21.
5. Includes cash outflows prior to IPO. Remains unchanged from Q2 FY21.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Aroa Biosurgery Limited

ABN

ARBN 638 867 473

Quarter ended ("current quarter")

31 December 2020

Consolidated statement of cash flows	Current quarter \$NZ'000	Year to date (9 months) \$NZ'000
1. Cash flows from operating activities		
1.1 Receipts from customers	5,859	15,984
1.2 Payments for		
(a) research and development	(334)	(1,096)
(b) product manufacturing and operating costs	(717)	(2,795)
(c) advertising and marketing	(1,585)	(5,183)
(d) leased assets	(4)	(13)
(e) staff costs	(2,866)	(8,085)
(f) administration and corporate costs	(1,966)	(4,369)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	2	5
1.5 Interest and other costs of finance paid	-	(853)
1.6 Income taxes paid	(22)	292
1.7 Government grants and tax incentives	518	1,971
1.8 Other (rent received)	46	101
1.9 Net cash from / (used in) operating activities	(1,069)	(4,041)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(319)	(782)
(d) investments	-	-
(e) intellectual property	(38)	(210)
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$NZ'000	Year to date (9 months) \$NZ'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(357)	(992)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	15	32,589
3.2	Proceeds from issue of convertible debt securities	-	19,804
3.3	Proceeds from exercise of options	18	2,273
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(2)	(4,357)
3.5	Proceeds from borrowings	-	265
3.6	Repayment of borrowings	(30)	(12,600)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (lease liability payments)	(209)	(511)
3.10	Net cash from / (used in) financing activities	(208)	37,463

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	38,683	3,850
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,069)	(4,041)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(357)	(992)

Consolidated statement of cash flows		Current quarter \$NZ'000	Year to date (9 months) \$NZ'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(208)	37,463
4.5	Effect of movement in exchange rates on cash held	(234)	535
4.6	Cash and cash equivalents at end of period	36,815	36,815

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$NZ'000	Previous quarter \$NZ'000
5.1	Bank balances	16,815	18,683
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (term deposits >90 days)	20,000	20,000
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	36,815	38,683

6.	Payments to related parties of the entity and their associates	Current quarter \$NZ'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	105
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7. Financing facilities	Total facility amount at quarter end \$NZ'000	Amount drawn at quarter end \$NZ'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	10,805	9,335
7.2 Credit standby arrangements	446	326
7.3 Other (please specify)	-	-
7.4 Total financing facilities	11,251	9,661
7.5 Unused financing facilities available at quarter end		1,590
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
Includes the following: <ol style="list-style-type: none"> 1. an unsecured loan of NZ\$9.3m from Hollister Incorporated at 6.25% p.a. with a maturity date of 31 March 2022; and 2. a secured facility of NZ\$1.5m with the Bank of New Zealand at 5.16% p.a., which remained undrawn as at 31 December 2020. 		

8. Estimated cash available for future operating activities	\$NZ'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,069)
8.2 Cash and cash equivalents at quarter end (item 4.6)	36,815
8.3 Unused finance facilities available at quarter end (item 7.5)	1,590
8.4 Total available funding (item 8.2 + item 8.3)	38,405
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	35.9
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: N/A	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: N/A	

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 27 January 2021.....

Authorised by: By the board.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.