ASX ANNOUNCEMENT/MEDIA RELEASE
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AROA BIOSURGERY HALF YEARLY REPORT H1 FY21

HIGHLIGHTS

- H1 FY21 product revenues (unaudited) of NZ$9 million was down 10% compared to H1 FY20 but ahead of the Company's COVID-19 adjusted planning assumptions. The Company expects to deliver revenue growth on H2 FY20 (NZ$11.9m) as COVID-19 restrictions are expected to ease, equating to more than NZ$21.0m for FY21
- Aroa lists on the ASX on 24 July 2020 after raising $45m at $0.75/share, with an indicative market capitalisation of A$225m
- Received US FDA clearance for Aroa's Symphony™ product in July for complex wounds in patients with severely impaired healing and a reimbursement application has been submitted to support a limited commercial launch in 2021
- Received CE Mark approval for Aroa's Myriad™ product in July to allow commercialisation to begin in the EU
- Study published in peer reviewed journal, *PLOS ONE,* provides further insights on the ability of components found within the Aroa ECM platform technology to recruit stem cells from surrounding healthy tissue to support soft tissue repair
- Aroa's Myriad™ peer-reviewed publication in Journal of Wound Care after clinical study found high success rates from use of Myriad™ in tissue reconstruction after surgical treatment of Hidradenitis Suppurativa, an inflammatory skin condition affecting around 1% of the adult population.

Soft tissue regeneration company Aroa Biosurgery Limited (ASX:ARX, 'Aroa' or the 'Company') is pleased to report on its operations and financial performance for the half-year ended 30 September 2020. This is the first financial report following Aroa's listing on the ASX on 24 July 2020 after raising A$45m.

Financial Commentary

After sales earlier in the half-year were impacted by the COVID-19 pandemic, Aroa saw improvement in sales towards the end of the half with recovery from the COVID-19 downturn exceeding Aroa's internal expectations. H1 FY21 product revenues were down 10% compared to H1 FY20, but ahead of the Company's COVID-19 adjusted planning assumptions.

The company ended the half-year in a strong financial position with cash on hand of NZ$38.7 million.

Normalised Profit or Loss	Unaudited 30 September 2020 NZ$000	Unaudited 30 September 2019 NZ$000
Product sales	9,002	10,037
Other revenue	178	3,128
Total revenue	**9,180**	**13,165**
Cost of sales	(3,145)	(3,057)
Gross profit	**6,035**	**10,108**
Gross margin %	**66%**	**77%**
Other income	1,869	480
Normalised selling and administrative expenses	(8,561)	(7,030)
Research and development	(2,791)	(2,474)
Normalised other losses	(2)	(2)
Total normalised operating expenses	**(11,354)**	**(9,506)**
Normalised EBIT	**(3,450)**	**1,082**
Add back: Depreciation & amortisation	1,134	1,071
Normalised EBITDA	**(2,316)**	**2,153**

Note: The Normalized Profit or Loss is non-conforming financial information, as defined by the NZ Financial Markets Authority, and has been provided to assist users of financial information to better understand and assess the Group's comparative financial performance without any distortion from NZ GAAP accounting treatment specific to the one-off, non-cash fair value adjustment of pre-offer shares issued in February and May 2020 and the one-off transaction costs associated with the initial public offering on ASX in July 2020. This approach is used by management and the Board assess the Group's comparative financial performance.

Product sales

Product sales of $9.0 million for the half-year were down 10%, compared to H1 FY20 ($10.0 million). Product sales in the first quarter were impacted by the COVID-19 pandemic, however the Company has seen an improvement throughout the second quarter, exceeding management's internal expectations.

Other revenue

Other revenue represents Royalties, received under the Company's licensing agreement with Tela Bio Inc. and Project fees income, received for product development projects undertaken with TelaBio Inc. No Royalties were payable under the licensing agreement for the half-year, compared to the $3.0 million received in H1 FY20.

Gross margin %

Gross margin % of 66% for the half-year was down 11%, compared to H1 FY20 (77%), primarily due to the one-off Royalties received in H1 FY20. Product gross margin % of 65% for the half-year was down 5% compared to H1 FY20 (70%) as a result of the lower product revenues (due to COVID-19) combined with the higher level of fixed indirect costs invested in during H2 FY20 to support higher sales volumes.

Other income

Other income represents government grants and subsidies.

Normalised operating expenses

Selling and administrative expenses for the half-year were up $1.5 million, compared to H1 FY20, primarily reflecting the increased investment into the Company's US based sales operations. Share based payments of $0.5 million for the half-year were up $0.4 million, compared to H1 FY20 and are a non-cash expense attributable to share options issued to Directors, key management and certain employees. The increase is a result of the new options issued upon the completion of the IPO in July 2020.
In addition, expenses increased as a result of becoming a publicly listed entity.

Research and development expenses for the half-year were up $0.3 million, compared to H1 FY20, reflecting the increase in staffing on pipeline products.

Management Commentary

Stepping up US commercial presence & international expansion

Buoyed by the improving outlook for the second half of FY21, Aroa will strengthen its US commercial team with three new field and two inside sales representatives and two medical science liaisons. The Company intends to add a further 10 field sales representatives in FY22 to primarily focus on sales of Myriad™ which has a total estimated market size globally of US$350 million. Similarly, Aroa's US partner, TELA Bio, has added a further 10 field sales representatives to drive increased adoption of Ovitex and Ovitex PRS in hernia and breast surgery. Increased sales resources will allow a deeper penetration within existing accounts to expand usage in more procedures.

Outside of United States, Aroa is continuing to execute its international market expansion strategy and secure new regulatory approvals and local distributors. In the last six months Myriad™ has been approved by regulatory authorities in Europe, Malaysia, Thailand, Israel, Jordan and Saudi Arabia, while Endoform® has been approved in Malaysia and Mexico. In addition, local distributors have been appointed in Italy, Portugal, Malaysia, Indonesia, Mexico, Israel, Kuwait, Oman, Qatar, UAE and Saudi Arabia.

Staged product pipeline supports growth

Myriad™ particles provide Aroa's ECM in a convenient powdered format for surgical use in complex wounds in patients with impaired healing. In the last six months the Company has filed for a 510k clearance and is currently in a review process with the FDA. Aroa expects clearance in Q4 FY21 and with an immediate opportunity for this product to contribute to Myriad™ sales and increase gross margin.

Symphony was cleared by the US FDA in July 2020 and an application has been filed with Centres for Medicare and Medicaid Services (CMS) for reimbursement coding. The product has successfully been transferred to manufacturing and Aroa expects product to be available early in CY21 for clinical studies and a limited commercial launch. Full commercial launch is targeted for CY22.
Positive progress has been made with Aroa's negative pressure wound therapy (NPWT) development programme in pre-clinical models and the Company expects to provide an update on development activities and commercialisation plans in Q4 FY21 The development team for this project has been expanded to 21 and a further patent application has been filed to build on the previous application for a fluid drainage and delivery device.

Manufacturing productivity gains & commencing facility expansion

Aroa secured additional premises at the beginning of 2020, adjacent to the existing facility, to allow for further expansion of manufacturing facilities. Over the last six months, process improvements in manufacturing have led to significant improvements in capacity, which have helped to delay capital expenditure and will lead to margin improvements. With growing demand across the portfolio, the Company has initiated expansion plans and expects the first stage to be completed by December 2021.

Regenerative science underpins Aroa ECM platform

The Company continues to add to the substantial body of evidence which demonstrates that Aroa's ECM has unique regenerative characteristics which distinguish it from synthetics and traditional biologics. A peer reviewed study published in July 2020 showed that a protein released from Aroa's ECM during healing, was shown to communicate with stem cells and play an important role during normal soft tissue repair (https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0235784). This study builds on previous peer reviewed studies which have shown that the Aroa ECM platform includes over 150 proteins which are known to play an important role in wound healing and tissue regeneration.

Strong clinical outcomes in challenging cases

Aroa continues to be very encouraged by emerging clinical evidence which shows that the healing properties of Aroa's ECM consistently contributes to positive outcomes across the product portfolio in a mix of procedures. These benefits are pronounced in complex cases where the presence of infection and inflammation are a major challenge and can lead to high rates of complications. A recent investigator-led study by Parker et al from Indiana University titled "A novel biosynthetic scaffold mesh reinforcement affords the lowest hernia recurrence in the highest risk patients" (Surgical Endoscopy https://doi.org/10.1007/s00464-020-08009-1, published on-line 24 September 2020) compared 50 high risk patients with Ovitex implants versus 50 low risk patients implanted with synthetic mesh. Despite the marked difference in risk, Ovitex recurrence rates were 8% versus 12% for synthetic mesh. Similarly, in the multi-centre BRAVO study of complex hernia, where infection and inflammation are common, only one recurrence was reported in 57 patients at 12 months and there were no recurrences for the 20 patients at two years follow up. These studies are contributing to growing interest and demand for Ovitex which has now been used in over 10,000 patients.

Pleasingly, early use of Myriad™ in soft tissue reconstruction is showing similar outcomes. A recent study in six patients with Hydradenitis Supprativa (a skin condition where the tissue becomes highly inflamed and often involves infected lesions), showed 100% healing when Myriad™ was used for both implant procedures and dermal reconstruction in eight surgical sites. The complication rates in these patients typically ranges from 5-26%.

The Ovitex and Myriad™ outcomes are also consistent with previous Endoform® studies in diabetic foot ulcers and venous leg ulcers. In these conditions, Endoform® is frequently used in the presence of inflammation, bacterial colonisation and infection. Aroa expects to present further results from a 6,500 patient post market real world retrospective study in chronic wounds in Q4 FY21.

Importantly, for the product portfolio, Aroa's ECM platform is continuing to demonstrate that it can provide robust tissue regeneration in patients with impaired healing in the presence of inflammation and infection. The existing clinical evidence coupled with an upcoming readout in Q4 CY20 from the Bravo Study, Myriad™ studies investigating use as a graft over exposed tendon and bone and a further study in complex non-healing wounds are expected to provide further evidence to drive increased adoption for both complex and more routine cases.

Emphasis on virtual promotion

With reduced face-to-face physical meetings, the Company has placed a strong focus on virtual presentations, webinars and their presence at major conferences. Increased focus has been placed on the engagement of key opinion leaders to highlight the use of Aroa's Endoform® "high flow" product with negative pressure wound therapy and Myriad™ for soft tissue reconstruction. In the future, Aroa believes there is an increasing opportunity to build on its San Diego-based inside sales capability to complement the field sales team.

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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 Aroa ECM 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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