

PolyNovo FY21 Results

26 August 2021

Improving outcomes. Changing lives.



PolyNovo Reaches Breakeven

Despite Covid PolyNovo has achieved significant revenue growth and achieved a small profit (excluding non-cash items).

- Cash increased 0.4% between 1H21 and FY21
- Continued account acquisition in all regions
- Signed 3 US GPOs
- Expanded geographical reach in US
- Entered 8 new markets throughout EU and Asia
- Manufactured Syntrel hernia device and commenced an animal study to demonstrate bio-absorption rates, biocompatibility, toxicology profile, and efficacy in hernia repair.
- Commissioned new factory



* Excluding non-cash items, refer to reconciliation on p. 30

Top Line Summary – FY21 Dashboard

NovoSorb® BTM USA Sales (\$USD)



NovoSorb BTM Group Sales



Total Group Revenue



BARDA Revenue



Total Employees



Employee Related Expenditure

(excl. share-based payments)



Cash on Hand FY21/1H21



Net Cash Outflow Operating Activities



Capital Expenditure



United States

Our US business is profitable and our largest revenue contributor. We have continued to expand our sales and marketing team. We see further investment in expanding the capacity to drive revenue growth. The NovoSorb SynPath chronic wound study has completed the first 10 patients and we now embark on the second phase of this clinical trial. Our BARDA funded pivotal trial is in progress with 20 sites being enrolled and a further five Canadian sites to be added.



South Africa

Our South African distributor, Ascendis Medical, is achieving reasonable sales through the public hospital system. Access to the Private Health system has been limited due to reimbursement constraints of health insurers. We will continue to support Ascendis in their endeavours for reimbursement.



Europe

Our European expansion has been significant in FY21. Our distributor model in Europe is allowing PolyNovo to rapidly expand across Europe without significant cost and should generate profit in FY22. We have a new 3PL partner for Europe allowing us to efficiently service many markets.



UK / Ireland

Until January UK/Ireland has been highly restricted by Covid. We are seeing a gradual increase in surgical activity and the re-engagement of face-to-face sales calls. Sales are trending well, and we have added a sales role in Ireland, and a further three roles in the UK. Ireland has seen a rapid uptake of NovoSorb BTM and we see good growth opportunities throughout UK / Ireland.



Middle East

Good potential delayed due to Covid. As vaccination programs allow greater access, we anticipate market entries in H2 FY22.



Asia

Direct sales in Singapore are progressing well with eight hospitals purchasing NovoSorb BTM for use in a wide range of elective and trauma cases. We also appointed a distributor in Taiwan in October with a first sale in December 2020. Taiwan is an advanced medical market, and we anticipate FY22 to be a strong year. Surgeon feedback is excellent.

Australia

Very strong sales growth in FY21 despite Covid restrictions. Our penetration of the burn market is significant, and we have achieved solid growth in elective surgery with sales to many public and private hospitals. We added two additional salespeople and see strong growth continuing throughout FY22.



New Zealand

Strong sales growth in New Zealand across all major hospitals. The expansion of BTM use across a wide variety of surgical applications has been exciting with market penetration expected to continue in FY22. Peer to peer referrals are strong and the surgical outcomes are outstanding.



Distributors appointed in:

- Finland – September '20
- Taiwan – October '20
- Belgium, Netherlands, Luxembourg (Benelux) – November '20
- Greece – November '20
- Turkey – January '21
- Poland – January '21
- Italy – February '21



Marketing and Sales

Highlights by region

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- NovoSorb®BTM sales revenue grow to \$USD 15.5M, representing **49%** YoY growth.
- 2H21 outpaced 1H21 by 38% or \$USD 2.5M.
- Q3 and Q4 were both record quarters, with Q4 coming in just shy of all 2019 sales.
- Added 44 new accounts and recorded sales from 92% of our current accounts.
- Recruited top level talent and doubled our sales team from **18** to **36**, providing greater account penetration, new account acquisition, and geographical representation.
- Added key functional roles in the US over the course of the year, including Clinical, Finance, Marketing, and Human Resources.
- Expanded our Canadian reach with an additional large center through special access/exemption scheme – benefiting patient outcomes.
- Commenced the BARDA funded Pivotal Trial which will recruit patients in up to 30 North American sites, US and Canada.
- Commenced SynPath (Chronic Wound/DFU) reimbursement trial with first 10 patients completed. Final report due in September but early results show complete healing within 12 weeks.
- Signed 3 GPO/IDN agreements in late FY21 that increase PolyNovo's account access and sales. Ongoing discussions with an additional 3 major GPO's.
- Developed and executed a successful digital marketing/sales campaign ensuring strong growth throughout the pandemic.

- Grew NovoSorb BTM revenue in Australia by 25% and volume 35%. Volume increase reflecting penetration into smaller wounds/elective procedures.
- Appointed two additional sales people enabling greater territory penetration and coverage.
- New Zealand -5% growth YoY which is strong without FY20 White Island disaster.
- New account acquisitions throughout the region.
- Expansion into private hospital network with NovoSorb BTM use in elective surgery.
- Excellent digital campaigns building our customer engagement.

- NovoSorb BTM sales in 23 NHS.
- Sales predominantly in elective and trauma. FY22 will see expansion into burns with 70% of Burns Centres having purchased.
- Maintained and developed staff through Covid lockdown, enabling us to build relationships with key customers to quickly engage post lockdown.
- Established direct sales in Ireland with strong sales momentum.
- Attended several chronic wound forums generating interest in smaller sizes of NovoSorb BTM for launch in late CY 2021.
- Currently recruiting additional sales people for revenue acceleration.
- We have seen the first data published from the UK, Ireland and German hospitals.
- This year we have worked with the BBC StoryWorks team, in conjunction with the ICBA and they have produced a film for us as part of their international Natures Building Blocks series.
- BTM was also recently featured in the BBC Hospital series following patients at a UK hospital.

- Strong performances in Germany, Austria, Switzerland, Belgium, Netherlands, Finland, Norway and Denmark. Other regions building well.
- 53% growth in distributor sales.
- Strong peer to peer referrals through webinars and conference presentations.
- Expanded geographical reach throughout FY21 with good sales momentum despite Covid.
- Establish a solid foundation for growth that will be enhanced with our Belgium based distribution centre coming on line in September 2021.
- Working on France, Portugal and Spain entry in FY22.

New Product Pipeline

Research & Development



Hernia Devices

- Factory complete and machinery commissioned/validate.
- Final fully commercial versions of product manufactured and large animal study commenced.
- Successfully manufactured 1300+ devices in various SKU sizes for the validation processes and testing programs.
- Large animal study in progress for resorption rate, toxicology and biocompatibility data.
- Submit 510(K) dossier to US FDA in circa March 2023.



Syntrel Hernia device



Polymer manufacturing

NovoSorb® BTM

- Addition of smaller sizes for chronic wounds
 - 2x2 cm
 - 5x5cm
- Additional sizes for reimbursement in some countries e.g.: 20x20cm.
- EU, Australia/New Zealand launch October 2021.
- Other markets to follow.

NovoSorb® SynPath™

US Alternate Care/ Community Market

- Unique sizes and shapes of NovoSorb BTM for the US Alternate care \$400m market (community/ non-hospital).
- DFU/VLU **reimbursement** study in progress, first patient 10 patients with diabetic foot ulcers healed.
- Next phase will recruit 100 patients.
- Launch once reimbursement established circa late 2023/early 2024.

NovoSorb®

Plastics and Reconstructive Device

- Development brought in house.
- Employed dedicated marketing resource.
- Project team established and surgeon engagements have commenced.
- Building detailed project plan and timelines which will be shared at half year results.
- Estimate a 3 year + development path.

Betacell Diabetes Treatment

- PolyNovo will supply Betacell with NovoSorb BTM for use in their studies. Betacell are ready to commence human trials as soon as Covid restrictions allow. Trial is being conducted in Adelaide.

- Remain agile in our response to Covid.
- Aggressive revenue growth through sales team expansion, geographic expansion and targeted marketing programs.
- Continue the expansion of R&D resources to concurrently develop multiple new NovoSorb devices.
- Execute the Pivotal Trial (BARDA).
- Launch small NovoSorb BTM sizes in EU/UK/Australia/New Zealand/Singapore.
- Continue the US SynPath reimbursement trial targeted at diabetic foot ulcers (DFU) and venous leg ulcers (VLU).
- Recruit patients into the Flinders University arterial leg ulcer trial.
- Continue to support clinical publications of NovoSorb BTM (see website).
- Continue the hernia animal study to demonstrate bio-absorption rates, biocompatibility, toxicology profile, and efficacy in hernia repair.

COVID-19

Sales / Marketing Innovations



Hospitals, globally, are still challenged by Covid and forecasting revenue is challenging despite our recent strong performance.

Some increase in logistic cost and workload however maintaining supply routes, holding high inventory levels.

Markets

- Vaccinations do seem to be opening hospital capacity. Some areas in the US remain challenging with low vaccination rates.
- US: generally improved face to face access for sales teams. Can enter operating rooms however sales calls will be a mix of digital and face to face.
- UK/Ireland: Hospital access has improved. Elective surgery rates are recovering. Steady revenue improvements.
- Maintaining surgeon engagement in Australia, however we continue to see fluctuations in elective surgery rates.
- Intermittent access to NZ from Australia, good digital engagement, good growth in sales and wide indications use.
- EU: Continued expansion in FY22. Virtual market support throughout FY21 however we see improving face to face access.

BTM Use in a Paediatric Population

Professor Roy Kimble, Paediatric Surgeon
Queensland Children's Hospital, Brisbane Australia

Paediatric surgeons manage additional complexities when treating acute injuries and complex wounds for small and growing patients. Professor Kimble will share his vast experience, observations and 10 Tips to improve outcomes using NovoSorb BTM.

[Read More](#)



Use of NovoSorb BTM for Complex Reconstruction of the Hand and Extremities

Dr. Shaun D. Mendenhall, Plastic Surgeon
University of Utah Medical Centre, UT, USA

Discover how a level 1 trauma centre successfully implemented NovoSorb BTM for their complex reconstructions.

[Read More](#)



BTM in Surgical Wounds. Cases from 5 years of experience

Dr Marcus Wagstaff, Plastic Surgeon
Royal Adelaide Hospital, SA, Australia

We are delighted that Dr Wagstaff will share insights, case experience and lessons learned over 5+ years using NovoSorb BTM; from the first necrotising fasciitis cases, to trauma, complex ulcers and cancer patients.

[Read More](#)



Full service 3PL warehouse facilities in:

- US
- New Zealand
- Australia
- Singapore
- England
- Belgium



All facilities well stocked with inventory to address forward demand expectations and FY22 sales targets.

We can service customers promptly in any region.



Other Matters

- BARDA
- Capital Works
- New Facility
- Talent
- Diversity
- ESG

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BARDA Trial Program Revenue



- Pivotal trial is open for recruitment, screening of eligible patients in progress.
- 25 US sites and 5 Canadian sites being enrolled.
- FY22 will see higher BARDA income commensurate with the patient recruitment activities.
- BARDA committed \$15m USD towards the trial.
- Strong relationship with BARDA.



We completed our build and commissioning of the Unit 1 manufacturing facility providing capacity and flexibility for the future.

Capabilities of facility:

- Synthesis polymers
- Extrude film, fibre and micro-spheres
- Ultrasonically weld NovoSorb devices
- Additional foam cutting capacity
- Automated packaging coming online September
- Provides redundant BTM manufacturing capacity.

FY22 committed capex is \$0.39m.



Inside new cleanroom facility: continuous foam cutting machine



Inside new cleanroom facility: shape cutting and ultrasonic welding table- Hernia

Take a virtual tour of our new facility

Dr Anthony Kaye COO provides an overview of the new factory facility in Unit 1.



Total employees at 13 August 110 compared with 78 June 2020.

- Expansion of sales and marketing roles will continue throughout FY22 to drive sales and market penetration.
- US will remain our largest market and focus.
- Will invest further in EU team for continued market penetration and supporting our distributor network.
- Research and Development team has expanded with further/recent scientist and laboratory assistance. Additions to these teams will continue through FY22 to expand our capacity to develop new devices concurrently.
- PolyNovo is currently working with an external consultancy group to assist in organizational structure to match the next 5 years of anticipated revenue and business growth.

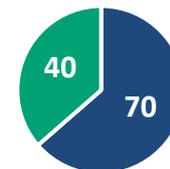


Staff Diversity and plans

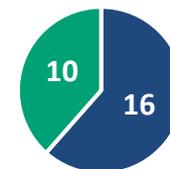
Total Staff by Department	Staff #s	Female	Middle East/African	Hispanic	Asian	Female	Middle East/African	Hispanic	Asian
Sales	43	15	1	1	4	35%	2%	2%	9%
Marketing	9	4	1	0	1	44%	11%	0%	11%
Rest of Company	58	21	5	2	28	36%	9%	3%	48%
Total Company	110	40	7	3	33	36%	6%	3%	30%
Managers/ Supervisors	26	10	1	0	8	38%	4%	0%	31%
C Suite	4	0	0	0	0	0%	0%	0%	0%

- PolyNovo is proud of our diverse head office team.
- PolyNovo has an affirmative action policy for the US business to increase diversity.
- PolyNovo is committed to gender and racial equality striving to have our staff representative of the communities in which we work.
- We will publish our diversity statistics each reporting session.
- Above table is at 13 August 2021.

All Employees



Managers / Supervisors



Board of Directors



■ Male ■ Female

- Continue our drive towards diversity in all our markets.
- Develop a detailed and measurable carbon offset plan.
- Continue to drive waste reduction and segregated recycling strategies.
- Drive towards a carbon neutral position by end of FY23.
- Maintain our strong corporate governance practices and audit compliance.
- Advance our IT infrastructure for improved systems integration across all geographies.

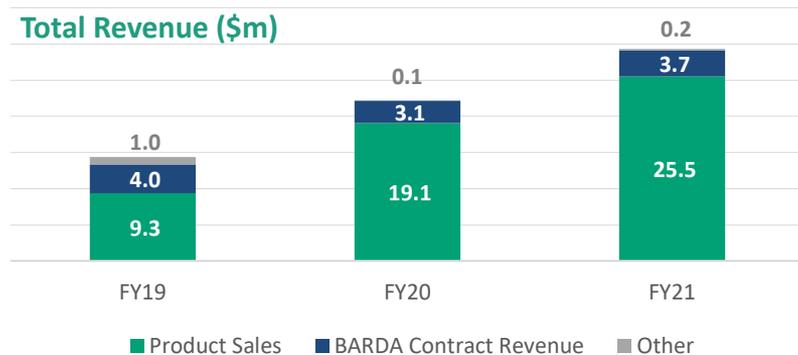


FY21 Financial Results Review

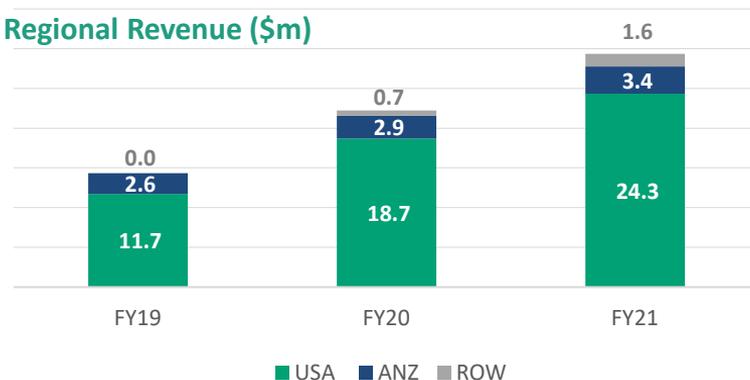
FY21 Financial Results Review



Total Revenue (\$m)



Regional Revenue (\$m)



Highlights

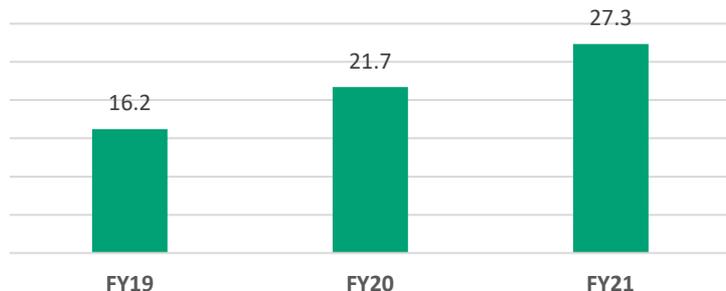
- Total revenue +32%
- BTM product sales +34%
- Total BTM sales \$25.5m
- 2H21 BTM sales +27% on 1H21
- Record monthly BTM sales of \$3.3m in June '21

Strong Growth in All Markets

- US
 - BTM product sales in \$US +49%
 - 2H21 BTM sales +38% on 1H21
- Australia BTM sales +25%
- Distributor sales +53%
 - Strong increases in DACH region (Germany, Switzerland, and Austria)
 - First sales in Finland, Italy and Taiwan
 - Further sales in South Africa and India
- 99 new customers (hospitals) in direct markets
- 7 new distributors covering 9 markets

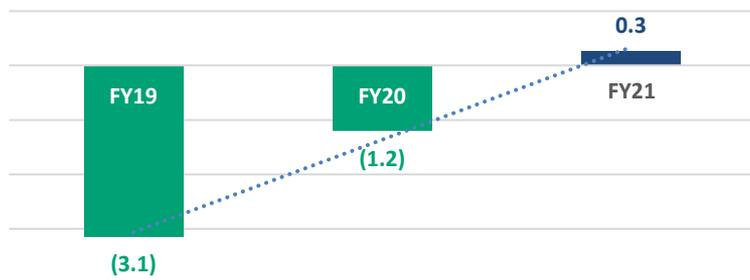
Operating Expenses (\$m)

(excl. Share Based Payments & Unrealised Forex)



Net Profit / (Loss) after Tax (\$m)

(Excl. Non-Cash Items)



Operating Expenses

(excl. Share based payments, unrealised forex loss)

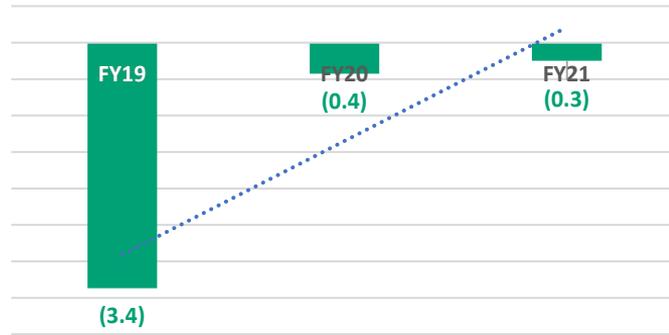
- Operating Expenses +26%
- Continued investment in growth
- Increase headcount by 36% from 78 to 106
- Entered 8 additional EU markets by signing 6 new distributors
- Expanded regional operations in the US and Australia
- US sales team increased to 36

Net Profit after Tax (excl. non-cash items*)

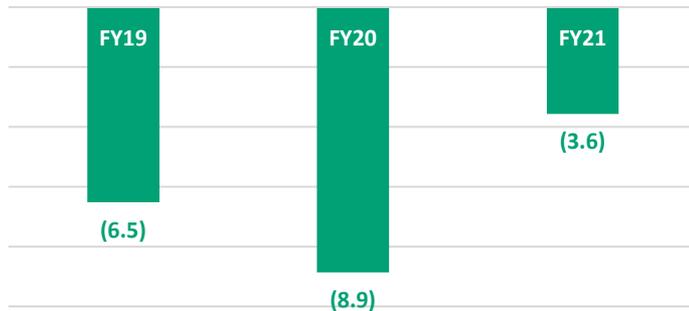
- NPAT \$259k (excl. non-cash items)
- EBITDA \$635k (excl. non-cash items)
- Break even achieved during FY21
- Profitable result due to strong revenue growth and effective management of costs

* Non-cash items comprise of unrealised forex loss, depreciation & amortisation, and share based payments (refer to reconciliation on p.30)

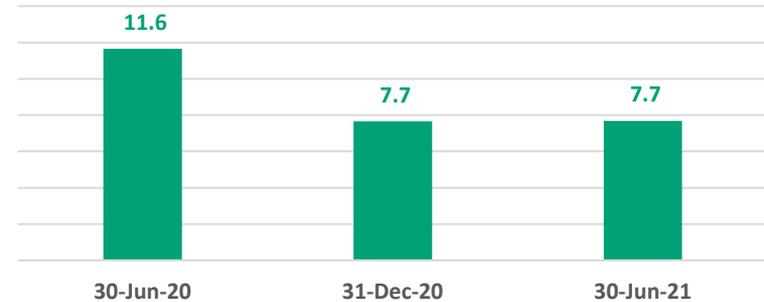
Net cash outflow from operations (\$m)



Capex (\$m)



Cash on hand (\$m)



Highlights

- Minimal cash burn from operations of -\$250k
- Cash burn trend continues to improve
- \$7.7m cash on hand - no change from 31 Dec 2020
- Capex investment for hernia & breast production:
 - new cleanroom - completed
 - manufacturing equipment - installed
- FY22 committed capex of \$0.39m

FY21 Financial Results Review



(\$m)	FY21	FY20	Change %
REVENUE			
Product Sales - BTM	25.5	19.1	34%
BARDA	3.7	3.1	18%
Other Income	0.2	0.1	151%
TOTAL REVENUE	29.3	22.2	32%
Changes in inventories & WIP	(1.6)	(1.7)	-9%
Operating Expenses			
Employee-related expenses (excl. share based payments)	(16.7)	(13.0)	29%
R&D Costs	(3.6)	(2.4)	55%
Corp, administrative & o'head expenses (excl. unrealised forex loss)	(6.9)	(6.3)	10%
Finance Costs	0.0	(0.02)	-100%
Total Operating Expenses	(27.3)	(21.7)	26%
Operating Profit / (Loss)	0.4	(1.2)	137%
Share Based Payments - non-cash	(2.6)	(2.1)	27%
Unrealised Forex Gain/(Loss) - non-cash	(1.1)	0.1	-1878%
EBITDA	(3.3)	(3.2)	4%
Depreciation & Amortisation	(0.9)	(0.8)	10%
EBIT	(4.2)	(4.0)	5%
Interest Expenses	(0.3)	(0.1)	225%
NET PROFIT / (LOSS) BEFORE TAX	(4.6)	(4.1)	10%
Income Tax Expense	(0.1)	(0.1)	-18%
NET PROFIT / (LOSS) AFTER TAX	(4.6)	(4.2)	10%
Add Back Non-Cash Items:			
Share Based Payments	2.6	2.1	
Unrealised Forex Gain/(Loss)	1.1	(0.1)	
Depreciation & Amortisation *	1.1	1.0	
NET PROFIT / (LOSS) - Excluding Non-Cash Items	0.26	(1.20)	121%

* Includes depreciation included in movement of inventories (manufacturing cost)

P&L Highlights

- Product sales +34%
- Revenue (incl. BARDA) +32%
- Product sales gross margin +3% (manufacturing efficiency gains)
- Employee related expenses +29% (increased headcount)
- Corp, admin & overhead expenses +10% (business expansion)
- R&D spend +55% (team expansion, DFU trial, hernia, & breast)
- Net loss after tax -\$4.6m
 - Includes \$2.6m in share-based payments (expensing of share options)
- **Net profit after tax \$0.26m (Excl. non-cash items)**

FY21 Results Summary

- Strong product sales growth 34%.
- Achieved break even during FY21.
- Profitable result of \$0.26m (excl. non-cash items).
- Entered new markets successfully.
- Improved gross margin on product sales +3%.
- Minimal cash burn from operations -\$250k.
- Cash on hand \$7.7m.

FY22

- The business will continue to reinvest cashflows to expand market share in existing markets, enter new markets, and develop new products.



