PolyNovo H1 FY21 Results

Summary points

23 February 2021

Improving outcomes. Changing lives.

Top line H1 FY'21

PolyNovo®

- **NovoSorb BTM sales $11.25m** ↑ 31.2%
  - USA BTM sales H1 FY21 ↑ **41%** on H1 FY20 (in $USD)
- BARDA revenue $1.35m
- Total Revenue $12.80m ↑ 25.3%

- NPAT is ($0.87m) excluding share-based payments and unrealised forex loss. Net Profit After Tax (NPAT) ($3.54m)
- Research &Development expenditure $1.28m
- Capital expenditure $2.37m and forward commitments $1.3m
- **Cash on hand $7.66m**

Highlights of H1

- Signing 22 new customers in US during CoVid challenges
- Sales Germany/Austria/Switzerland, 30 accounts and a further 30 evaluations in progress
- Continued strong webinar referrals, new account evaluations
- First 2 US GPOs and 1 IDN signed, further agreements in process
- Dr Anthony Kaye COO joined from CSL
- Hernia factory build progressed well after CoVid lockdown impacts
- Commissioning (but delayed) new hernia production equipment by PolyNovo team with video support from German supplier
- US FDA approval of Pivotal trial IDE, US full thickness burns
- BARDA commitment to support Pivotal trial with $15m USD contract

H1 Geographic Expansion, Market access

Distributors appointed in

- Finland – September'20
- Taiwan –October '20
- Belgium, Netherlands, Luxemburg (Benelux) – November '20
- Greece – November '20

Post-H1

- Turkey – January '21
- Poland – January '21
- Italy - February '21

CoVid challenges

Sales / Marketing Innovations

Improving outcomes. Changing lives.

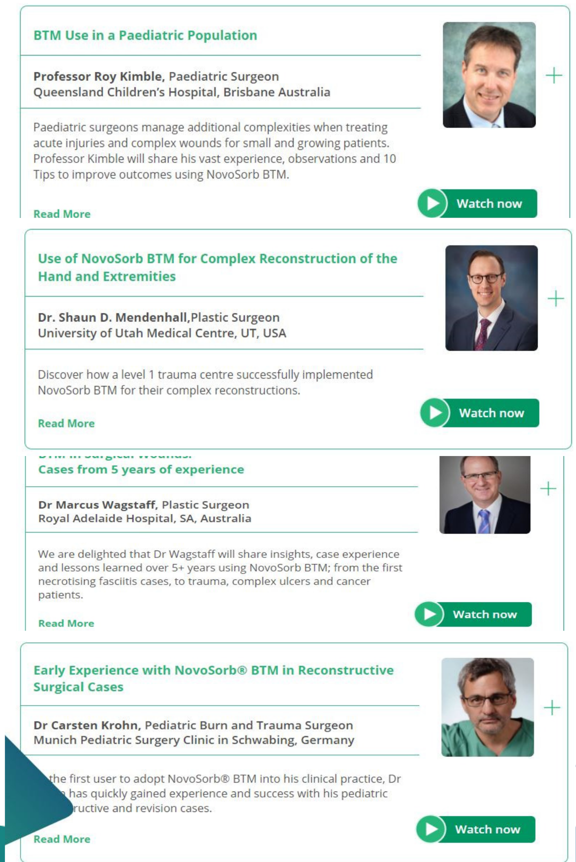
CoVid-19 Impacts

Revenues have been lumpy with reduced access and reduced elective surgery in all regions

Logistics, some increase in cost and workload to schedule however maintaining all supply routes, holding high inventory levels

Markets

- Reduced elective surgeries extends evaluation periods in all regions
- US: variable access across 50 states, strong digital program, winning new accounts, lower bed capacity for surgeries and elective surgeries postponed. Should see strong post-CoVid demand
- UK/Ireland: Access limited with 3 lockdowns. Still have evaluations and have established product in several NHS. Once elective surgery starts we should see corresponding sales increase. Vaccine roll out looks promising
- Aust: Variable access, good new account growth, in all major burn units, good uptake in private hospital network elective cases
- NZ: No access from Australia, good digital engagement, good growth in sales and wide indications use
- EU: Continued expansion. Switch to digital is working well for establishing and training new distributors. More EU regions in process for FY'21



BARDA Trial Program Revenue

- IDE approval
- Delay pushed out revenue and expenditure
- Forecast revenues H2 from increased activity will range $2-$2.5M AUD
- FY ’22 increased patient activity and further sites added expected to be $5+M AUD
- First five sites will be ready to recruit patients end of March/April
- Progressively add trial sites in US and Canada, total ~ 20-25

Building Talent, Driving for the Future

- Total employees at February **92** compared with 78 June 2020
  - Investing in roles that drive expansion COO, Head of R&D, Marketing roles in product development, further development scientist
  - US sales and marketing team expansion will continue in response to new account acquisition. Currently 21 territory managers and 4 sales regional directors. Recruitment will be ongoing through now and FY’22 in response sales revenue generation opportunities.
  - Australia/New Zealand challenged with interstate CoVid boarder closures. Makes servicing NZ, WA, SA and Tasmania challenging. Strong demand continues from these markets and we are servicing customers via video calls.
  - UK/Ireland 4 salespeople meeting the rolling CoVid challenges well. Will hold current staffing levels until CoVid congestion eases and revenues rise. Vaccine roll out is progressing well and show early signs of positive impact on NHS

Capital Works – Capacity and Flexibility for the Future

PolyNovo®

- Final factory area for Film extrusion will be finished in March ‘21
- Extrusion machines housed at Scoresby will be brought to Port Melbourne post hernia production product run, completed installation May. These hernia devices will be used in laboratory test, animal studies to meet regulatory requirements and Surgeon training/user acceptance testing
- $1.3m outstanding for FY21 in capital commitments
  - $1.1m hernia cleanroom (stage 2 / final stage)
  - $0.2m manufacturing equipment

Inside new cleanroom facility: continuous foam cutting machine

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

Inventory Status

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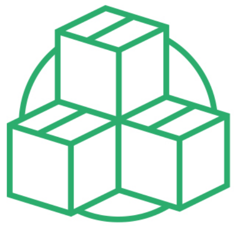

- Full service 3PL warehouse facilities in:
  - US
  - New Zealand
  - Australia
  - England
- All facilities well stocked with inventory to address forward demand expectations and sales targets
- We can service customers promptly in any region

H1 FY21 Financial Results Review

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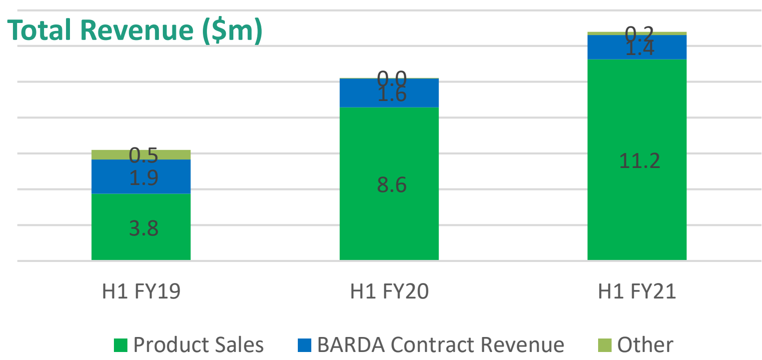
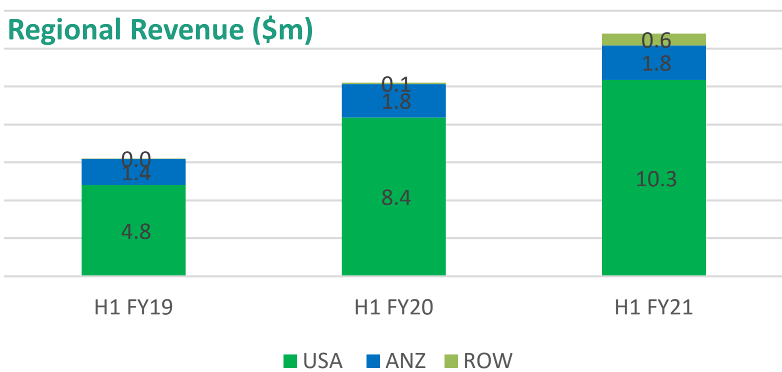




Highlights

- BTM product sales +31% on H1 FY20
- Total BTM sales $11.25m
- Total Revenue $12.80m
- Sales impacted by Covid-19 with restricted access to hospitals and surgeons, and a reduction in elective surgery

BTM Product Sales

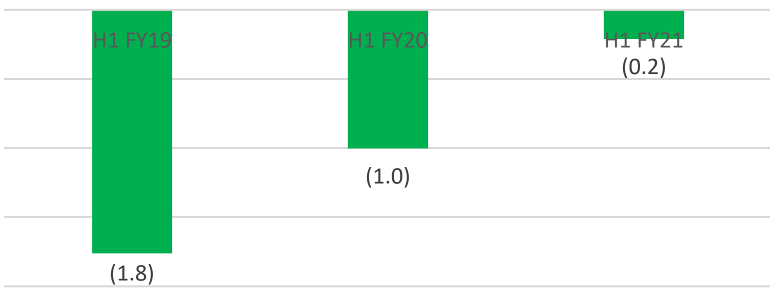
- Strong sales Q1 FY21 up 75% on Q1 FY20
- Slower than expected sales in October & November
- Strong December sales exceeded budget in US, NZ, and Taiwan

Growth in All Markets

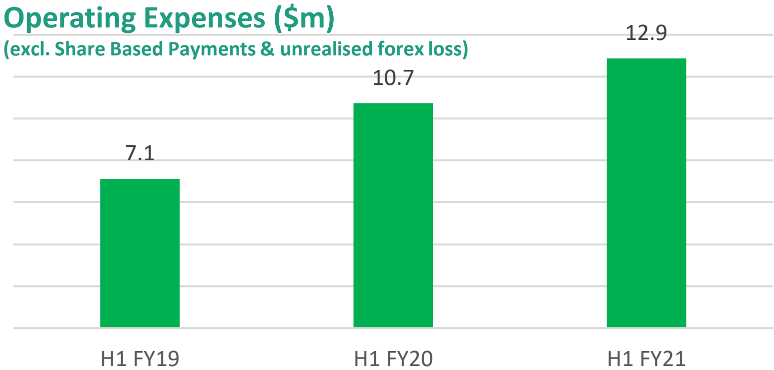
- H1 FY21 opened 35 new accounts across all direct markets
- CY20 opened 109 new accounts representing 89% growth on CY19
- **USA BTM sales H1 FY21 up 41% on H1 FY20 (in $USD)**
- Distributors:
  - Strong sales growth in the DACH region
  - Entered new markets Greece, Benelux, Sweden, Finland and Taiwan
- UK is building on its customer base with further evaluations underway
- First clinical evaluation performed in Ireland

H1 FY21 Financial Results Review

Operating Loss ($m)
(excl. interest costs and non-cash items of share based payments, unrealised loss on forex and depreciation)



Operating Expenses ($m)
(excl. Share Based Payments & unrealised forex loss)



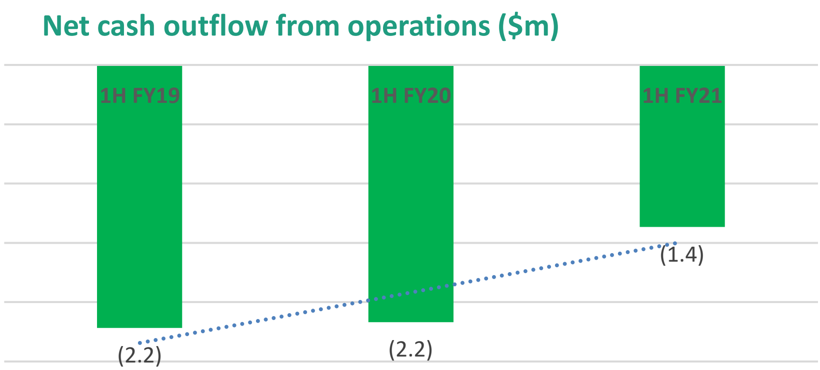
Operating Loss

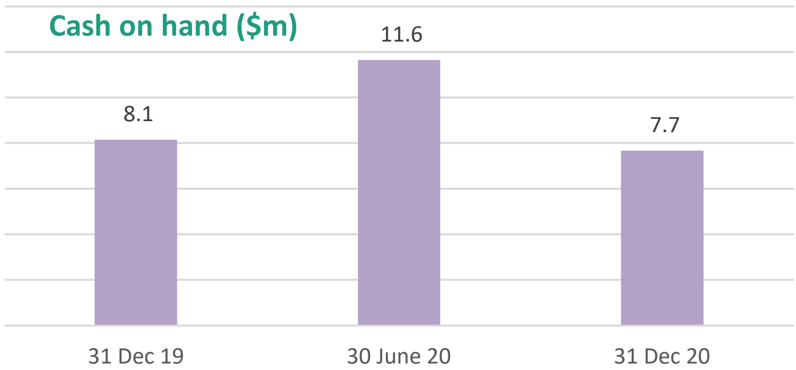
- Operating loss down -78.9%
- Revenue growth, gross margin improvement and cost management has minimised the loss
- USA and NZ are profitable on a standalone basis
- **Close to break even point during H1 FY21**

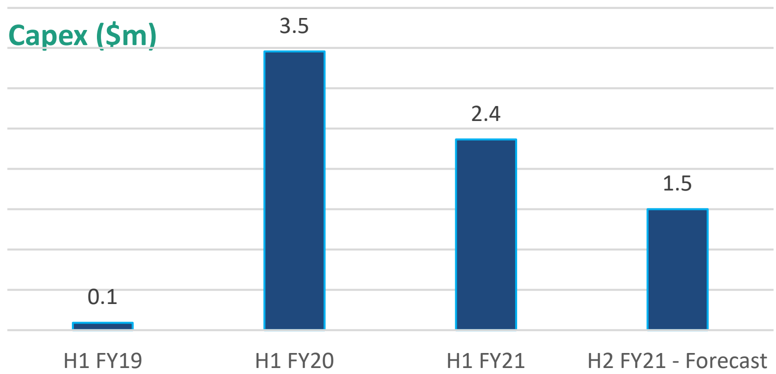
Operating Expenses (Opex)
(Excl. Share Based Payments & unrealized forex loss)

- Operating Expenses +19.8%
- Increase headcount by 40% from 65 to 91
- Annualised impact of prior period headcount increase
- Corporate, administrative and overhead +3.4%
- Entered new markets and expanded our regional operations in Ireland
- Continued investment in growth

H1 FY21 Financial Results Review







Highlights

- Cash burn from operations of -$1.4m
- Cash burn trend improving
- $7.7m cash on hand
- Capex investment for hernia:
  - new cleanroom (stage 2 of 2) on track for completion 31 May 21
  - manufacturing equipment on hand (packaging machine arriving in Mar/Apr 21)
- $6.9m of NAB equipment finance facility drawn down (facility limit $9.3m)
- H2 FY21 capex forecast of $1.5m

H1 FY21 Financial Results Review

($m)	1H FY21	1H FY20	Change %
Revenue	**12.8**	**10.2**	**25.3%**
Expenses			
Changes in inventories & WIP	(0.8)	(0.9)	**-16.6%**
Employee-related expenses	(7.8)	(5.9)	**32.6%**
R&D Costs	(1.28)	(1.4)	**-6.2%**
Corp, administrative & overhead expenses	(3.1)	(3.0)	**3.4%**
Total Expenses	**(13.0)**	**(11.2)**	
Operating Profit / (Loss)	**(0.2)**	**(1.0)**	**-78.9%**
Include Share Based Payments	(1.2)	(0.9)	**40.4%**
Unrealised Forex Gain/(Loss)	(1.4)	(0.1)	**1517.8%**
EBITDA	**(2.9)**	**(2.0)**	**46.2%**
Depreciation & Amortisation	(0.5)	(0.4)	**15.1%**
EBIT	**(3.3)**	**(2.4)**	**41.0%**
Interest Costs	(0.2)	(0.0)	**252.8%**
NET PROFIT BEFORE TAX	**(3.5)**	**(2.4)**	**45.1%**
Income Tax Benefit	(0.03)	0.0	**0.0%**
NET PROFIT AFTER TAX	**(3.54)**	**(2.42)**	**46.3%**
Add Back Non-Cash Items			
Include Share Based Payments	(1.2)	(0.9)	
Unrealised Forex Gain/(Loss)	(1.4)	(0.1)	
UNDERLYING LOSS	(0.87)	(1.45)	**-40.2%**

P&L Highlights

- Product sales +31.2%
- Revenue (incl. BARDA) +25.3%
- Product sales gross margin +3.9%
- Employee related expenses +32.6% (increased headcount)
- R&D spend -6.2% (reduced BARDA activity as transitioning to Pivotal trial)
- Corporate, admin & overhead +3.4%
- Net loss after tax -$3.5m
- Underlying Loss -$0.9m

H1 FY21 Financial Results Review

- Product sales growth 31.2%
- Entered new markets successfully
- 109 new accounts opened in CY20 (89% growth on CY19)
- Strong platform growth during a pandemic evident by significant account acquisition
- Improved gross margin on product sales +3.9%
- Improved underlying loss of -$0.9m
- Cash on hand $7.7m
- Net NAB debt facility headroom $1.5m (facility limit $9.3m)

New Product Pipeline

Research & Development

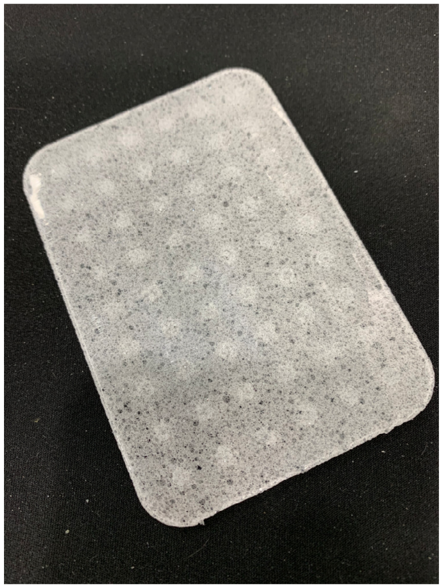
New Product Development -update

PolyNovo®

NovoSorb® SynTrel®

Hernia Devices

- Factory complete end March
- Film extrusion unique NovoSorb polymer film that is 100% resorbable
- Ultrasonically welded film/foam construct
- Production capability achieved
- Looking at additional product configurations for faster route to market
- Looking at partnership opportunities to accelerate market entry and penetration rate
- Preferred pathway to be announced by July ‘21



Syntrel Hernia device

Polymer manufacturing

New Products

NovoSorb BTM

- Addition of smaller sizes for chronic wounds
  - 2x2 cm
  - 5x5cm
- Additional sizes for reimbursement in some countries e.g.: 20x20cm
- Accelerated aging testing of packaging in progress
- Further qualification testing required to complete the quality standards

On track

NovoSorb SynPath

US Alternate Care/ Community Market

- Unique sizes and shapes of NovoSorb BTM for the US Alternate care $400+m market (community/ non-hospital)
- DFU/VLU reimbursement study in progress, first patient will be enrolled February. 2 year study. New sizes manufactured prior to study conclusion.
- Launch once reimbursement established

NovoSorb

Plastics and Reconstructive Device

- Development brought in house.
- Employed dedicated marketing resource
- Recruiting additional development scientist
- Estimate a 3 year + development path

Betacell Diabetes Treatment

- PolyNovo will supply BetaCell with NovoSorb BTM for use in their studies. Once these studies are complete we see this as a new segment opportunity for NovoSorb BTM sales.

H2 Activities

Lumpy sales anticipated with restart of elective surgery across the regions being difficult to project.

FY'21 – Other Activities

- Expand the R&D team to accelerate new product pipeline developments
- Enrolment of patients in Pivotal Trial (BARDA)
- Recruitment of patients in US chronic wound reimbursement study ready to commence
- Enter further EU and Middle East markets via distributors