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Polynovo (PNV)

Burns Notice

Recommendation
Buy (unchanged)
Price
$2.03
Target (12 months)
$2.30 (previously $1.90)

GICS Sector

Pharmaceuticals & Biotechnology

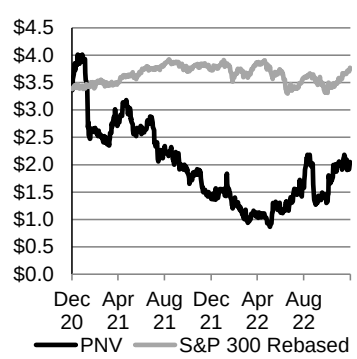
Expected Return	
Capital growth	**13.3%**
Dividend yield	**0.0%**
Total expected return	**13.3%**

Company Data & Ratios	
Enterprise value	**$1328.7m**
Market cap	**$1375.3m**
Issued capital	**677.5m**
Free float	**93%**
Avg. daily val. (52wk)	**$295,546**
12 month price range	**$0.84 - $2.25**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	1.96	1.64	1.46
Absolute (%)	4.86	25.00	40.89
Rel market (%)	-3.42	21.73	40.48

Absolute Price



SOURCE: IRESS

Bolstered pathway to profitability

The $30m placement conducted last week significantly strengthens the Polynovo balance sheet. This provides the growth platform facilitating the expansion of the US and global sales team with key markets in Asia (India, Hong Kong, China, Japan) & Canada being targeted. An important driver in US commercialisation has been through additional commercial hires and the capital raising allows acceleration with this process. The company intends to hire ~ 30 new staff during FY23. Product launch within Hong Kong and India has already taken place during 1H23 whilst entry into Japan/China is planned through a distributor model. These new operating segments increase the addressable market especially in regions with a significant healthcare burden of burns and complex/trauma wounds. Recent BTM registration within Canada is also an important achievement as this simplifies the process to use BTM which was previously only accessible via the Canadian Special Access scheme on a case-by-case basis.

Overview of funds allocation

The company intends to use the $33m ($30m placement, $3m director placement subject to shareholder approval at EGM in January 2023) in geographical expansion through additional hiring ($6m) and manufacturing facility extension ($25m) to facilitate annual revenue capacity of ~ $500m and accelerate R&D projects (breast, hernia devices, therapeutics). Expanding indications involve BTM and MTX devices with the launch of SynPath in the diabetic foot ulcer market targeted in late CY23.

Investment view: Maintain Buy, Increase PT to $2.30

Our price target is now generated purely from our DCF methodology as this best captures the longer-term earning potential for PNV. The strengthened balance sheet reduces financial risk and accordingly we decrease the WACC from 10.3% to 10.0%. Combining these strategic developments, we expect PNV to be profitable from FY24 in line with company expectations and this growth strategy to translate to improved earnings in the medium- to long-term (FY26 onwards).

Earnings Forecast

June Year End	FY22a	FY23e	FY24e	FY25e
Revenues	41.4	67.2	97.1	131.9
EBIT ($m)	-0.8	-4.3	9.8	24.6
NPAT ($m)	-1.3	-4.6	9.5	24.3
Diluted EPS (cps)	-0.2	-0.6	1.4	3.6
EPS growth %	-73%	221%	-314%	157%
PER (x)	nm	nm	146.5	57.1
EV/EBITDA (x)	nm	1,824.3	nm	49.5
Dividend (cps)	0.0	0.0	0.0	0.0
Franking	0.0	0.0	0.0	0.0
Yield %	0.0	0.0	0.0	1.0
ROE %	-8%	-9%	15%	28%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Earnings & Valuation

Use of Funds

Allocation of the $33m ($30m placement, $3m director placement) capital raise includes $6m towards geographic expansion, $25m in manufacturing facility expenditure to increase production capacity and $2m across costs of offer & working capital.

- Geographic expansion includes additional personnel in the US (target of adding ~ 30 commercial hires across sales representatives, associates, directors), India (20 total staff targeted by end of FY23) and Hong Kong.
- Product development strategy involves treating new indications with BTM and MTX devices. Launch of SynPath expected in late CY23 for treatment of diabetic foot ulcers. Ongoing R&D with breast & hernia devices and novel therapeutic applications (BTM in Type 1 Diabetes Mellitus treatment with the Beta-Cell Technologies).
- Capacity expansion with third co-located manufacturing facility adjacent to the current Port Melbourne site. This will support ~$500m in annual manufacturing capacity and will also include an in-house R&D lab to accelerate product development. Total spend of $25m expected across FY23 to FY25.

Earnings

We have updated our financial model for Polynovo post the $30m placement conducted last week with increased cash and number of shares on issue. At this stage we assume 50% participation ($8.5m) in the Share Purchase Plan. We recognise that there is the potential for subsequent placement of any shortfall and will adjust our forecasts accordingly once the SPP concludes.

Table 1 - Earnings changes FY23 to FY25

	2023			2024			2025		
A$m	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	67.2	66.3	1%	97.1	94.4	3%	131.9	123.9	6%
EBIT	-4.3	3.6	NM	9.8	15.4	-36%	24.6	27.9	-12%
NPAT	-4.6	3.3	NM	9.5	15.1	-37%	24.3	27.5	-12%
EPS (cps)	-0.6	0.5	NM	1.4	2.3	-40%	3.6	4.2	-15%

SOURCE: BELL POTTER SECURITIES ESTIMATES

We have upgraded our revenue forecasts for FY23 to FY25. The downgrade in earnings across this period is driven by the increase in operating expenses. There is ~ 6- to 12-month lag in sales representative profitability and with the manufacturing expansion planned from FY23 to FY25, we expect this combined growth strategy to translate to improvements in earnings in our later year forecasts (FY26 onwards).

Valuation

Our price target is now purely generated from our DCF methodology as this better captures the longer-term earning potential of PNV. We have assumed a total of $41.5m of capital raised ($30m placement, $3m director placement subject to shareholder approval at the EGM in January 2023, $8.5m share purchase plan). This represents ~ 3.3% dilution which has been reflected in our calculation of our price target. The terminal growth rate of 3% is unchanged.

Our price target is upgraded by 21% to $2.30. We maintain our Buy recommendation.

Polynovo Overview

Proprietary BTM technology the key to growth

Polynovo is a commercial stage medical device company and the key offering is the proprietary biodegradable temporising matrix (BTM) that can be applied to complex wounds and severe burns. BTM has been approved and commercialised in the US, Australia, Europe with additional targeted segments including Asia & the Middle East. It has regulatory approval in India, South Africa and has been granted CE-Mark.

Product pipeline includes MTX (modified BTM product without sealing membrane), extension within the hernia repair & breast reconstruction markets and novel therapeutic approaches in drug delivery (NovoSorb Drug Elution Depot) and Type 1 Diabetes Mellitus (Dermal Beta Cell Implant). However, NovoSorb BTM is the flagship product and driver for the current valuation.

Investment Thesis

Our investment thesis is based on the following:

- **Strengthened balance sheet:** Provides strong platform to implement the growth strategy through geographical expansion, increased manufacturing capacity and accelerated R&D projects.
- **Ongoing clinical validation of BTM in acute and chronic indications:** Highlights its versatility in the acute (burns, trauma, tumour excisions) and chronic (diabetic foot and venous ulcers) setting.
- **Pivotal study in full thickness burns for FDA application:** ~ 30 of 120 patients recruited. Investigation across 20 US and 5 Canadian burns centres. Enrolment completion targeted in 4Q23.
- **Second phase of SynPath study underway:** First patient enrolled in August 2022. Data from this study will assist in obtaining outpatient clinic reimbursement.
- **Commercial launch of smaller sized BTM products**: Launch in EU/UK/Australia/New Zealand/Singapore during FY22. Allows wider application in complex wounds and burns of variable sizes.
- **Sales team expansion prioritised:** Increasing total sales personnel to engage clinicians across US hospitals, Group Purchasing Organisations (GPOs) & Integrated Delivery Networks (IDNs).
- **New geographic segments targeted**: Accelerated market entry into Asia and extension through North America (US and Canada).
- **Easing of SARS-CoV-2 impact**: Reduced elective surgeries and hospital trauma & burns presentations. Reduced restrictions and increased procedure volumes will present greater growth opportunities especially within the US market. The return of face-to-face medical conferences & plenary sessions allows increased clinician engagement and presentation of important clinical data.
- **Portfolio expansion and pipeline:** MTX simplifies the BTM product without the sealing membrane and may have potential to coordinate structured healing in deep wounds or cavities. FDA 510k clearance is targeted in 1H23 followed by commercialisation in 2H23. Design validation ongoing for hernia repair product with launch targeted in FY24. Ongoing evaluation of breast reconstruction device continues. Therapeutic application with Islet cell implantation with successful implantation achieved in first patient in July 2022 and implantation in two other patients is underway.

Key Risks

Financial risk

The capital raising in November 2022 ($33m) along with the share purchase plan (of up to $17m) strengthens the balance sheet and reduces the financial risks for the company. This will provide funding for geographic growth within Asia (India, Hong Kong, Japan, China) and North America (Canada), manufacturing facility expansion and R&D (MTX, Breast, Hernia devices). We recognise that the company may still require additional shareholder equity or debt to fund this growth strategy.

Intellectual property risk

Protection of IP is critical to the commercial success of Polynovo. Current patent portfolio provides protection of the biodegradable polyurethane & urea composition, its preparation techniques including tissue engineering and design features. Method of use of key agents and device composition patents are valid until 2029 in the US. There is a risk that competitors may be able to compete with PNV by designing around the patent claims. Our forecasts are dependent on the ability of the company to maintain its current IP and protect ongoing product development.

Clinical trial risks and clinician adoption

Increased adoption amongst surgeons is dependent on clinical data indicating superior performance of Polynovo products. To achieve this the Polynovo portfolio is being evaluated in multiple indications. Failure to meet primary and secondary endpoints can significantly delay the commercial strategy due to the need to re-design studies and re-evaluate technology. Outside of failure to meet endpoints, poor trial design and execution can also lead to suboptimal performance and this must be carefully considered. If clinical data does not warrant further assessment, clinical programs can be discontinued completely.

Interaction between clinicians especially within conference settings and plenary sessions is also critical. As SARS-CoV-2 related restriction ease, the submission of abstracts to important international conferences should form part of the ongoing strategy for Polynovo to increase clinician awareness.

Sales execution and clinical adoption risk

Our forecasts are contingent on the ability of the sales team to effectively engage with clinicians and hospital systems across different geographical segments. This commercial strategy involves targeting GPO formularies and IDNs to underpin rapid growth in sales. Failure in execution will hinder the expansion in key segments. The company has maintained that increasing its current sales team in the US is a significant priority. As previously addressed, the sales execution risk ties in with the current financial risk and cash balance. Inability to fund a larger sales team will impede the expansion strategy.

Competitor risks

There are a number of key competitors within the dermal template market including Integra, Alloderm and Oasis. In total there are over 60 companies with graft products and over 70 within the hernia repair sector. Larger companies in both markets have greater access to resources for ongoing clinical trials and validation studies. Accordingly, it is imperative that Polynovo continues its efforts in optimising its product pipeline and evaluating its clinical performance. The successful commercialisation of Polynovo relies upon superior performance of its products as this will drive clinical adoption and revenue growth. If competitors are able to illustrate superiority in valid head-to-head clinical trials, this will significantly affect utilisation of the Polynovo portfolio.

Polynovo
as at 1 December 2022

Recommendation	Buy
Price	$2.03
Target (12 months)	$2.30

Table 2 - Financial summary

Polynovo (ASX:PNV)

Share price:	**$2.03**	**Target price:**		**$2.30**
No. of issued shares:	**677.5m**	**Market cap:**		**$1,375.3m**

Profit & Loss (A$m)

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
Product revenue	29.2	41.4	62.7	92.6	130.1
BARDA revenue	3.7	3.5	4.5	4.5	1.8
Total revenue (excl. int.)	**32.8**	**44.9**	**67.2**	**97.1**	**131.9**
Change		*37%*	*50%*	*45%*	*36%*
Δ Inventories and Work in progress	-1.6	-2.2	-2.8	-3.1	-4.5
Employee-related expenses	-19.4	-21.4	-39.6	-52.5	-65.6
R&D expenses	-3.6	-5.7	-6.6	-6.9	-7.6
Operating leases	0.0	0.0	-0.3	-0.3	-0.3
General & Admin	-8.1	-10.4	-20.3	-23.3	-26.8
Total expenses (excl. D&A, int.)	**-32.6**	**-41.1**	**-69.5**	**-86.2**	**-104.9**
% of revenue	*-100%*	*-92%*	*-103%*	*-89%*	*-80%*
EBITDA	**-3.6**	**0.8**	**-2.3**	**11.0**	**27.0**
Depreciation	-0.3	0.0	-1.7	-0.9	-2.1
Amortisation	-0.2	0.0	-0.2	-0.2	-0.2
EBIT	**-4.6**	**-0.8**	**-4.3**	**9.8**	**24.6**
Net interest (expense)/revenue	-0.3	-0.3	-0.3	-0.3	-0.3
Pre-tax profit	**-4.9**	**-1.2**	**-4.6**	**9.5**	**24.3**
Income tax expense	-0.1	0.0	0.0	0.0	0.0
NPAT	**-4.9**	**-1.3**	**-4.6**	**9.5**	**24.3**
Change		*73%*	*-242%*	*307%*	*-157%*
Non recurring items	0.0	1.5	0.0	0.0	0.0
Adjusted NPAT	**-4.9**	**0.2**	**-4.6**	**9.5**	**24.3**

Cash Flow (A$m)

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
EBITDA	-3.6	0.8	-2.3	11.0	27.0
Change in working capital	3.3	-2.8	-6.4	-4.5	-5.2
Gross cash flow	**0.0**	**-2.0**	**-8.7**	**6.5**	**21.8**
Net other	-0.2	-0.1	-0.3	-0.3	-0.3
Operating cash flow	**-0.3**	**-2.1**	**-9.1**	**6.2**	**21.5**
Proceeds from short Term Deposits	0.0	0.0	0.0	0.0	0.0
Payments for PPE	-3.6	-0.5	-3.5	-16.0	-4.0
Investing cash flow	**-3.6**	**5.9**	**-3.5**	**-16.0**	**-4.0**
Proceeds from borrowings	7.3	1.9	0.0	0.0	0.0
Repayment of principal on borrowings	-7.1	-7.1	-1.1	-1.1	-0.6
Repayment of principal on lease liabilities	-0.4	-0.3	0.0	0.0	0.0
Proceeds from issue of shares	0.0	0.0	40.5	0.0	0.0
Proceeds from the exercise of options	0.2	0.2	0.0	0.0	0.0
Financing cash flow	**-0.1**	**-5.4**	**39.4**	**-1.1**	**-0.6**
Net change in cash	**-3.9**	**-1.6**	**26.8**	**-10.9**	**16.9**
Cash at start of period	11.6	7.7	6.1	32.9	22.0
Effect of exchange rate changes	-0.1	0.0	0.0	0.0	0.0
Cash at end of period	**7.7**	**6.1**	**32.9**	**22.0**	**38.9**

Balance Sheet (A$m)

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
Cash and cash equivalents	7.7	6.1	32.9	22.0	38.9
Trade and other receivables	5.7	6.1	13.4	19.4	26.4
Contract cost assets	0.1	0.1	0.1	0.1	0.1
Inventories	2.0	2.5	6.7	9.7	13.2
Property, Plant and equipment	17.6	9.9	11.8	26.8	28.7
Right-of-use assets	2.2	6.8	6.8	6.8	6.8
Intangibles	1.7	1.4	1.2	0.9	0.7
Total assets	**38.3**	**35.0**	**74.9**	**87.8**	**116.7**
Trade and other payables	5.0	5.0	10.1	14.6	19.8
Interest-bearing loans and borrowings	2.5	1.3	1.3	1.3	1.3
Lease liability	0.4	0.5	0.5	0.5	0.5
Total liabilities	**16.0**	**17.3**	**21.3**	**24.7**	**29.3**
Net assets	**22.4**	**17.7**	**53.6**	**63.1**	**87.4**
Issued capital	139.3	139.4	179.9	179.9	179.9
Reserves	-1.6	-5.3	-5.3	-5.3	-5.3
Accumulated losses	-115.3	-116.5	-121.0	-111.6	-87.3
Total shareholder's equity	**22.4**	**17.7**	**53.6**	**63.1**	**87.4**

Valuation data

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
NPAT (A$m) reported	-4.9	-1.3	-4.6	9.5	24.3
Diluted EPS (cps) (Reported)	**-0.7**	**-0.2**	**-0.6**	**1.4**	**3.6**
Change		*-73%*	*221%*	*-314%*	*157%*
P/E ratio (x)	**nm**	**nm**	**nm**	**146.5**	**57.1**
CFPS (cps)	0.0	0.0	0.0	0.0	0.0
Price/CF (x)	**nm**	**nm**	**nm**	**nm**	**nm**
DPS (cps)	0.0	0.0	0.0	0.0	0.0
Yield	**0%**	**0%**	**0%**	**0%**	**0%**
Franking	0%	0%	0%	0%	0%
EV/EBITDA (x)	**nm**	**1824**	**nm**	**124**	**50**
NTA per share (cps)	0.0	0.0	0.1	0.1	0.1
Price/NTA (x)	**0.6**	**0.8**	**0.3**	**0.2**	**0.2**

Performance ratios

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
EBITDA margin	**-12.4%**	**1.8%**	**-3.5%**	**11.3%**	**20.5%**
EBIT margin	-15.6%	-2.0%	-6.3%	10.1%	18.7%
Return on assets	-12.8%	-3.8%	-6.1%	10.8%	20.8%
Return on equity	-22.0%	-7.5%	-8.5%	15.0%	27.8%
ROIC	nm	nm	nm	nm	nm
Payout ratio	nm	nm	nm	nm	nm
Effective tax rate	1.1%	3.6%	0.0%	0.0%	0.0%

Leverage ratios

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
Net debt/(cash) (A$m)	-0.1	-2.0	-29.9	-20.1	-37.6
Net debt/equity	nm	nm	nm	nm	nm

Segmentals (NZ$m)

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
Operating revenue					
US	24.3	35.9	53.8	75.3	101.7
ANZ	3.2	3.2	4.2	5.8	7.6
ROW	1.6	2.4	4.8	9.5	18.1

Interims (A$m)

Year end 30 Jun	2H21	1H22	2H22	1H23e
BARDA revenue	1.4	1.8	1.7	2.3
BTM sales revenue	**12.6**	**18.1**	**23.3**	**26.0**
Change		*44%*	*29%*	*11%*
Total expenses	**-14.2**	**-15.6**	**-25.6**	**-31.3**
% of revenue	*-113%*	*-86%*	*-110%*	*-120%*
EBITDA	**-3.1**	**2.6**	**-1.8**	**-3.1**
Total D&A expense	-0.5	-0.7	-0.8	-1.0
EBIT	**-3.5**	**1.8**	**-2.7**	**-4.0**
Income tax expense	0.0	-0.1	0.0	0.0
NPAT	**-3.7**	**1.6**	**-3.0**	**-4.0**
Change		*-144%*	*-283%*	*36%*

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

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