



PALLA PHARMA

Palla Pharma Limited

ABN 26 107 872 453

Preliminary interim report for the half-year ended 30 June 2021

Appendix 4D

The following information is presented in accordance with ASX listing rule 4.2A.3.

1. Details of the reporting period and previous corresponding period

Reporting period: half-year ended 30 June 2021
Previous corresponding period: half-year ended 30 June 2020

2. Results for announcement to the market

	Consolidated entity		
	30 June 2021 \$	30 June 2020 \$	Change %
2.1 Revenue from ordinary activities	7,060,872	12,328,942	-42.7%
2.2 Loss from ordinary activities after tax attributable to members	(33,105,663)	(9,014,762)	-267.2%
2.3 Net loss for the period attributable to members	(33,105,663)	(9,014,762)	-267.2%
2.4 There were no dividends paid, recommended or declared during the current or previous reporting period.			
2.5 The record date for determining entitlements to dividends – not applicable.			
2.6 Supplementary commentary on figures presented in 2.1 to 2.4 above – please refer to the Preliminary interim report for the half-year ended 30 June 2021 attached.			

3. Net tangible assets

	Consolidated entity		
	30 June 2021 \$	30 June 2020 \$	Change %
Net tangible assets per security	0.11	0.34	-68.7%

4. Details of entities over which control has been gained or lost during the period

Not applicable.

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5. Dividend payments

Not applicable.

6. Dividend reinvestment plans

Not applicable.

7. Associate or joint venture entities

Not applicable.

8. Foreign entities

Not applicable.

9. Independent review of financial statements

The financial statements presented in the Preliminary interim report attached for the half-year ended 30 June 2021 are in the process of being reviewed.

The Group is relying on relief provided by ASIC Corporations (Extended Reporting and Lodgement Deadlines—Listed Entities) Instrument 2020/451 which extends the lodgement deadline for listed entities to lodge their half yearly reports by allowing up to one additional month.

Given the current financial position of the Group and the Group's ability to continue as a going concern, the Group has recently been provided with an extension to its standby debt facility with Washington H. Soul Pattinson and Company Limited, a substantial shareholder.

The additional month to release the reviewed accounts will enable the auditor to form a view on the going concern basis of preparation of the financial statements for the Group following the completion of the debt facility extension. The Group considers it likely that the review report will be subject to an emphasis of matter in relation to the Group's ability to continue to operate as a going concern.

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**Preliminary interim report
for the half-year ended 30 June 2021**

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Preliminary interim report for the half-year ended 30 June 2021

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This preliminary interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report should be read in conjunction with the annual report for the year ended 31 December 2020 and any public announcements made by Palla Pharma Limited during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

Palla Pharma Limited is a company limited by shares, incorporated and domiciled in Australia. The shares of Palla Pharma Limited are publicly traded on the Australian Securities Exchange under the ASX issuer code PAL.

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Review of operations

Financial Results Summary

	Consolidated entity	
	30 June 2021	30 June 2020
	\$	\$
Sales of:		
Narcotic Raw Material ("NRM") and Poppy Seed	859,817	2,484,293
Active Pharmaceutical Ingredients ("API")	4,516,655	5,976,262
Finished Dosage Formulations ("FDF")	1,681,130	3,792,890
Total sales	7,057,602	12,253,445
Statutory Earnings Before Interest, Tax, Depreciation and Amortisation (EBITDA)	(30,938,432)	(6,660,764)
Statutory Earnings Before Interest and Tax (EBIT)	(32,172,696)	(8,015,396)
Statutory (Loss) for the year after Interest and Tax	(33,105,663)	(9,014,762)
Net cash (outflow) from operating activities	(13,347,993)	(5,438,063)
Operating EBITDA	(11,044,505)	(6,745,306)

Operating EBITDA, a non-GAAP financial measure, is used internally within the Group to monitor and manage financial performance. It is determined by adding back to Statutory EBITDA significant non-recurring items (2021: \$19.8 million related to impairment of non-financial assets, impairment of inventory and litigation settlement expenses / 2020: nil) and deducting other income and gains / losses on non-core asset disposals. A \$4.3 million increase in the reported Operating EBITDA loss from \$6.7 million for the 2020 half-year period to an Operating EBITDA loss of \$11.0 million for the 2021 half-year period reflected a decline in reported Gross Profit (Total Sales less Raw Materials & Production related employee benefits expenses) for the period.

Sales for the 2021 half-year period revenue reduced to \$7.1 million compared to \$12.3 million for the corresponding half-year period.

The decline in Gross Profit is attributed to:

- Delay in the launch of Marketing Authorisation (MA) FDF products mainly due to an unanticipated delay in manufacturing site change and packaging regulatory approval from COVID-19 delays in the UK;
- Reduced API sales due to reduced API demand due to the impact of COVID-19 on elective surgery volumes in Europe and the UK;
- Manufacturing inefficiencies associated with reduced production volumes resulting from lower API sales and the timing of the planned early exit from a legacy non-opiate based FDF supply agreement in Norway, an action intended to free up production capacity for new Marketing Authorisation products, whose production was ultimately delayed by the later than expected receipt of UK regulatory approval;
- Rework of previous FDF products supplied to a Contract Manufacturing customer; and
- Reduced poppy seed sales following reduction in domestic harvest growing area due to climatic conditions and pricing.

Gross Profit margins were expected to significantly improve in 2021 due to an improved product sales mix; in particular, an increased weighting of opiate based FDF products produced under the newly acquired Marketing Authorisations. The delay in UK regulatory approval of the Marketing Authorisations manufacturing site transfer and associated product packaging until March 2021 resulted in the expected improvement in sales and Gross Profit margins being delayed.

Review of operations

The reduction in sales was primarily driven by reduced API demand due to the impact of COVID-19 on delayed elective surgeries and the planned early exit from the legacy non-opiate based FDF supply agreement from February 2020, with this FDF production capacity intended to be directed to opiate based FDF Marketing Authorisation products. The delay in manufacturing site change and associated product packaging regulatory approval for Marketing Authorisation products delayed the commencement of sales until the second quarter of 2021. NRM and Poppy Seed sales revenue was down from the previous half-year period due to reduced domestic poppy straw growing area.

A trade receivables impairment loss charge of \$1.0 million was recognised during the prior half-year period in relation to API product shipped in 2019, with this impairment loss being reversed in the 2021 half-year period due to the receivable being recovered in full.

Impairment charges relating to the Australia Cash Generating Unit (CGU) which were allocated to non-financial assets totalling \$8.2 million were recognised during the 2021 half-year period mainly due to a revision in the after-tax discount rate assumption being used for determining the recoverable amount of the CGU to reflect forecasting risk with the evolution of the Group's business model. The Group also impaired its high thebaine content straw inventory by \$1.4 million due to a pending sale agreement, and NRM work in progress inventory by \$10.1 million due to a modification in the production process requiring a change in inventory obsolescence provisioning methodology.

The Group reported a statutory loss after income tax for the half-year ended 30 June 2021 of \$33.1 million (2020: \$9.0 million) and a statutory Earnings Before Interest, Tax, Depreciation and Amortisation ("EBITDA") loss of \$30.9 million (2020: \$6.7 million).

Net debt reduced during the half-year period as a result of an equity capital raising of \$16.9 million.

Marketing Authorisation acquisitions

During 2020, the Group acquired seven Marketing Authorisations for the supply of Finished Dosage products into the United Kingdom which all require an opiate based active ingredient as an excipient. The ownership of the Marketing Authorisations was transferred to the Group and all necessary approvals for the two highest volume and value MA's were granted in March 2021 for the change of site of manufacture for its Co-Codamol tablet and caplet products and associated product packaging, with manufacture and sales of these products commencing during the 2021 half-year period.

The Group prioritised the manufacturing site change for the Co-Codamol products to target the United Kingdom's largest market opportunity. Further submissions to change the site of manufacture for the remaining Marketing Authorisations acquired in 2020 will be made to the United Kingdom medicines regulator throughout 2021. In the interim to maximise the value of the Marketing Authorisations, the Company has entered contract manufacturing and licensing agreements with UK based pharmaceutical company, M&A Pharmachem, to manufacture the products whose site of manufacture is yet to be transferred to Norway.

FDF production in Norway

The early exit from a non-opiate based FDF supply agreement in 2020 positioned the Group for increased future profitability by releasing significant FDF tableting and packaging capacity for the manufacture of higher margin contribution opiate based FDF products via existing CMO supply agreements and the acquired Marketing Authorisations. Approval is concurrently being sought for other European Marketing Authorisations via the Ireland medicines regulator.

With the manufacturing site change and associated product packaging approvals having been granted in March 2021, production of MA products commenced in late March 2021 with the production, after some initial mechanical issues, ramping up and achieving the planned production run rate in May 2021.

Review of operations

The process for supplying MA products requires that intending purchasers be qualified as customers to meet quality and regulatory requirements. The Group qualified for supply to a number of large wholesale customers with first sales to these customers in May and June 2021. The Group continues to make progress with onboarding additional new wholesale customers and has experienced strong month over month sales volume growth in both July and August.

In June 2021 the Group appointed Alloga UK Limited, a pan-European healthcare logistics provider as its exclusive pre-wholesale supply chain services provider, and after having completed an extensive qualification and on-boarding process with Alloga, the Group began supplying product through Alloga's market leading network in July.

API production in Norway

During 2021 half-year period, the Group continued to experience softer API demand due to paracetamol (used in a number of its customers' Finished Dosage products) shortages, impacting ordering patterns, along with the COVID-19 impact of delayed elective surgeries in Europe and the UK. API production was reduced to match the lower demand and to reduce API and NRM inventory levels.

NRM production in Australia

The majority of the Group's NRM production is transferred to Norway for conversion into both Codeine Phosphate and Pholcodine APIs. With a reduced API requirement for production in Norway, and to address inventory levels being carried in Australia, a lower-straw input extraction process was carried out during the first half of 2021 to reduce inventory levels. Whilst reducing inventory, the process has proved not as efficient as the regular production process and negatively impacted production costs for the 2021 half-year period compared to the previous half-year period.

COVID-19 restrictions and impacts on operations

In March 2020, the World Health Organisation declared the COVID-19 outbreak a pandemic. In an effort to contain the spread of the virus, quarantine restrictions, travel restrictions, limitations on social gatherings, the closure of business and schools and other restrictive measures have been introduced across the world in jurisdictions in which the Group operates. Hospitals have been adversely impacted by severe reductions in elective surgery volumes as bed capacity has been allocated to the treatment of COVID patients and both medical staff and prospective patients cancelled operations based upon the risk of exposure to the disease in the hospital environment.

To date COVID-19 restrictions have had some impact on the financial performance of the Group, primarily from travel restrictions and social distancing limitations impacting on new market development activities, paracetamol shortages impacting Codeine Phosphate ordering patterns, the impact of delayed elective surgeries in Europe and the UK impacting Codeine Phosphate API and FDF demand, the impact of potential new customers remaining focussed on managing their own businesses through the pandemic and being less open to new supply partners in the short term, along with availability of freight (both inbound and outbound) and additional freight cost imposts due to late flight cancellations for air freight. It is not possible to quantify the pervasive impacts of COVID-19 on the business from other external factors impacting on the business for the full-year reporting period.

With a third, or in some countries up to a sixth wave, of the Delta variant under way, the Group remains subject to volatility in customer order patterns, supply chain interruptions and the possibility of disruptions in labour supply due to local lockdowns. The Group is mitigating these risks by holding higher than normal inventory levels across all aspects of the business, which has impacted the Group's financial position

In many markets where the Group's is active, its products are classified as essential medication consistent with the World Health Organisation essential medicines listing and the Group's operations are exempted from many of the COVID-19 restrictions industries are otherwise experiencing.

Review of operations

As a result of the longevity and evolving nature of the COVID-19 pandemic and rapidly evolving government policies and restrictive measures being put in place to contain it, as at the date of this report, it is not possible to reasonably estimate the potential effects of the COVID-19 pandemic on the future financial performance and financial position of the Group. These impacts may be positive as well negative as there is no doubt that the postponed elective surgeries will in most cases need to take place and with these operations will come an increase in demand for pain management medicines.

Reconciliation of Operating EBITDA to Statutory EBITDA and Loss After Tax

The consolidated financial statements comply with International Financial Reporting Standards (IFRS's) adopted by the International Accounting Standards Board (IASB). In the presentation of its financial results the Group uses a non-GAAP financial measure which is not prepared in accordance with IFRS being:

- Operating EBITDA: calculated by adding back (or deducting) finance expense / (income), income tax expense / (benefit), depreciation, amortisation, litigation settlement expenses, acquisition related expenses, transaction integration services, agricultural area trialling expenses, inventory impairments, goodwill and non-financial asset impairments, losses from discontinued operations, gains / losses on disposal of non-core plant and equipment, and deducting other income and depreciation expense from discontinued operations, to net profit / (loss) after tax.

The Group uses this measure internally and believes that this non-GAAP financial measure provides useful information to readers to assist in the understanding of the Group's financial performance, financial position and returns, as it is the predominant measure of financial performance used by management. It represents the best measure of performance as a result of initiatives and activities directly controlled by management. Non-GAAP financial measures should not be viewed in isolation, nor considered as a substitute for measures reported in accordance with IFRS. Non-GAAP financial measures may not be comparable to similarly titled amounts reported by other companies.

The table below reconciles the Operating EBITDA to Statutory EBITDA and Loss After Tax:

	Consolidated entity	
	30 June 2021	30 June 2020
	\$	\$
Statutory (Loss) after income tax	(33,105,663)	(9,014,762)
Add: Net finance expenses	932,967	999,366
Statutory Earnings Before Interest and Tax (EBIT)	(32,172,696)	(8,015,396)
Add: Depreciation and amortisation expense	1,234,264	1,354,632
Statutory Earnings Before Interest, Tax, Depreciation and Amortisation (EBITDA)	(30,938,432)	(6,660,764)
Add:		
Loss/(gain) on disposal of non-core property, plant and equipment	48,680	(9,045)
Litigation settlement expenses	97,286	-
Impairment of inventory to net realisable value	11,526,271	-
Impairment of non-financial assets	8,224,960	-
Deduct:		
Other income	(3,270)	(75,497)
Operating EBITDA	(11,044,505)	(6,745,306)

Palla Pharma Limited
Consolidated statement of profit or loss and other comprehensive income
For the half-year ended 30 June 2021

		Consolidated entity	
		30 June	30 June
		2021	2020
	Notes	\$	\$
Revenue			
Sale of goods		7,057,602	12,253,445
Other income		3,270	75,497
		<u>7,060,872</u>	<u>12,328,942</u>
Expenses			
Raw materials, consumables and other production expenses		(7,522,129)	(7,213,427)
Employee benefits (production) expenses	3	(3,042,819)	(3,324,152)
Employee benefits (non-production) expenses	3	(5,751,758)	(4,836,481)
Legal and listing compliance expenses		(307,314)	(157,280)
Market development expenses		(20,536)	(195,378)
Occupancy expenses		(1,270,282)	(1,048,065)
(Loss)/profit on disposal of property, plant and equipment		(48,680)	9,045
Litigation settlement expenses		(97,286)	-
Consulting expenses		(111,006)	(138,884)
Outsourced quality consulting expenses		(217,197)	(72,742)
Impairment of inventory to net realisable value		(11,526,271)	-
Impairment of non-financial assets		(8,224,960)	-
Impairment reversal/(loss) on trade receivables		1,053,089	(1,050,000)
Other expenses		(912,155)	(962,342)
Total expenses		<u>(37,999,304)</u>	<u>(18,989,706)</u>
Earnings Before Interest, Tax, Depreciation and Amortisation (EBITDA)		<u>(30,938,432)</u>	<u>(6,660,764)</u>
Depreciation and amortisation expense	3	(1,234,264)	(1,354,632)
Earnings Before Interest and Tax (EBIT)		<u>(32,172,696)</u>	<u>(8,015,396)</u>
Finance income		171,601	11,635
Finance expenses		(1,104,568)	(1,011,001)
Net finance expenses	3	<u>(932,967)</u>	<u>(999,366)</u>
(Loss) before income tax		<u>(33,105,663)</u>	<u>(9,014,762)</u>
Income tax benefit/(expense)		-	-
(Loss) for the period		<u>(33,105,663)</u>	<u>(9,014,762)</u>
Other comprehensive income/(loss)			
<i>Item that may be reclassified to profit or loss</i>			
Exchange differences on translation of foreign operations		(5,820)	(795,805)
Total comprehensive (loss) for the period		<u>(33,111,483)</u>	<u>(9,810,567)</u>

The above consolidated statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes.

Palla Pharma Limited
Consolidated statement of profit or loss and other comprehensive income
For the half-year ended 30 June 2021
(continued)

	Consolidated entity	
Notes	30 June 2021	30 June 2020
	\$	\$
(Loss) is attributable to:		
Owners of Palla Pharma Limited	(33,105,663)	(9,014,762)
Total comprehensive (loss) for the period is attributable to:		
Owners of Palla Pharma Limited	(33,111,483)	(9,810,567)
	Cents	Cents
Earnings per share for the (loss) from continuing operations attributable to the ordinary equity holders of the Company:		
Basic (loss) per share	(22.42)	(7.16)
Diluted (loss) per share	(22.42)	(7.16)

The above consolidated statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes.

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Palla Pharma Limited
Consolidated statement of financial position
As at 30 June 2021

		Consolidated entity	
		30 June	31 December
		2021	2020
	Notes	\$	\$
ASSETS			
Current assets			
Cash and cash equivalents	4	897,312	609,665
Trade and other receivables		3,415,734	6,683,578
Inventories	5	24,836,489	26,890,559
Contract assets		159,291	816,701
Prepayments		1,369,182	1,584,247
Total current assets		30,678,008	36,584,750
Non-current assets			
Inventories	6	273,092	2,255,455
Property, plant and equipment	7	15,747,417	23,517,976
Right-of-use assets	8	480,039	750,407
Intangible assets	9	2,707,922	4,310,976
Total non-current assets		19,208,470	30,834,814
Total assets		49,886,478	67,419,564
LIABILITIES			
Current liabilities			
Trade and other payables		11,500,627	9,213,517
Borrowings	10	15,044,897	5,002,840
Lease liabilities	8	49,239	39,404
Provisions		1,509,729	1,793,791
Total current liabilities		28,104,492	16,049,552
Non-current liabilities			
Trade and other payables		539,579	1,063,352
Borrowings	11	-	13,000,000
Lease liabilities	8	457,627	493,937
Provisions		717,542	689,155
Total non-current liabilities		1,714,748	15,246,444
Total liabilities		29,819,240	31,295,996
Net assets		20,067,238	36,123,568
EQUITY			
Contributed equity	12	227,878,876	210,994,087
Reserves	13	3,232,492	3,067,948
(Accumulated losses)		(211,044,130)	(177,938,467)
Total equity		20,067,238	36,123,568

The above consolidated statement of financial position should be read in conjunction with the accompanying notes.

Palla Pharma Limited
Consolidated statement of changes in equity
For the half-year ended 30 June 2021

Consolidated entity	Notes	Attributable to owners of Palla Pharma Limited				Total equity \$
		Contributed equity \$	Share-based payments \$	Foreign currency translation reserve \$	(Accumulated losses) \$	
Balance at 1 January 2020		210,997,191	2,791,792	803,431	(143,182,411)	71,410,003
(Loss) for the half-year Other comprehensive (loss)		-	-	-	(9,014,762)	(9,014,762)
Total comprehensive (loss) for the period		-	-	(795,805)	-	(795,805)
Transactions with owners in their capacity as owners:						
Contributions of equity, net of transaction costs and tax		(3,104)	-	-	-	(3,104)
Share-based payments		-	143,709	-	-	143,709
		(3,104)	143,709	-	-	140,605
Balance at 30 June 2020		210,994,087	2,935,501	7,626	(152,197,173)	61,740,041
Balance at 1 January 2021		210,994,087	2,968,751	99,197	(177,938,467)	36,123,568
(Loss) for the half-year Other comprehensive (loss)		-	-	-	(33,105,663)	(33,105,663)
Total comprehensive (loss) for the period		-	-	(5,820)	-	(5,820)
Transactions with owners in their capacity as owners:						
Contributions of equity, net of transaction costs and tax		16,884,789	-	-	-	16,884,789
Share-based payments		-	170,364	-	-	170,364
		16,884,789	170,364	-	-	17,055,153
Balance at 30 June 2021		227,878,876	3,139,115	93,377	(211,044,130)	20,067,238

The above consolidated statement of changes in equity should be read in conjunction with the accompanying notes.

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Palla Pharma Limited
Consolidated statement of cash flows
For the half-year ended 30 June 2021

		Consolidated entity	
		30 June	30 June
		2021	2020
Notes		\$	\$
Cash flows from operating activities			
	Receipts from customers (inclusive of VAT)	9,627,890	21,135,368
	Payments to suppliers and employees (inclusive of GST and VAT)	(22,327,122)	(25,788,677)
		<u>(12,699,232)</u>	<u>(4,653,309)</u>
	Interest received	15,618	11,635
	Interest and finance costs paid	(664,379)	(796,389)
	Net cash (outflow) from operating activities	15 (13,347,993)	(5,438,063)
Cash flows from investing activities			
	Payments for property, plant and equipment	(155,473)	(478,501)
	Payments for capitalised development costs and patents	(318,596)	(1,692,602)
	Proceeds from sale of non-current assets	92,146	24,727
	Net cash (outflow) from investing activities	(381,923)	(2,146,376)
Cash flows from financing activities			
	Share issuance transaction costs	12 (343,501)	(3,104)
	Proceeds from issues of shares	12 17,228,290	-
	Proceeds from borrowings	2,558,873	7,810,591
	Repayment of borrowings	(5,516,816)	(437,655)
	Net cash inflow from financing activities	13,926,846	7,369,832
Net increase (decrease) in cash and cash equivalents			
		196,930	(214,607)
	Cash and cash equivalents at the beginning of the financial period	609,665	2,019,087
	Effects of exchange rate changes on the balance of assets held in foreign currencies	90,717	(160,257)
	Cash and cash equivalents at end of period	4 897,312	1,644,223

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

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1 Basis of preparation of preliminary interim report

This consolidated preliminary interim report for the half-year reporting period ended 30 June 2021 has been prepared in accordance with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Act 2001*. Compliance with AASB 134 ensures compliance with International Financial Reporting Standard IAS 34 *Interim Financial Reporting*.

This condensed preliminary interim report does not include all of the notes of the type normally included in an annual financial report, however selected explanatory notes are included to explain events and transactions that are significant to understanding the changes to the Group's financial position and performance since 31 December 2020. Accordingly, it should be read in conjunction with the Annual Report for the year ended 31 December 2020 and any public announcements made by Palla Pharma Limited, since 31 December 2020, in accordance with continuous disclosure requirements of the *Corporations Act 2001*. This preliminary interim report has been prepared in accordance with the measurement and recognition requirements of Australian Accounting Standards, Accounting Interpretations and the *Corporations Act 2001*.

This preliminary interim report has been prepared on the basis of historical cost, except for the revaluation of certain non-current assets and financial instruments. Cost is based on the fair values of the consideration given in exchange for the assets. All amounts are presented in Australian dollars, unless otherwise noted. All values are rounded to the nearest dollar.

The accounting policies and methods of computation adopted in the preparation of the preliminary interim report are consistent with those adopted and disclosed in the Group's annual financial report for the year ended 31 December 2020.

This preliminary interim report was authorised for issue by the Group's Board of Directors on 31 August 2021.

(a) Significant accounting policies

The accounting policies applied in this preliminary interim report are the same as those applied in the Group's consolidated financial report as at and for the year ended 31 December 2020.

(b) Use of estimates and judgements

The preparation of consolidated financial statements in conformity with Australian Accounting Standards requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimates are revised and in any future periods affected.

Information about assumptions and estimation uncertainties that have a significant risk of resulting in a material adjustment in the half-year ended ending 30 June 2021 is included in the following notes:

Note 1(c) - Going concern: key assumptions associated with the cash flow forecast.

Note 5 - Inventories: key assumptions underlying recoverable amounts of inventory.

Notes 7 and 9 - Impairment testing: key assumptions underlying recoverable amounts of property, plant and equipment and intangible assets.

1 Basis of preparation of preliminary interim report (continued)

(c) Going concern

The consolidated financial statements have been prepared on a going concern basis, which assumes continuity of normal business activities and the realisation of assets and settlement of liabilities in the ordinary course of business for a period of at least 12 months from the date that these financial statements are approved.

For the half-year ended 30 June 2021 the Group generated a loss after income tax of \$33,105,663 (2020: \$9,014,762) and had cash outflows from operations of \$13,347,993 (2020: \$5,438,063).

To facilitate the Group's working capital requirements, the Group has a standby debt facility in place with Washington H. Soul Pattinson and Company Limited, a substantial shareholder. In conjunction with the establishment of the facility, the Group obtained shareholder approval to grant security over its assets for advances under the facility totalling \$25,000,000. At 30 June 2021, the facility, which is secured against the assets of the Group, provides access to funds of up to \$15,000,000 and has a maturity date of 1 April 2022.

Subsequent to balance date, on 13 July 2021 the standby debt facility with Washington H. Soul Pattinson and Company Limited was increased to \$20,000,000 with an interest rate of 13% to apply on funds drawn up to \$15,000,000 and 17.5% on the whole of the drawn funds, if the facility was drawn down above \$15,000,000 (Tranche 1).

Subsequently, on 31 August 2021, the facility was further increased by a second tranche of funding totalling \$5,000,000 (Tranche 2) providing a total facility of \$25,000,000. Interest on both tranches of funding is able to be capitalised rather than being paid monthly as previously required and the rate of interest charged on Tranches 1 and Tranche 2 will be reduced to 10% and 12% respectively if certain milestones are achieved by the business prior to maturity of the facility in April 2022.

In addition, on 20 July 2021 the Group appointed an agent to commence a process to execute a sale and leaseback of its Melbourne based property where its Australian manufacturing operations are located with the objective that the property sale proceeds will be used to reduce debt, with any excess sale proceeds to be used for ongoing working capital requirements.

The Directors remain confident in the continued support from existing shareholders and the Group's ability to attract new investors and debt providers to fund growth and future working capital requirements, when required, as demonstrated by previous capital and debt raisings.

In the event that the forecast financial performance of the Group is not met as anticipated, and the Group is unable to attract new debt or equity funding, material uncertainty exists as to whether the Group may be able to continue as a going concern, and therefore it may be required to realise its assets and extinguish its liabilities other than in the normal course of business, and at amounts different to those stated in the financial report.

The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts, or to the amounts and classification of liabilities that may be necessary should the Group be unable to continue as a going concern.

Further details of the going concern preparation basis of the consolidated financial statements will be provided in the Group's interim financial report for the half-year ended 30 June 2021 to be issued by the end of September 2021.

2 Segment information

Operating segments are presented using the 'management approach', where the information presented is on the same basis as the internal reports provided to the Chief Operating Decision Maker ('CODM') of the Group. The CODM is responsible for the allocation of resources to operating segments and assessing their performance. The CODM has been identified as the CEO. Segment information is presented to the CEO comprising two segments: Australia and Norway.

Australia

Segment activities: Narcotic Raw Material and Poppy Seed production and distribution.

Norway

Segment activities: Active Pharmaceutical Ingredient and Finished Dosage Formulation production and distribution.

	Australia		Norway		Eliminations		Consolidated	
	30 June 2021	30 June 2020	30 June 2021	30 June 2020	30 June 2021	30 June 2020	30 June 2021	30 June 2020
Consolidated entity	\$	\$	\$	\$	\$	\$	\$	\$
External revenue	863,087	2,555,986	6,197,785	9,772,956	-	-	7,060,872	12,328,942
Inter-segment revenue	4,884,956	9,926,497	-	-	(4,884,956)	(9,926,497)	-	-
Total segment revenue	<u>5,748,043</u>	<u>12,482,483</u>	<u>6,197,785</u>	<u>9,772,956</u>	<u>(4,884,956)</u>	<u>(9,926,497)</u>	<u>7,060,872</u>	<u>12,328,942</u>
Reportable segment (loss)/profit before tax	<u>(24,967,620)</u>	<u>(536,650)</u>	<u>(7,247,401)</u>	<u>(7,091,832)</u>	<u>42,325</u>	<u>(386,914)</u>	<u>(32,172,696)</u>	<u>(8,015,396)</u>
<i>Unallocated amounts</i>								
Net financing costs							(932,967)	(999,366)
Consolidated (loss) before tax							<u>(33,105,663)</u>	<u>(9,014,762)</u>

2 Segment information (continued)

	Australia		Norway		Eliminations		Consolidated	
	30 June 2021	30 June 2020	30 June 2021	30 June 2020	30 June 2021	30 June 2020	30 June 2021	30 June 2020
Consolidated entity	\$	\$	\$	\$	\$	\$	\$	\$
Timing of External revenue recognition:								
Narcotic Raw Material & Poppy Seed								
- at a point in time	859,817	2,484,293	-	-	-	-	859,817	2,484,293
Active Pharmaceutical Ingredient								
- at a point in time	-	-	4,516,655	5,976,262	-	-	4,516,655	5,976,262
Finish Dosage Formulation - over time	-	-	1,450,137	3,792,890	-	-	1,450,137	3,792,890
Finish Dosage Formulation - at a point in time	-	-	230,993	-	-	-	230,993	-
Other revenue - at a point in time	3,270	71,693	-	3,804	-	-	3,270	75,497
	863,087	2,555,986	6,197,785	9,772,956	-	-	7,060,872	12,328,942

2 Segment information (continued)

	Consolidated entity	
	30 June 2021 \$	31 December 2020 \$
Non-current assets		
Australia	16,511,898	28,210,686
Europe	2,696,572	2,624,128
	19,208,470	30,834,814

3 Expenses

	Consolidated entity	
	30 June 2021 \$	30 June 2020 \$
(Loss) before income tax includes the following specific expenses:		
<i>Employee benefits expenses</i>		
Salaries and wages	7,186,566	7,313,580
Other associated personnel expenses	795,305	165,704
Defined contribution superannuation expenses	235,064	304,014
Increase in liability for long service leave	28,387	37,884
Increase in liability for annual leave	378,891	195,742
Share-based payments	170,364	143,709
Total employee benefits expenses	8,794,577	8,160,633
<i>Depreciation</i>		
Buildings	74,287	204,732
Contract equipment	43,515	82,149
Manufacturing plant and equipment	853,462	882,642
Office equipment	140,982	109,125
Motor vehicles	9,200	12,685
Right-of-use assets	38,017	-
Total depreciation	1,159,463	1,291,333
<i>Amortisation</i>		
Patents	69,738	63,299
Capitalised development costs	5,063	-
Total amortisation	74,801	63,299
Total depreciation and amortisation	1,234,264	1,354,632

3 Expenses (continued)

(continued)

	Consolidated entity	
	30 June 2021	30 June 2020
	\$	\$
<i>Finance income</i>		
Interest income	(15,618)	(11,635)
Net exchange gains on foreign currency	(155,983)	-
	<u>(171,601)</u>	<u>(11,635)</u>
<i>Finance costs</i>		
Interest and finance expenses on financial liabilities measured at amortised cost	985,519	514,221
Unwind of discount on trade payable	119,049	214,612
Net exchange losses on foreign currency	-	282,168
	<u>1,104,568</u>	<u>1,011,001</u>
Net finance expenses recognised in profit or loss	<u>932,967</u>	<u>999,366</u>

4 Current assets - Cash and cash equivalents

	Consolidated entity	
	30 June 2021	31 December 2020
	\$	\$
Cash at bank	<u>897,312</u>	<u>609,665</u>

5 Current assets - Inventories

	Consolidated entity	
	30 June 2021	31 December 2020
	\$	\$
Raw materials and consumables	10,472,897	3,904,701
Work in progress	8,578,209	20,275,119
Finished goods	5,785,383	2,710,739
	<u>24,836,489</u>	<u>26,890,559</u>

During the six months ended 30 June 2021, the Group impaired its high thebaine content straw inventory by \$1,395,483 due to a pending sale agreement, and NRM work in progress inventory by \$10,130,788 due to a modification in the production process requiring a change in inventory obsolescence provisioning methodology. These inventory impairments totalling \$11,526,271 are shown as "impairment of inventory to net realisable value" in the consolidated statement of profit or loss and other comprehensive income.

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6 Non-current assets - Inventories

	Consolidated entity	
	30 June 2021 \$	31 December 2020 \$
Raw materials and consumables	-	1,982,363
Work in progress	250,901	250,901
Finished goods	22,191	22,191
	273,092	2,255,455

7 Non-current assets - Property, plant and equipment

	Land and buildings \$	Manufacturing plant and equipment \$	Office equipment \$	Motor vehicles \$	Contract plant and equipment \$	Total \$
At 31 December 2020						
Cost	9,403,975	27,754,209	1,897,218	249,801	1,595,517	40,900,720
Accumulated depreciation	(915,756)	(14,823,637)	(812,749)	(125,809)	(704,793)	(17,382,744)
Net book amount	8,488,219	12,930,572	1,084,469	123,992	890,724	23,517,976
Period ended 30 June 2021						
Opening net book amount	8,488,219	12,930,572	1,084,469	123,992	890,724	23,517,976
Exchange differences	6,456	43,347	7,431	-	-	57,234
Additions	46,826	74,875	23,319	-	-	145,020
Disposals	-	(96,549)	-	-	(44,277)	(140,826)
Impairment charge	-	(5,784,606)	(405,219)	(65,133)	(455,583)	(6,710,541)
Depreciation charge	(74,287)	(853,462)	(140,982)	(9,200)	(43,515)	(1,121,446)
Closing net book amount	8,467,214	6,314,177	569,018	49,659	347,349	15,747,417
At 30 June 2021						
Cost	9,466,725	27,528,712	1,936,401	250,076	1,349,547	40,531,461
Accumulated depreciation	(999,511)	(21,214,535)	(1,367,383)	(200,417)	(1,002,198)	(24,784,044)
Net book amount	8,467,214	6,314,177	569,018	49,659	347,349	15,747,417

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7 Non-current assets - Property, plant and equipment (continued)

Impairment testing

During the half-year ended 30 June 2021, the Group continued to record operating losses and accordingly has performed impairment testing to assess whether the recoverable amount of its property, plant and equipment and intangible assets are in excess of their carrying value.

For the purpose of impairment testing the Group has defined two Cash Generating Units (CGU) the Australia CGU and the Norway CGU.

The recoverable amount for the CGU's was determined based on value-in-use calculations which require the use of assumptions.

Value in use as at 30 June 2021 was determined for the Australia CGU, based on the following key assumptions:

- Cash flows were forecast based on the Group's five-year business plan and risk adjusted to reflect uncertainty created by possible COVID-19 impacts, with the terminal value based on the fifth-year cash flow and a long-term growth rate of 2.5%, which is consistent with the long-term inflation and growth targets for Australia of between 2% and 3%.
- Forecast sales volumes are based on past performance and management's expectations of new market development and performance of Marketing Authorisation FDF products in the UK.
- Forecast foreign currency rates are set based on a range of external market commentator forecasts.
- Sales prices are based on current industry trends for each sales territory and contracted pricing where applicable.
- Forecast gross margins are based on past performance and management's expectations for the performance of Marketing Authorisation FDF products in the UK.
- Other operating costs of the CGU, which do not vary significantly with sales volumes or prices, have been forecast by management based on the current structure of the business, but not reflecting any future restructurings or cost saving measures.
- Poppy straw harvesting yields were considered based on historical yield performance, climate-induced variations such as severe weather events, past plant losses and new growing areas coming into production.
- Annual capital expenditure is based on the historical experience of management. No incremental cost savings are assumed in the value-in-use model as a result of this expenditure.
- An after-tax discount rate of 10.0% (2020: 8.5%) for the Australia CGU reflecting an increased risk factored into the discount rate as a result of the increased forecasting risk associated with the underlying forecast cashflows for this CGU, and 8.6% for the Norway CGU was applied in determining the recoverable amount of the CGU's based on an industry average weighted-average cost of capital and applying a premium to the industry average due to the Group's size and stage of lifecycle.

Significant assumptions used in the impairment testing referred to above are inherently subjective, and in times of economic uncertainty the degree of subjectivity is higher than it might otherwise be. Accordingly, it should be noted that the risks and uncertainties associated with the possible impacts of the COVID-19 pandemic and the economic environment could cause the actual results to differ from management's projections used in the assessment, which could lead to significant changes in the recoverable amount of the Australia CGU.

The carrying amount of the Australia CGU was determined to be higher than its recoverable amount and an impairment loss of \$8,224,960 at 30 June 2021 was recognised. The impairment loss was allocated to intangible assets, right of use assets, and property, plant and equipment and is included in the impairment of non-financial assets expense in the consolidated statement of profit or loss and other comprehensive income.

8 Leases

The Group has leased facilities for seasonal poppy straw storage for an initial five year term with extension options of an additional five years at the conclusion of the initial term. In determining the right-of-use asset and lease liability at the lease commencement date, the Group has assessed that it is reasonably certain that it will exercise the extension options.

(a) Amounts recognised in the consolidated statement of financial position

The consolidated statement of financial position shows the following amounts relating to leases:

	Consolidated entity	
	30 June 2021 \$	31 December 2020 \$
Right-of-use assets		
Buildings - Cost	767,166	756,713
Buildings - Accumulated depreciation	(44,323)	(6,306)
Buildings - Accumulated impairment	(242,804)	-
	480,039	750,407
Lease liabilities		
Current	49,239	39,404
Non-current	457,627	493,937
	506,866	533,341
Provisions		
Non-current	227,014	227,014
	227,014	227,014

Additions to right-of-use assets during the half-year ending 2021 financial period were \$10,453.

(b) Amounts recognised in the consolidated statement of profit or loss and other comprehensive income

The consolidated statement of profit or loss and other comprehensive income shows the following amounts relating to leases:

	Consolidated entity	
	30 June 2021 \$	30 June 2020 \$
Depreciation charge of right-of-use assets		
Buildings - Depreciation	38,017	-
Buildings - Impairment	242,804	-
	280,821	-
Interest expense (included in finance costs)	21,024	-

The total cash outflow for leases for the half-year ending 2021 was \$47,499.

9 Non-current assets - Intangible assets

	Goodwill \$	Patents, trademarks and other rights \$	Capitalised development costs \$	Total \$
At 31 December 2020				
Cost	13,955,503	3,091,664	1,422,853	18,470,020
Accumulated amortisation and impairment	(13,955,503)	(203,541)	-	(14,159,044)
Net book amount	-	2,888,123	1,422,853	4,310,976
Period ended 30 June 2021				
Opening net book amount	-	2,888,123	1,422,853	4,310,976
Exchange differences	-	874	1,338	2,212
Additions	-	11,188	307,408	318,596
Transfers between asset classes *	-	(577,446)	-	(577,446)
Impairment charge	-	(743,059)	(528,556)	(1,271,615)
Amortisation charge	-	(69,738)	(5,063)	(74,801)
Closing net book amount	-	1,509,942	1,197,980	2,707,922
At 30 June 2021				
Cost	13,955,503	3,105,637	1,731,599	18,792,739
Accumulated amortisation and impairment	(13,955,503)	(1,595,695)	(533,619)	(16,084,817)
Net book amount	-	1,509,942	1,197,980	2,707,922

* Transfer of poppy straw license right costs to inventory.

Impairment testing

The intangible assets and development costs were tested as part of the CGU testing performed.

Refer to note 7 for further details of the Group's impairment testing for the half-year ended 30 June 2021.

10 Current liabilities - Borrowings

This note provides information about the Group's current interest-bearing loans and borrowings, which are measured at amortised cost.

	Consolidated entity	
	30 June 2021	31 December 2020
	\$	\$
Shareholder loan facility	15,000,000	4,400,000
Other loans	44,897	602,840
Total current borrowings	15,044,897	5,002,840

Refer to note 11 for movements during the half-year, and the contractual terms of the Group's current borrowings.

11 Non-current liabilities - Borrowings

This note provides information about the Group's non-current interest-bearing loans and borrowings, which are measured at amortised cost.

	Consolidated entity	
	30 June 2021	31 December 2020
	\$	\$
Shareholder loan facility	-	13,000,000
Total non-current borrowings	-	13,000,000

Washington H. Soul Pattinson and Company Limited, a substantial shareholder has provided the Group with a standby debt facility with a limit of up to \$15,000,000 (31 December 2020: \$20,000,000) to meet the Group's short term working capital needs. As at 30 June 2021 the Group had drawn down \$15,000,000 of the facility (31 December 2020: \$17,400,000), and the maturity date of this facility was 1 April 2022.

Subsequent to balance date, on 13 July 2021 the standby debt facility with Washington H. Soul Pattinson and Company Limited was increased to \$20,000,000 with an interest rate of 13% to apply on funds drawn up to \$15,000,000 and 17.5% on the whole of the drawn funds, if the facility was drawn down above \$15,000,000 (Tranche 1).

Subsequently, on 31 August 2021, the facility was further increased by a second tranche of funding totalling \$5,000,000 (Tranche 2) providing a total facility of \$25,000,000. Interest on both tranches of funding is able to be capitalised rather than being paid monthly as previously required and the rate of interest charged on Tranches 1 and Tranche 2 will be reduced to 10% and 12% respectively if certain milestones are achieved by the business prior to maturity of the facility in April 2022.

This facility is secured by a General Security Deed in favour of Washington H. Soul Pattinson and Company Limited over all present and after-acquired assets of the Group, and mortgage over the Group's Melbourne based property where its Australian manufacturing operations are located.

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11 Non-current liabilities - Borrowings (continued)

(a) Movements during the half-year

	Currency	Nominal interest rate	Year of maturity	Movement	Carrying amount (\$)
At 1 January 2021					18,002,840
<i>(Repayments)/drawings</i>					
Shareholder loan facility - Tranche A	AUD	8.25%	2022	(13,000,000)	-
Shareholder loan facility - Tranche B	AUD	13.00%	2022	(4,400,000)	-
Shareholder loan facility - Tranche C	AUD	12.00%	2022	15,000,000	15,000,000
Insurance premium funding	AUD	5.31%	2021	(228,905)	-
Insurance premium funding	AUD	3.44%	2021	(77,804)	-
Insurance premium funding	AUD	2.82%	2021	(296,604)	-
Insurance premium funding	AUD	3.79%	2022	43,352	43,352
Corporate credit card	AUD	-	2021	2,018	1,545
Carrying amount 30 June 2021				(2,957,943)	15,044,897

(b) Terms and debt repayment schedule

Terms and conditions of outstanding loans were as follows:

	Currency	Nominal interest rate	Year of maturity	30 June 2021 Carrying amount (\$)	31 December 2020 Carrying amount (\$)
Shareholder loan facility - Tranche A	AUD	8.25%	2022	-	13,000,000
Shareholder loan facility - Tranche B	AUD	13.00%	2022	-	4,400,000
Shareholder loan facility - Tranche C	AUD	12.00%	2022	15,000,000	-
Insurance premium funding	AUD	5.31%	2021	-	228,905
Insurance premium funding	AUD	3.44%	2021	-	77,804
Insurance premium funding	AUD	2.82%	2021	-	296,604
Insurance premium funding	AUD	3.79%	2022	43,352	-
Corporate credit card	AUD	-	2021	1,545	(473)
Total interest bearing liabilities				15,044,897	18,002,840

The carrying value of financial assets and liabilities represents a reasonable approximation of fair value.

12 Contributed equity

(a) Share capital

	30 June 2021 Shares	31 December 2020 Shares	30 June 2021 \$	31 December 2020 \$
Ordinary shares Fully paid	161,913,363	125,947,977	227,878,876	210,994,087

(b) Movements in ordinary shares:

Details	Number of shares	\$
Opening balance 1 January 2021	125,947,977	210,994,087
Shares issued for cash	35,965,386	17,982,593
Less: Transaction costs arising on share issues	-	(1,097,804)
Closing balance 30 June 2021	161,913,363	227,878,876

(c) Ordinary shares

The Company does not have authorised capital or par values in respect of its issued shares. All issued shares are fully paid. All shares rank equally.

Ordinary shares participate in dividends and the proceeds on winding up of the Company in equal proportion to the number of shares held. At shareholder meetings each ordinary share is entitled to one vote when a poll is called, otherwise each shareholder has one vote on a show of hands. In respect of the Company's shares that are held by the Company, all rights are suspended until those shares are reissued.

The holders of ordinary shares are entitled to receive dividends as declared from time to time, and are entitled to one vote per share at meetings of the Company.

13 Reserves

Foreign currency translation reserve

Exchange differences relating to translation from functional currencies of the Group's foreign controlled entities into Australian Dollars are brought to account by entries made directly to the foreign currency translation reserve.

Other reserves

Other reserves comprise a share-based payment reserve.

14 Contingencies

The Group had no contingent liabilities at 30 June 2021 (2020: nil).

15 Cash flow information

Reconciliation of (loss) after income tax to net cash (outflow) from operating activities

	Consolidated entity	
	30 June 2021 \$	30 June 2020 \$
(Loss) for the year	(33,105,663)	(9,014,762)
Depreciation expense	1,159,463	1,291,333
Amortisation expense	74,801	63,299
Net loss/(gain) on sale of non-current assets	48,680	(9,045)
Impairment of inventory to net realisable value	11,526,271	-
Impairment of non-financial assets	8,224,960	-
Impairment (reversal)/loss of trade receivables	(1,053,089)	1,050,000
Unwind of discount on trade payable	119,049	214,612
Foreign currency translation movement	-	421,633
Equity-settled share-based payment transactions	170,364	143,709
Interest income	(171,601)	(11,635)
Interest expense	985,519	796,389
Change in operating assets and liabilities:		
Decrease in trade, other receivables and contract assets	2,567,018	8,583,857
(Increase) in inventories	(4,501,067)	(5,068,047)
Decrease/(increase) in prepayments	215,065	(945,749)
Increase/(decrease) in trade and other payables	1,296,673	(1,804,197)
Decrease in provisions	(255,675)	(364,706)
Interest received	15,618	11,635
Interest paid	(664,379)	(796,389)
Net cash (outflow) from operating activities	<u>(13,347,993)</u>	<u>(5,438,063)</u>

16 Events occurring after the reporting period

On 20 July 2021 the Group appointed an agent to commence a process to execute a sale and leaseback of its Melbourne based property where its Australian manufacturing operations are located with the objective that the property sale proceeds will be used to reduce debt, with any excess sale proceeds to be used for ongoing working capital requirements.

On 13 July 2021 the standby debt facility with Washington H. Soul Pattinson and Company Limited was increased to \$20,000,000 with an interest rate of 13% to apply on funds drawn up to \$15,000,000 and 17.5% on the whole of the drawn funds, if the facility was drawn down above \$15,000,000 (Tranche 1).

Subsequently, on 31 August 2021, the facility was further increased by a second tranche of funding totalling \$5,000,000 (Tranche 2) providing a total facility of \$25,000,000. Interest on both tranches of funding is able to be capitalised rather than being paid monthly as previously required and the rate of interest charged on Tranches 1 and Tranche 2 will be reduced to 10% and 12% respectively if certain milestones are achieved by the business prior to maturity of the facility in April 2022. Tranche 2 includes funding from other major shareholders who have sub-participated through the existing Washington H. Soul Pattinson and Company Limited facility. The Group does not have any direct agreements with the shareholders who are sub-participating in the facility.

No other matters or circumstances have occurred subsequent to year end that has significantly affected, or may significantly affect, the operations of the Group, the results of those operations or the state of affairs of the Group or economic entity in subsequent financial years.