

ASX Announcement 23 February 2017

# Financial Report – Half Year ended 31 December 2016 Half Yearly Report - Appendix 4D

Sydney, Australia – 23 February 2017: OncoSil Medical Ltd (ASX: OSL) (OncoSil or the Company), a late stage medical devices company focused on localised treatments for patients with pancreatic and liver cancer, is pleased to report its financial results for the half year ended 31 December 2016 (the Half-Year) (the Financial Report) and its Appendix 4D. All financial results are in Australian dollars and are unaudited.

# **Highlights - Operational**

The Company completed a number of milestones during the Half-Year, with the key focus being the continued progress on the Company's CE Mark application, the Investigational Device Exemption (**IDE**) approval from the Food and Drug Administration (FDA) and the commencement of the OncoPac clinical study program. The highlights included the following:

- IDE approval from the FDA enabling the commencement of OncoPac-1 global pivotal study for the treatment of patients with pancreatic cancer
- Completed a number of successful hot calibration runs testing the production and logistics function with the Royal North Shore Hospital, Sydney; Monash Health, Victoria; Westmead Hospital, Sydney, and The Guy's and St Thomas' Hospital, London which included initial training and calibration of their equipment to ensure dose accuracy
- 12 centres have confirmed participation in OncoPac clinical study, including the MD Anderson Cancer Centre in Texas, The Johns Hopkins University Hospital in Maryland, The Guy's and St Thomas' Hospital in the UK, The Institute of Jules Bordet in Brussels. All these centres have commenced their respective internal and/or ethics approval processes. Monash Health in Melbourne received Ethics approval on February 2<sup>nd</sup>.
- Continued engagement with BSI, the Company's Notified Body, on the progress of the CE Mark with the company announcing on 8 February 2017, that BSI has requested the provision of supplemental data from 20 locally advanced pancreatic cancer patients supporting the existing safety and clinical performance data already reviewed, and undertake a post marketing clinical follow-up programme as the remaining conditions to the grant of a CE Mark.

# **Key Points - Financial**

- Cash, cash equivalents and financial assets balance as at 31 December 2016 was \$11.6m
- R&D tax incentive refund of \$2.3m received (2015: \$1.5m)

OncoSil Chief executive Officer, Daniel Kenny commented:

"These past six months have been productive and exciting for Oncosil with the granting of the IDE from the FDA and the commencement of OncoPac clinical study program. We have a number of prestigious centres confirmed for the study and additional centres who have expressed interest in participating, highlighting physicians' interest in our novel device.

We are committed to achieving our CE Mark and now have a clear path forward from the regulators."

# – ENDS –

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# About OncoSil

OncoSil Medical is a medical device company seeking to advance radiation for cancer patients. OncoSil Medical's lead product, OncoSil<sup>™</sup> is a targeted radioactive isotope (Phosphorous-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with OncoSil<sup>™</sup> is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted four clinical studies with encouraging results on tolerability, safety and efficacy. A CE Mark application to commercially sell OncoSil<sup>™</sup> in the European Union (EU) is under review with commercial launch, subject to approval.

An Investigational Device Exemption (IDE) has been granted by the United States Food and Drug Administration (FDA) to conduct a clinical study of the OncoSil<sup>™</sup> device aimed at supporting a PMA approval. Pancreatic cancer is typically diagnosed at a later stage, when there is a poor prognosis for long-term survival. The World Cancer Research Fund estimated that in 2012, 338,000 people globally were diagnosed with pancreatic cancer. The prognosis for patients diagnosed with pancreatic cancer, regardless of stage, is generally poor; the relative five-year survival rate for all stages combined is approximately 5%. The estimated world-wide market opportunity for OncoSil<sup>™</sup> in pancreatic cancer exceeds \$1b.

Hepatocellular carcinoma (HCC) or liver cancer, is the 6th most common cancer in the world with 782,000 new cases diagnosed in 2012. While hepatocellular carcinoma can be treated by surgery or transplantation, the majority of patients with HCC have disease which is too advanced for surgery and their survival ranges from a few months to two or more years. The value of the hepatocellular cancer market is expected to triple in size to \$1.4b by 2019.

#### **Forward Looking Statements**

This document contains certain forward-looking statements, relating to OncoSil's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil Medical is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.

#### OncoSil Medical Ltd Appendix 4D Half-year report

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#### 1. Company details

Name of entity:	OncoSil Medical Ltd
ABN:	89 113 824 141
Reporting period:	For the half-year ended 31 December 2016
Previous period:	For the half-year ended 31 December 2015

### 2. Results for announcement to the market

			\$
Revenues from ordinary activities	down	59.8% to	1,056,046
Loss from ordinary activities after tax attributable to the owners of OncoSil Medical Ltd	up	75.7% to	(3,111,923)
Loss for the half-year attributable to the owners of OncoSil Medical Ltd	up	75.7% to	(3,111,923)

#### Dividends

There were no dividends paid, recommended or declared during the current financial period.

#### Comments

The loss for the Group after providing for income tax amounted to \$3,111,923 (31 December 2015: \$1,770,689).

Further information on the results is detailed in the 'Review of operations' section of the Directors' report which is part of the Interim Report.

#### 3. Net tangible assets

	Reporting period Cents	Previous period Cents
Net tangible assets per ordinary security	2.64	1.81

#### 4. Control gained over entities

Not applicable.

#### 5. Loss of control over entities

Not applicable.

#### 6. Dividend reinvestment plans

Not applicable.

#### 7. Details of associates and joint venture entities

#### Not applicable.

#### 8. Foreign entities

Details of origin of accounting standards used in compiling the report:

Not applicable.

# 9. Audit qualification or review

Details of audit/review dispute or qualification (if any):

The financial statements were subject to a review by the auditors and the review report is attached as part of the Interim Report.

#### **10. Attachments**

Details of attachments (if any):

The Interim Report of OncoSil Medical Ltd for the half-year ended 31 December 2016 is attached.

11. Signed

Signed

Date: 23 February 2017

Dr Roger Aston Non-Executive Chairman Sydney





# **OncoSil Medical Ltd**

ABN 89 113 824 141

Interim Report - 31 December 2016



The directors present their report, together with the financial statements, on the consolidated entity (referred to hereafter as the 'Group') consisting of OncoSil Medical Ltd (referred to hereafter as the 'Company' or 'parent entity') and the entities it controlled at the end of, or during, the half-year ended 31 December 2016.

#### Directors

The following persons were directors of OncoSil Medical Ltd during the whole of the financial half-year and up to the date of this report, unless otherwise stated:

Dr Roger Aston Mr Daniel Kenny Dr Chris Roberts Mr Martin Rogers (resigned on 18 October 2016) Non-Executive Chairman Chief Executive Officer and Managing Director Non-Executive Director Non-Executive Director

#### **Principal activities**

The principal activities of the Group during the financial half-year focused on the development of its lead product candidate, the OncoSil<sup>™</sup> localised radiation therapy for the treatment of pancreatic cancer.

#### Review of operations

The loss for the Group after providing for income tax amounted to \$3,111,923 (31 December 2015: \$1,770,689).

OncoSil Medical Ltd is an Australian based and ASX listed, late stage medical device company focused on localised treatments for patients with pancreatic and liver cancer. OncoSil's lead product, OncoSil™, is a silicon and phosphorus (p32) beta emitter, able to be implanted endoscopically in localised solid tumours of patients with pancreatic cancer. This treatment, known as brachytherapy, is intended to deliver more concentrated and localised radiation.

The company's main focus during the six month period has been to progress its application for CE Mark of OncoSil<sup>™</sup> in the European Union and the commencement of its OncoPac global clinical study programme, following the approval for an Investigational Device Exemption (IDE) from the United States Food and Drug Administration (FDA) in July 2016. The key developments in these applications and other highlights for first half of the 2017 financial year are as follows;

- The company continues its engagement with BSI, the company's notified body. In November 2016, the company had a successful meeting with BSI and many aspects of the review have now been closed out. On 8 February 2017, the company announced that BSI has requested the provision of supplemental data from 20 locally advanced pancreatic cancer patients supporting the existing safety and clinical performance data already reviewed, and undertake a post marketing clinical follow-up programme as the remaining conditions to the grant of a CE Mark.
- The company has undertaken a number of steps during the half-year in preparation for the commencement of OncoPac clinical study, including a full hot calibration runs of OncoSil<sup>™</sup> with Monash Health, Melbourne, the Department of Nuclear Medicine, Royal North Shore Hospital, Westmead Hospital and St Vincent's Hospital, Sydney and The Guy's and St Thomas' Hospital in London. The hot runs were completed successfully and included initial training and calibration of the hospital's equipment to ensure dose accuracy of OncoSil<sup>™</sup>.
- During the half-year period, a number of shareholder engagement initiatives were undertaken including meeting a number of existing and potential new institutional shareholders in Australia and Asia.
- In late July 2016, the company obtained an IDE approval from the FDA to begin the OncoPac global clinical study treating up to 300 patients in centres in the United States and internationally. Following this approval, the Company has taken active steps to initiate OncoPac clinical study programme and began active engagement with clinicians and trial centres;
- United States of America The University of Texas, MD Anderson Cancer Centre in Texas, and The Johns Hopkins University Hospital, University Medical School in Maryland, have both agreed to participate as leading centres in the OncoPac-1 study and have commenced the Investigational Review Board process.

A further three centres have confirmed their participation in the study, The Moffitt Cancer Centre in Tampa, Northwestern Memorial Hospital in Chicago, and Cedars-Sinai Hospital in Los Angeles.



• United Kingdom - The Guy's and St Thomas' Hospital, who had previously participated in two early cancer studies using OncoSiITM, will be the lead centre in the UK. The Royal Liverpool, Hammersmith Hospital London, and Addenbrookes Hospital in Cambridge have also agreed to participate in the programme.

The Company has applied for central regulatory and governance applications in the UK, which was granted on 13 February 2017.

- Belgium The Institute Jules Bordet, Brussels has agreed to participate as the lead centre in Belgium.
- Australia Monash Health, the largest public health service in Melbourne, and St Vincent's Hospital, Sydney, have confirmed their participation in the programme.

On 11 November 2016, the company filed its Ethics Committee (HREC) submission which was granted in February 2017. This Ethics Approval will facilitate Australian wide (except WA) ethics approval for other participating trial centres.

The company continues to be in active dialogue with a further seven centres across the UK, Europe and Australia who have expressed interest in participating in the OncoPac programme.

The company hosted its Annual General Meeting on 18 October 2016 with Martin Rogers retiring as a director at the AGM. The Board is continuing to seek additional non-executive directors to bring additional skills and experience as the company moves into its next phase of development.

The company received \$2,300,000 as a cash refund under the R&D Tax Incentive Refund scheme in November 2016 and at 31 December 2016, held \$11,600,000 in cash and cash equivalents and financial assets.

#### Significant changes in the state of affairs

There were no significant changes in the state of affairs of the Group during the financial half-year.

#### Auditor's independence declaration

A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is set out immediately after this directors' report.

This report is made in accordance with a resolution of directors, pursuant to section 306(3)(a) of the Corporations Act 2001.

On behalf of the directors

Dr Roger Aston Non-Executive Chairman

23 February 2017 Sydney



23 February 2017

The Board of Directors OncoSil Medical Ltd Suite 402, Level 4 50 Berry Street NORTH SYDNEY NSW 2000 **Crowe Horwath Sydney** ABN 97 895 683 573 Member Crowe Horwath International

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**Dear Board Members** 

# OncoSil Medical Ltd

In accordance with section 307C of the Corporations Act 2001, I am pleased to provide the following declaration of independence to the Directors of OncoSil Medical Ltd.

As lead audit partner for the review of the half-year financial statements of OncoSil Medical Ltd for the half-year ended 31 December 2016, I declare that to the best of my knowledge and belief, that there have been no contraventions of:

- (i) the auditor independence requirements of the Corporations Act 2001 in relation to the review; and
- (ii) any applicable code of professional conduct in relation to the review.

Yours sincerely

Crowe Howath Sydney

**CROWE HORWATH SYDNEY** 

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JOHN HAYDON Senior Partner

#### OncoSil Medical Ltd Contents 31 December 2016



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# OncoSil Medical Ltd Statement of profit or loss and other comprehensive income For the half-year ended 31 December 2016



		Consol	idated
	Note	31/12/2016 \$	31/12/2015 \$
Revenue Other income	4	1,056,046	2,624,066
Expenses Employee benefits expense Research and development expenses Occupancy expenses Consulting, finance and legal expenses Gain/(loss) on financial assets at fair value through profit or loss Share-based payments Other administrative expenses		(1,874,113) (838,812) (103,602) (553,769) 57,051 (674,150) (180,574)	(1,210,685) (2,107,082) (163,117) (338,639) (24,960) (394,220) (156,052)
Loss before income tax expense		(3,111,923)	(1,770,689)
Income tax expense			<u> </u>
Loss after income tax expense for the half-year attributable to the owners of OncoSil Medical Ltd		(3,111,923)	(1,770,689)
Other comprehensive income			
Items that may be reclassified subsequently to profit or loss Foreign currency translation		(13,556)	<u> </u>
Other comprehensive income for the half-year, net of tax		(13,556)	
Total comprehensive income for the half-year attributable to the owners of OncoSil Medical Ltd		(3,125,479)	(1,770,689)
		Cents	Cents
Basic earnings per share Diluted earnings per share	11 11	(0.67) (0.67)	(0.49) (0.49)

#### OncoSil Medical Ltd Statement of financial position As at 31 December 2016



		Consol	idated
	Note	31/12/2016 \$	30/06/2016 \$
Assets			
Current assets Cash and cash equivalents Trade and other receivables Financial assets at fair value through profit or loss Other Total current assets	5 6	10,736,895 921,526 816,160 <u>118,991</u> 12,593,572	9,780,326 2,627,943 3,258,787 138,199 15,805,255
Non-current assets Plant and equipment Total non-current assets		<u> </u>	91,713 91,713
Total assets		12,674,783	15,896,968
Liabilities			
Current liabilities Trade and other payables Employee benefits Total current liabilities	7	198,278 117,178 315,456	967,886 118,426 1,086,312
Total liabilities		315,456	1,086,312
Net assets		12,359,327	14,810,656
Equity Issued capital Reserves Accumulated losses	8	35,694,596 3,256,792 (26,592,061)	35,694,596 2,596,198 (23,480,138)
Total equity		12,359,327	14,810,656

# **OncoSil Medical Ltd** Statement of changes in equity For the half-year ended 31 December 2016



Consolidated	Issued capital \$	Reserves \$	Accumulated losses \$	Total equity \$
Balance at 1 July 2015	23,806,347	1,866,643	(18,711,540)	6,961,450
Loss after income tax expense for the half-year Other comprehensive income for the half-year, net of tax	-	-	(1,770,689)	(1,770,689)
Total comprehensive income for the half-year	-	-	(1,770,689)	(1,770,689)
<i>Transactions with owners in their capacity as owners:</i> Contributions of equity, net of transaction costs Share-based payments	1,037,500	- 394,220		1,037,500 394,220
Balance at 31 December 2015	24,843,847	2,260,863	(20,482,229)	6,622,481
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Consolidated	Issued capital \$	Reserves \$	Accumulated losses \$	Total equity
	Issued capital	Reserves	Accumulated losses	Total equity
Consolidated	Issued capital \$	Reserves \$	Accumulated losses \$	Total equity \$
Consolidated Balance at 1 July 2016 Loss after income tax expense for the half-year	Issued capital \$	Reserves \$ 2,596,198	Accumulated losses \$ (23,480,138) (3,111,923)	<b>Total equity</b> \$ 14,810,656 (3,111,923)
Consolidated Balance at 1 July 2016 Loss after income tax expense for the half-year Other comprehensive income for the half-year, net of tax	Issued capital \$	Reserves \$ 2,596,198 - (13,556)	Accumulated losses \$ (23,480,138) (3,111,923)	<b>Total equity</b> \$ 14,810,656 (3,111,923) (13,556)

#### OncoSil Medical Ltd Statement of cash flows For the half-year ended 31 December 2016



Consolidated

	31/12/2016 \$	31/12/2015 \$
Cash flows from operating activities Payments to suppliers and employees Dividends received Interest received Research and development tax incentive	(4,094,801) 16,763 118,658 2,297,446	(2,898,710) 55,080 37,473 1,535,444
Net cash used in operating activities	(1,661,934)	(1,270,713)
Cash flows from investing activities Payments for property, plant and equipment Proceeds from disposal of listed securities	(2,256) 2,620,759	(21,629)
Net cash from/(used in) investing activities	2,618,503	(21,629)
Cash flows from financing activities Proceeds from issue of shares		1,037,500
Net cash from financing activities		1,037,500
Net increase/(decrease) in cash and cash equivalents Cash and cash equivalents at the beginning of the financial half-year	956,569 9,780,326	(254,842) 2,522,626
Cash and cash equivalents at the end of the financial half-year	10,736,895	2,267,784

#### OncoSil Medical Ltd Notes to the financial statements 31 December 2016



# Note 1. General information

The financial statements cover OncoSil Medical Ltd as a Group consisting of OncoSil Medical Ltd (the 'Company' or 'parent entity') and the entities it controlled at the end of, or during, the half-year (the 'Group'). The financial statements are presented in Australian dollars, which is OncoSil Medical Ltd's functional and presentation currency.

OncoSil Medical Ltd is a listed public company limited by shares, incorporated and domiciled in Australia. Its registered office and principal place of business is:

Suite 402, Level 4 50 Berry Street North Sydney NSW 2060

A description of the nature of the Group's operations and its principal activities are included in the directors' report, which is not part of the financial statements.

The financial statements were authorised for issue, in accordance with a resolution of directors, on 23 February 2017. The directors have the power to amend and reissue the financial statements.

#### Note 2. Significant accounting policies

These general purpose financial statements for the interim half-year reporting period ended 31 December 2016 have been prepared in accordance with Australian Accounting Standard AASB 134 'Interim Financial Reporting' and the Corporations Act 2001, as appropriate for for-profit oriented entities. Compliance with AASB 134 ensures compliance with International Financial Reporting Standard IAS 34 'Interim Financial Reporting'.

These general purpose financial statements do not include all the notes of the type normally included in annual financial statements. Accordingly, these financial statements are to be read in conjunction with the annual report for the year ended 30 June 2016 and any public announcements made by the Company during the interim reporting period in accordance with the continuous disclosure requirements of the Corporations Act 2001.

The principal accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period, except for the policies stated below.

#### **Comparatives**

Certain comparatives in the statement of profit or loss and other comprehensive income have been reclassified for consistency with the current period presentation.

#### New or amended Accounting Standards and Interpretations adopted

The Group has adopted all of the new or amended Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB') that are mandatory for the current reporting period.

The adoption of these Accounting Standards and Interpretations did not have any significant impact on the financial performance or position of the Group during the financial half-year ended 31 December 2016 and are not expected to have any significant impact for the full financial year ending 30 June 2017. Any new or amended Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

#### Note 3. Operating segments

#### Identification of reportable operating segments

The Group operates in one segment being the drug development for new medical treatments. This is based on the internal reports that are reviewed and used by the Board of Directors (who are identified as the Chief Operating Decision Makers ('CODM')) in assessing performance and in determining the allocation of resources. There is no aggregation of operating segments.

The information reported to the CODM is on at least a monthly basis. The financial information presented in these financial statements are the same as that presented to the CODM.

#### OncoSil Medical Ltd Notes to the financial statements 31 December 2016

# Note 4. Other income



	Conso	lidated
	31/12/2016 \$	31/12/2015 \$
Research and development tax incentive	900,000	2,500,444
Dividends	16,763	55,080
Interest	118,658	37,473
Net gain on disposal of asset	18,476	-
Net gain on foreign exchange	2,149_	31,069
Other income	1,056,046	2,624,066

### Note 5. Current assets - trade and other receivables

	Consol	Consolidated	
	31/12/2016 \$	30/06/2016 \$	
Other receivables Research and development tax incentive receivable	21,526 900.000	330,497 2,297,446	
	921.526	2,627,943	

# Note 6. Current assets - financial assets at fair value through profit or loss

	Consol 31/12/2016 \$	idated 30/06/2016 \$
Listed shares - designated at fair value through profit or loss	816,160	3,258,787
<i>Reconciliation</i> Reconciliation of the fair values at the beginning and end of the current financial half-year is set out below:		
Opening fair value Fair value movement Disposals	3,258,787 (110,211) (2,332,416)	3,597,675 (37,704) (301,184)
Closing fair value	816,160	3,258,787

Refer to note 9 for further information on fair value measurement.

Note 7. Current liabilities - trade and other payables

	Consol	Consolidated		
	31/12/2016 \$	30/06/2016 \$		
Trade payables Payroll liabilities	66,097 109,833	216,698 662,961		
Other payables	22,348	88,227		
	198,278	967,886		

#### Note 8. Equity - reserves



	Consolidated	Consolidated		
	31/12/2016 30/06/2016 \$ \$			
Foreign currency reserve Share-based payments reserve	(92,704) (79,148) 3,349,496 2,675,346			
	3,256,792 2,596,198			

#### Foreign currency reserve

The reserve is used to recognise exchange differences arising from the translation of the financial statements of foreign operations to Australian dollars. It is also used to recognise gains and losses on hedges of the net investments in foreign operations.

#### Share-based payments reserve

The reserve is used to recognise the value of equity benefits provided to employees and directors as part of their remuneration, and other parties as part of their compensation for services.

#### Movements in reserves

Movements in each class of reserve during the current financial half-year are set out below:

Consolidated	Foreign currency \$	Share-based payments \$	Total \$
Balance at 1 July 2016 Foreign currency translation Share-based payments	(79,148) (13,556) -	2,675,346 - 674,150	2,596,198 (13,556) 674,150
Balance at 31 December 2016	(92,704)	3,349,496	3,256,792

#### Note 9. Fair value measurement

#### Fair value hierarchy

The following tables detail the Group's assets and liabilities, measured or disclosed at fair value, using a three level hierarchy, based on the lowest level of input that is significant to the entire fair value measurement, being:

Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date

Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly

Level 3: Unobservable inputs for the asset or liability

Consolidated - 31/12/2016	Level 1	Level 2	Level 3	Total
	\$	\$	\$	\$
<i>Assets</i> Financial assets at fair value through profit or loss - investments Total assets	816,160 816,160	<u>-</u>	<u> </u>	816,160 816,160
Consolidated - 30/06/2016	Level 1	Level 2	Level 3	Total
	\$	\$	\$	\$
Assets Financial assets at fair value through profit or loss - investments Total assets	3,258,787 3,258,787	<u> </u>		3,258,787 3,258,787

#### Note 9. Fair value measurement (continued)

There were no transfers between levels during the financial half-year.

#### Note 10. Contingent liabilities

On 16 April 2013, OncoSil Medical Ltd settled the acquisition of OncoSil Medical (UK) Limited (formerly Enigma Therapeutics Limited) ("OncoSil UK"). OncoSil UK holds a licence to commercialise OncoSil™ (formerly BrachySil™), a targeted brachytherapy product for the treatment of cancer under a licence agreement from pSiMedica.

pSiMedica has granted to OncoSil UK an exclusive world-wide royalty-bearing license for the term of the pSiMedica Transaction (with limited rights to sub-license) under the Licensed Patents solely to make, use, sell, offer to sell and import the Product in the field of therapy in human neoplastic disease (cancer). Key terms of the license agreement have been summarised below:

• OncoSil UK is required to make a payment of up to US\$100,000 to pSiMedica annually to support existing patents; and

• OncoSil UK is required to make the following payments for patents and subject to the OncoSil completing positive clinical trials and becoming registered for sale.

During the term of the licence, 8% of future net sales (future sales which cannot be guaranteed) of the Product or any other product protected by the rights arising from the Assigned Patents (if sold by OncoSil UK or its affiliates) and services performed using the Product or such other products, on a product-by-product and country-by-country basis. Only half of this payment must be made whenever approved generic competitor products derived from the Product maintain at least a 20% world-wide market share of sales, on a country-by-country and product-by-product basis.

20% of any form of consideration, payments, royalties, third party net sales income and other payments received from third party licensing deals and various other agreements with third parties in relation to OncoSil<sup>™</sup> or any other product protected by the rights arising from the Assigned Patents, for the term of the pSiMedica licence, on a product-by-product and country-by-country basis.

Potential milestone payments based only upon OncoSil<sup>™</sup> being a commercial success, which cannot be guaranteed now or in the future (ranging from US\$1,000,000 to US\$5,000,000) upon:

• OncoSil UK, its affiliates and any of OncoSil UK's third party transferees together potentially achieving US\$5,000,000 aggregate net sales for OncoSil<sup>™</sup> and any other product protected by the rights arising from the Assigned Patents, for (i) an indication and (ii) a second indication;

• Aggregate net sales of OncoSil<sup>™</sup> and any other product protected by the rights arising from the Assigned Patents, paid to OncoSil UK, its affiliates and third party transferees in a calendar year first potentially equals or exceeds US\$20,000,000; and

• Aggregate net sales of OncoSil<sup>™</sup> and any other product protected by the rights arising from the Assigned Patents, paid to OncoSil UK, its affiliates and third party transferees in a calendar year first potentially equals or exceeds US\$100,000,000.

#### Termination of licence agreement

Unless terminated early for customary reasons such as a material breach, or by pSiMedica due to a patent challenge being brought against pSiMedica in certain circumstances (including by OncoSil UK), the term of the licence for the Licensed Patents and OncoSil UK's rights to exploit the product and any other products arising from the Assigned Patents, remain in effect on a country-by-country and product-by-product basis, until the later to occur of:

• the date on which the product or any other product protected by the rights arising from the Assigned Patents in such country is no longer covered or protected by a potential claim of the Licensed Patents or the Assigned Patents in such country; and

• ten years from the date of first commercial sale of a product or any other product protected by the rights arising from the Assigned Patents in such country.

#### OncoSil Medical Ltd Notes to the financial statements 31 December 2016



#### Note 10. Contingent liabilities (continued)

In addition, if OncoSil UK reasonably forms the view that it is not capable of commercialising OncoSil™, OncoSil UK shall have the right to terminate the license agreement by 60 days prior written notice to pSiMedica.

The directors are not aware of any other commitments or contingencies as at 31 December 2016.

Note 11. Earnings per share

	Conso 31/12/2016 \$	lidated 31/12/2015 \$
Loss after income tax attributable to the owners of OncoSil Medical Ltd	(3,111,923)	(1,770,689)
	Number	Number
Weighted average number of ordinary shares used in calculating basic earnings per share	467,564,164	358,900,232
Weighted average number of ordinary shares used in calculating diluted earnings per share	467,564,164	358,900,232
	Cents	Cents
Basic earnings per share Diluted earnings per share	(0.67) (0.67)	(0.49) (0.49)

Options have not been included in the diluted earnings per share calculation as they are anti-dilutive.

#### Note 12. Events after the reporting period

No matter or circumstance has arisen since 31 December 2016 that has significantly affected, or may significantly affect the Group's operations, the results of those operations, or the Group's state of affairs in future financial years.

#### OncoSil Medical Ltd Directors' declaration 31 December 2016



In the directors' opinion:

- the attached financial statements and notes comply with the Corporations Act 2001, Australian Accounting Standard AASB 134 'Interim Financial Reporting', the Corporations Regulations 2001 and other mandatory professional reporting requirements;
- the attached financial statements and notes give a true and fair view of the Group's financial position as at 31 December 2016 and of its performance for the financial half-year ended on that date; and
- there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of directors made pursuant to section 303(5)(a) of the Corporations Act 2001.

On behalf of the directors

Dr Roger Aston Non-Executive Chairman

23 February 2017 Sydney



**Crowe Horwath Sydney** ABN 97 895 683 573 Member Crowe Horwath International

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# Independent Auditor's Review Report to the members of OncoSil Medical Ltd

# **Report on the Half-year Financial Report**

We have reviewed the accompanying half-year financial report of OncoSil Medical Ltd and its controlled entities (the consolidated entity) which comprises the consolidated statement of financial position as at 31 December 2016, the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity, consolidated statement of cash flows for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information and the directors' declaration.

# Directors' Responsibility for the Half-year Financial Report

The directors of the company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards (including Australian Accounting Interpretations) and the Corporations Act 2001 and for such control as the directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement, whether due to fraud or error.

# Auditor's Responsibility for the Half-year Review of the Financial Report

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410: Review of an Interim Financial Report Performed by the Independent Auditor of the Entity, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the financial report is not in accordance with the Corporations Act 2001 including giving a true and fair view of the consolidated entity's financial position as at 31 December 2016 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134: Interim Financial Reporting and the Corporations Regulations 2001. As the auditor of OncoSil Medical Ltd, ASRE 2410 requires that we comply with the ethical requirements relevant to the review of the half-year financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.



### Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*.

# Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of OncoSil Medical Ltd is not in accordance with the *Corporations Act 2001* including:

- (i) giving a true and fair view of the consolidated entity's financial position as at 31 December 2016 and of its performance for the half-year ended on that date; and
- (ii) complying with AASB 134: Interim Financial Reporting and the Corporations Regulations 2001.

Crowe Horwath Sydney

**CROWE HORWATH SYDNEY** 

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JOHN HAYDON Senior Partner

Dated this 23<sup>rd</sup> day of February 2017