

# Appendix 4E

## Preliminary Final Report

### Virax Holdings Limited

ACN 006 569 106

**Financial Year Ended 30 June 2010**

**Announcement to the Market**

				\$A'000
<b>Revenues from ordinary activities</b>	Down	33%	to	\$429
<b>Loss from Ordinary activities after tax</b> attributable to members	Up	38%	to	\$1,864 (Loss)
<b>Loss from extraordinary items after tax</b> attributable to members			to	Nil
<b>Net Loss for the Period</b> attributable to members	Up	38%	to	\$1,864 (Loss)

<b>Dividends (distributions)</b>	Amount per security	Franked amount per security
Final dividend	Nil	Nil
Previous corresponding period	Nil	Nil

#### **Significant Technical Developments – VIR201 Clinical Trial in South Africa**

Since the end of the previous financial year the Company reported the preliminary results as announced on 16 August 2010 for the Phase IIa Clinical Trial in South Africa. The South African trial design differed from the earlier Australian trials as it used an increased dose of a more highly purified VIR201 vaccine and included both ART treatment naïve and experienced participants. The trial was conducted on 131 patients, with 65 patients undergoing antiretroviral (ART) treatment and 66 patients being naïve to ART treatment.

The major aim of the trial was to compare the immune responses to VIR201 in both patient populations.

The primary immunological endpoint of the trial was T-cell immune response via ELIspot assay. Such T-cells are critical in the detection and removal of HIV infected cells. The secondary immunological endpoint was the measurement of Antibody isotype responses (IgG1, IgG2 and IgG3). The effects of VIR201 vaccination on HIV viral load in the ART naïve group and CD4 count were also measured as secondary efficacy endpoints.

VIR201 did not meet its primary or secondary immunological endpoints, failing to elicit a statistically significant increase in immune response relative to the control group in both T-cell assay (ELIspot) and assays of antibody isotype.

Effect of viral load was measured as time weighted mean change from baseline to the end of the trial (pVL). An interesting result of the trial was that ART naïve patients receiving VIR201 had a 0.61 log reduction over the trial period relative to placebo in pVL ( $p=0.0934$ ). The reduction in viral load was more pronounced soon after the first vaccination. The VIR201 group had a statistically significant 1.49 log reduction relative to placebo ( $p=0.0001$ ) one week after the first vaccination with VIR201.

The Company is reviewing and further evaluating the trial results and will further update shareholders in due course.

The review will focus on interpreting the observed reduction of viral load. The final clinical study report of the trial, is scheduled to be received in Q4 2010. This report will underpin the rationale for undertaking further work. Such work could be undertaken by the Company or third party researchers at their own cost.

Virax is appreciative of the support provided by the following global coalition of multinational and South African companies which funded the trial:

- African Rainbow Minerals Limited
- Anvil Mining Limited
- Assmang Limited
- BHP Billiton Limited
- Gold Fields Limited
- Harmony Gold Mining Company Ltd
- Lonmin Plc
- Mitsubishi Materials Corporation
- Nippon Mining and Metals Co. Ltd
- Paladin Energy Limited
- Rio Tinto Limited
- Sumitomo Metal Mining Co. Ltd

### **Company Pursuing New Clinical Program**

The Virax Board has previously communicated its desire to undertake a suitable value accretive corporate transaction to further expand its product and technology portfolios.

The Company has been very active in this area in recent months and can advise that it is in advanced discussions with a large international immunotherapeutic company regarding a new clinical program that has the potential to add significant value for shareholders. This cancer focused clinical program fits well with the Company's expertise in immunotherapeutic vaccines and its clinical trial experience. The Company hopes to announce the results of these discussions in due course.

### **Co-X-Gene™ Technology**

Virax retains a key technology asset, the Co-X-Gene™ technology. The company will continue its strategy of adding value to this key technology asset through its strategic out-licensing to a major French biopharmaceutical company, Transgene, in two cancer vaccine products, both in advanced development (the products use Modified vaccine Ankara as the delivery system).

These products are:

- TG4001 (cervical cancer vaccine) - Currently in Phase IIb trials and partnered with Roche; and
- TG4010 (lung cancer vaccine) - Phase IIb trials completed and now entering Phase III trials. This is subject to an Option Agreement negotiated by Transgene with Novartis.

The success of both products to date provides clinical validation of the Co-X-Gene™ technology. The Co-X-Gene™ technology asset, through the Transgene license, remains of significant value to Virax.

In light of the South African trial results, the Company will now review its future plans for VIR201, which also uses the Co-X-Gene™ Technology with a fowlpox delivery system.

### **ASX Announcements**

The Company has made the following announcements to the ASX since the end of the Financial Year:

7 July 2010	Update on VIR201 HIV Vaccine Clinical Trial in South Africa
23 July 2010	Convertible Note Quarterly Report – 30 June 2010
9 August 2010	Update on VIR201 HIV Vaccine Clinical Trial in South Africa – Data Lock achieved
12 August 2010	Publication of Paper – Professor Martyn French – Immunological Testing of VIR201
16 August 2010	VIR201 Clinical Trial Results - Preliminary

### **Report of Directors on Financials**

The net loss for the Financial Year ended 30 June 2010 of \$1,864,000 (2009: \$1,346,000) reflects the net costs of operating the Company and conducting its business as an early stage biotechnology drug development company. The Company continued to progress the Co-X-Gene™ technology through:

- the Company's lead program, VIR201, in clinical trials in South Africa;
- a sub-licence with the French publicly listed company - Transgene S.A. (which is conducting clinical trials of its TG4001 and TG4010 products utilising the Co-X-Gene™ technology);
- seeking further clinical program(s) and opportunities for participation.

The reduction in revenue to \$429,000 (2009: \$636,000) is primarily due to a reduced tax credit on research and development expenditures. There were no milestones receipts from Transgene under the sub-licence received during the financial year. Transgene did however enter into an option agreement with Novartis for \$US10 million in respect to the Non Small Lung Cell Cancer program (TG4010). This option provides Novartis with the ability to acquire an exclusive licence for TG4010 during the Phase IIb/III trial being undertaken by Transgene. Although Transgene originally intended to complete a licence agreement with a global pharma in respect to TG4010, it is understood that the prevailing circumstances resulted in the completion of the Option Agreement.

Expenses increased to \$2,293,000 (2009: \$1,982,000). This amount includes non-cash items totalling \$642,000 (2009: \$276,000) in relation to the following:

- Employee shares and options \$190,000
- Directors' fees: share settled \$259,000
- Convertible note finance charges \$193,000

The options and shares issued to employees and directors were approved by shareholders at the general meeting on 25 February 2010. The share and option plans are designed to secure the services of key personnel through the use of long term incentives linked to the performance of the company.

The expense in relation to the settlement of outstanding directors' fees has arisen as a result of application of the relevant accounting standard and accounting guidance. IFRIC 19 requires financial liabilities that are extinguished through the issue of securities to be measured at the fair value of those securities at the date the liability is settled. The amount of directors' fees outstanding was \$185,000 and as at 1 January 2010, it was agreed that this amount would be settled by the issue of 3,696,918 shares at 5 cents each. However, the share price on the date the outstanding fees were actually settled (being 8 March 2010 after the shareholder approval at general meeting on 25 February 2010) was 12 cents per share. This reflects a spike in the company's share price which occurred between the date the arrangements were agreed between the parties and the date of the approval and implementation.

Consequently, an additional expense of \$259,000 arose (3,696,918 shares at 7 cents per share, being the change in the share price). This is a non-cash expense which has arisen as noted due to application of the accounting standard and accounting guidance for extinguishment of financial liabilities by equity settled transactions.

As at 30 June 2010, the Company's share price closed at 6.7 cents.

The finance costs of the convertible notes of \$193,000 represent the implicit effective cost of funds recognised over the term (including the extended term) of the convertible notes in accordance with the accounting standard on Financial Instruments: Recognition and Measurement. This is a non cash item as the finance charges are only payable upon redemption. During the financial year, the redemption date of the notes was extended to 31 December 2011.

The underlying net operating cash flow for the year was \$(949,000) (2009: \$(1,183,000)).

### **Other Factors which are Likely to Affect Results in the Future**

#### Co-X-Gene™ Technology and the Transgene Sub-licence

In March 2007 Transgene (Eurolist Paris: FR0005175080) executed a Licence Agreement (the "Transgene Sub-licence") with the Company for access to Co-X-Gene™ technology for use in two of Transgene's immunotherapeutic products:

- *TG4001* - a treatment for pathologies relating to human papilloma virus (HPV) infection; and
- *TG4010* - a treatment for non-small cell lung cancer (NSCLC).

On 11 April 2007, based upon having conducted a further Phase II trial with TG4001, Transgene announced a partnering with the Roche Group of TG4001 and partnering payments receivable of €23 million for an upfront payment and a near term milestone. The Transgene announcement also stated that Roche may pay Transgene up to an additional €195 million, plus royalties on sales. The Company has received AUD 1.352 million (net) under the sublicense in respect to TG4001. Transgene has stated that TG4001 has a market potential of €250 million per annum.

Transgene has announced the following achievements in respect of these products:

#### TG4001/R3486

- Successfully completed a Phase II trial for treatment of severe precancerous cervical lesions. Partnership with Roche achieved based upon this result.
- Commenced a Phase IIb trial with results anticipated in Q2 calendar 2011.

#### TG4010

- Primary endpoints of Phase IIb trial of TG4010 for NSCLC cancer successfully completed.
- Overall positive survival data from Phase IIb trial presented in December 2008.
- Final Phase IIb trial results were presented in June 2009 demonstrating an increased six months survival benefit.
- Approval from the FDA for the planned Phase III testing.
- Transgene anticipated completing a partnering of the program with a global pharma in mid 2009. This did not eventuate. On 11 March 2010 Transgene announced the completion of an Option Agreement with Novartis

granting Novartis the right to acquire an exclusive global licence for TG4010 after the results of the Phase IIb portion of the Phase III clinical trial being undertaken by Transgene are available. These results are expected to be available in the first quarter 2012. Under the Option Agreement, Transgene noted that it is eligible to earn up to €700 million (\$A1 billion) upon achievement of development, regulatory and commercial milestones in various indications, in addition to royalties on global sales.

The Company expected that a partnership agreement with TG4010 was likely to trigger milestone payments under the sub-licence. A payment under the Option Agreement is not currently expected at this time.

Transgene has estimated that TG4010 has a market potential of \$US 1.4 billion per annum.

### ***Validation of Virax's Co-X-Gene™ Technology poised to significantly enhance shareholder value***

Co-X-Gene™ has been validated by:

- Transgene's successful Phase II testing of its human papilloma virus (HPV) based vaccine (TG4001) for the treatment of precancerous lesions of cervical cancer.
- Transgene's successful Phase IIb testing of its lung cancer vaccine (TG4010).
- The licensing by Transgene SA of the Co-X-Gene™ technology from Virax in April 2007 for application in TG4001 and TG4010;
- Roche milestone payment of Euro 23 million upon partnering with Transgene to develop TG4001 in April 2007;
- Novartis's \$US10 million option to exclusively licence TG4010 with milestone payments of up to €700 million.

### **Funding and Share Capital**

In November 2009, the Company convened a general meeting of Convertible Noteholders that approved:

- The extension of the maturity date of the Convertible Notes to 31 December 2011;
- The amendment of the Redemption Price from 12 cents per note to 14 cents; and
- The opportunity for Noteholders until 18 December 2009 to convert their notes at a ratio of 2 notes into 5 ordinary shares (a bonus entitlement of 25%).

As a result of this approval, 14,056,601 fully paid ordinary shares were issued following the conversion of 5,619,257 VHLG Convertible Notes.

A further 326,888 fully paid ordinary shares were issued following the conversion of 163,444 VHLG Convertible Notes under the normal terms of the notes.

On 15 December 2009, 13,473,526 VHLOB options exercisable at 20 cents per ordinary share expired.

The Company undertook a 1 for 5 rights issue at 5 cents per ordinary fully paid share to raise approximately \$1.3 million with an extended closing date of 21 January 2010. This rights offer was supported by Shortfall Placement Agreements of \$750,000. The rights offer concluded with the issue of 26,154,933 ordinary shares that resulted in the receipt of approximately \$1.3 million.

The rights issue was over subscribed and there was no shortfall. The Shortfall Placement agreements also provided (not conditional upon the existence of a shortfall) for the issue of 7,000,000 unlisted options with an exercise price of 10 cents expiring in December 2010.

The payment of Directors remuneration was deferred during the financial year. As at 17 December 2009, the Directors resolved to settle their remuneration outstanding to 31 December 2009 by the issue of ordinary shares on the same terms as the 1 for 5 rights issue – 5 cents per share. The issue of securities to Directors requires approval from shareholders under the ASX Listing Rules. This approval was sought and obtained on 25 February 2010. Accordingly 3,696,918 fully paid ordinary shares were issued to Directors.

The payment of the Directors' remuneration from 1 January 2010 continues to be deferred. It is intended that the deferred remuneration up to 30 June 2010 will again be settled through the issue of ordinary shares. This will require approval of shareholders to be sought at the Company's AGM.

The Directors are monitoring the Company's cash flows, future commitments and future capital raising requirements, which will be dictated by developments in the near future, including the development and requirements of a corporate transaction.

## **Summary**

The Company did not succeed in achieving the desired immunological end points in its clinical trial of VIR201 in South Africa. The final report on the Trial is scheduled to be available in Q4 2010. This report will be the basis for any further work to be undertaken on VIR201, including whether such work is undertaken by the Company or third party researchers at their own cost.

The Company's positives during the Financial Year were the achievement of the following significant value accretive milestones:

- Initiation by Transgene/Roche of further late-stage clinical testing of a product that uses the Co-X-Gene™ technology
- Transgene's completion of an Option Agreement with Novartis for Lung Cancer product TG4010
- Initiation of discussions that may conclude in an expansion of the Company's participation in immunotherapeutic technologies

<b>Preliminary Consolidated Income Statement</b>	Current period	Previous corresponding period
	\$A'000	\$A'000
Details of revenues		
Revenue from sales or services	-	-
Interest revenue	18	36
Other revenue - Tax Credit	96	204
Other relevant revenue - Recoupment of project expenses	315	396
<b>Total Revenue</b>	<b>429</b>	<b>636</b>
Details of expenses		
- Research and Development	389	580
- Administration	208	256
- Corporate	1,031	854
- Finance costs – convertible notes	193	276
- Employee share based expenses	190	-
- Employee expenses – equity settled (deferred directors fee)	259	-
- Business Development	22	14
Depreciation and amortisation excluding amortisation of intangibles	1	2
<b>Total Expenses</b>	<b>2,293</b>	<b>1,982</b>
<b>Net Loss</b>	<b>1,864</b>	<b>1,346</b>

<b>Consolidated Retained Earnings</b>	Current period	Previous corresponding period
	\$A'000	\$A'000
Retained profits (accumulated losses) at the beginning of the financial period	(33,612)	(32,266)
Net profit (loss) attributable to members	(1,864)	(1,346)
Net transfers from (to) reserves	78	-
Net effect of changes in accounting policies	-	-
Dividends and other equity distributions paid or payable	-	-
<b>Retained profits (accumulated losses) at end of financial period</b>	<b>(35,398)</b>	<b>(33,612)</b>

<b>Earnings Per Share</b>	Current period	Previous corresponding period
Basic EPS (Loss)	(1.22) Cents	(1.21) Cents
Diluted EPS (Loss)	(1.22) Cents	(1.21) Cents

<b>NTA Per Share</b>	Current period	Previous corresponding period
Basic NTA PS	0.1589 Cents	(0.4628) Cents

<b>Profit (loss) from ordinary activities attributable to members</b>	Current period	Previous corresponding period
	\$A'000	\$A'000
Profit (loss) from ordinary activities after tax	(1,864)	(1,346)
Less outside equity interests	-	-
<b>Profit (loss) from ordinary activities after tax, attributable to members</b>	<b>(1,864)</b>	<b>(1,346)</b>

<b>Consolidated Balance Sheet</b>	At end of current period \$A'000	As shown in last annual report \$A'000
<b>Current assets</b>		
Cash	1,384	1,071
Receivables	112	28
Other receivables	20	28
Prepaid expenses	45	51
Other	2	2
<b>Total current assets</b>	<b>1,563</b>	<b>1,180</b>
<b>Non-current assets</b>		
Investments	-	-
Other investments	-	-
Inventories	-	-
Other property, plant and equipment (net)	5	2
Other	-	-
<b>Total non-current assets</b>	<b>5</b>	<b>2</b>
<b>Total assets</b>	<b>1,568</b>	<b>1,182</b>

<b>Current liabilities</b>		
Payables	320	225
Tax liabilities	-	-
Provisions	72	53
Convertible Notes	-	1,508
<b>Total current liabilities</b>	<b>392</b>	<b>1,786</b>
<b>Non-current liabilities</b>		
Payables	-	-
Convertible Note & Issue Costs	897	-
<b>Total non-current liabilities</b>	<b>897</b>	<b>-</b>
<b>Total liabilities</b>	<b>1,289</b>	<b>1,786</b>
<b>Net assets</b>	<b>279</b>	<b>(604)</b>

<b>Equity</b>		
Capital/contributed equity	35,103	32,642
Convertible Note - equity component	96	78
Share Option Reserves	478	288
Retained profits (accumulated losses)	(35,398)	(33,612)
<b>Equity attributable to members of the parent entity</b>	<b>279</b>	<b>(604)</b>
Outside equity interests in controlled entities	-	-
<b>Total equity</b>	<b>279</b>	<b>(604)</b>

<b>Consolidated Cash Flows Statement</b>	Current period	Previous corresponding period
	\$A'000	\$A'000
<b>Cash flows related to operating activities</b>		
Receipts from customers	-	-
Payments to suppliers and employees	(1,319)	(1,822)
Dividends received from associates	-	-
Other dividends received	-	-
Interest and other items of similar nature received	18	36
Tax credit from R & D tax concession	97	204
Other Income	255	399
<b>Net operating cash flows</b>	<b>(949)</b>	<b>(1,183)</b>
<b>Cash flows related to investing activities</b>		
Payment for purchases of property, plant and equipment	(4)	-
Proceeds from sale of property, plant and equipment	-	27
Payment for purchases of equity investments	-	-
Proceeds from sale of equity investments	-	-
<b>Net investing cash flows</b>	<b>(4)</b>	<b>27</b>
<b>Cash flows related to financing activities</b>		
Proceeds from issue of ordinary shares	1,308	620
Issue cost of ordinary shares	(17)	(24)
Convertible Note refinancing cost	(25)	-
Dividends paid	-	-
<b>Net financing cash flows</b>	<b>1,266</b>	<b>596</b>
<b>Net increase (decrease) in cash held</b>	<b>313</b>	<b>(560)</b>
<b>Cash at beginning of period (See Reconciliation of cash)</b>	<b>1,071</b>	<b>1,631</b>
<b>Cash at end of period (See Reconciliation of cash)</b>	<b>1,384</b>	<b>1,071</b>

<b>Reconciliation of Cash</b>	Current period	Previous corresponding period
	\$A'000	\$A'000
Cash on hand and at bank	1,384	1,071
Deposits at call	-	-
<b>Total cash at end of period</b>	<b>1,384</b>	<b>1,071</b>

<b>Reconciliation of the loss after tax from ordinary activities to net cash flow used in operations</b>	Current period	Previous corresponding period
	\$A'000	\$A'000
<b>Loss from ordinary activities after tax</b>	(1,864)	(1,346)
<b>Non Cash Items</b>		
Depreciation/write off of non-current assets	1	4
Provision for employee entitlements	19	(25)
Director remuneration – settled by share allotment	185	-
Employee expenses – equity settled (deferred directors fee)	259	-
Share based transaction expenses		
Share option expense	133	-
Share plan incentive expense	56	-
Professional services – share placement	44	-
Convertible Note financing cost	193	276
Profit on disposal of fixed assets	-	(26)
<b>Changes in assets and liabilities</b>		
(Increase)/decrease in trade and other receivables	(70)	4
Increase/(decrease) in trade and other creditors	95	(70)
<b>Net cash flow used in operating activities</b>	<b>(949)</b>	<b>(1,183)</b>

<b>Number of Shares on Issue and the Basis of Earnings per Share (EPS) Calculation</b>			
The amount of the loss used as the numerator in calculating basic EPS was <b>(\$1,864,000)</b> .			
For determining the denominator in calculating basic EPS, there is only one class of ordinary shares.			
<b>The number of shares on issue at 1 July 2009</b>			<b>130,602,316</b>
During the financial year the following shares were issued:			
<b>Type of Issue</b>	<b>Issue Date</b>	<b>Type of Share</b>	<b>No. of Shares</b>
Placement for third party services	Dec-09	Fully Paid	377,306
Rights Issue	Jan-10	Fully Paid	26,154,933
Placement for third party services	Mar-10	Fully Paid	88,223
Placement – deferred director remuneration	Mar-10	Fully Paid	3,696,918
Placement for third party services	Jun-10	Fully Paid	151,692
Conversion of Convertible Notes	Dec-09	Fully Paid	14,139,133
Conversion of Convertible Notes	Mar-10	Fully Paid	244,356
Exercise of Options	Nov-09	Fully Paid	1,138
Total			<b>44,853,699</b>
<b>The number of shares on issue at 30 June 2010</b>			<b>175,456,015</b>

Shares	Total number	Number quoted	Issue price per security (cents)	Amount paid up per security (cents)
<b>Ordinary Shares at 1 July 2009</b>	<b>130,602,316</b>	<b>130,602,316</b>		
Changes during current period:				
Issued during the period	377,306	377,306	5.83 cps	5.83 cps
Issued during the period	29,851,851	29,851,851	5 cps	5 cps
Issued during the period	88,223	88,223	12.5 cps	12.5 cps
Issued during the period	151,692	151,692	7.25 cps	7.25 cps
Increases through issues conversions of Convertible Note	14,383,489	14,383,489	6 cps	6 cps
Increases through issues conversions of Options VHLOB	1,138	1,138	20 cps	20 cps
<b>Ordinary Shares at 30 June 2010</b>	<b>175,456,015</b>	<b>175,456,015</b>		

Options	Approx Date Issued		No. Quoted	Exercise Price (cents)	Expiry date
<b>Quoted Options: ASX code: VHLOB</b>					
<b>Outstanding at 1 July 2009</b>		<b>13,474,664</b>	<b>13,474,664</b>		
Converted during the period		(1,138)	(1,138)	20 cps	
Lapsed during the period		(13,473,526)	(13,473,526)	20 cps	15-Dec-09
<b>Outstanding at 30 June 2010</b>		<b>Nil</b>	<b>Nil</b>		
<b>Unquoted Options</b>					
<b>Outstanding at 1 July 2009</b>					
	Nov-04	250,000		50 cps	31-Dec-09
	Nov-04	250,000		65 cps	31-Dec-10
	Feb-05	422,500		65 cps	31-Dec-09
	Nov-05	250,000		17 cps	31-Dec-11
	Dec-05	641,333		17 cps	31-Dec-11
	Dec-05	100,000		17 cps	31-Dec-11
	Nov-06	800,000		25 cps	31-Dec-09
Issued during the period	Dec-09	1,500,000		10 cps	9-Dec-10
	Dec-09	500,000		10 cps	16-Dec-10
	Dec-09	5,000,000		10 cps	14-Dec-10
	Feb-10	1,250,000		10 cps	30-Jun-11
	Feb-10	1,250,000		15 cps	30-Jun-12
	Feb-10	1,250,000		20 cps	30-Jun-13
	Feb-10	950,000		10 cps	30-Jun-11
		<b>14,413,833</b>			
Lapsed during the period	Nov-04	(250,000)		50 cps	31-Dec-09
	Feb-05	(422,500)		65 cps	31-Dec-09
	Nov-06	(800,000)		25 cps	31-Dec-09
		<b>(1,472,500)</b>			
<b>Outstanding at 30 June 2010</b>		<b>12,941,333</b>	<b>12,941,333</b>		
<b>Total of All Options Extant at 30 June 2010</b>		<b>12,941,333</b>	<b>Nil</b>		

<b>Convertible Notes: ASX code: VHLG</b>	<b>Total number</b>	<b>Number quoted</b>	<b>Issue price per security (cents)</b>	<b>Amount paid up per security (cents)</b>
<b>Outstanding at 1 July 2009</b>	13,672,928	13,672,928	10 c	10 c
Changes during current period:				
Converted during the period – bonus conversions	(5,619,257)	(5,619,257)		
Converted during the period – normal conversions	(163,444)	(163,444)		
<b>Outstanding at 30 June 2010</b>	<b>7,890,227</b>	<b>7,890,227</b>		

The Convertible Note redemption date of 31 December 2009 and redemption price of 12 cents per note were amended by Noteholder resolution on 6 November 2009 with an extended redemption date of 31 December 2011 and new redemption price of 14 cents per note.

### **Segment Reporting**

The Company is an early stage biotechnology drug development company operating within Australia with overseas customers and collaborators. Since October 2008 the Company (through a wholly owned subsidiary's foreign registered branch in South Africa) has undertaken the management of the Clinical Trial of VIR201 in South Africa on behalf of a Public Benefits Organisation – the Theravax Foundation. Included in the management of the Clinical Trial is the Company's access and use of the clinical data for future commercial development and exploitation. There are no Company assets located in South Africa and the foreign branch is reimbursed for its costs of operation.

### **Tax Consolidation and Carry Forward Losses**

The Company and its subsidiaries form a consolidated group for tax purposes and the utilisation of carried forward tax losses to offset against future taxable income is subject to specific provisions of the tax law. The Company estimates \$35.4 million of accumulated consolidated tax losses as at 30 June 2010, may be available for future use.

The availability of these accumulated consolidated tax losses is subject to the Continuity of Ownership Test (COT) and the Same Business Test (SBT).

As the share ownership changes or the nature of the business activities change the application of the COT and the SBT, the amount of these losses available to be offset against future taxable income may be diminished.

### **Accounting Policies**

This financial report has been prepared on a going concern basis, which assumes sufficient funding from capital raising, completion and/or development of income generating commercial agreements, the Transgene sub-licence, restructuring transactions and/or other appropriate initiatives.

In common with other drug development biotechnology companies:

- the Company's operations are subject to considerable risks due primarily to the nature of the development and commercialisation being undertaken; and
- to allow the Company to execute its longer-term plans, it is anticipated that it will be necessary to raise additional capital in the future.

The Directors cannot be certain of the success of any fund raising activities, other transactional initiatives or developments under licences, including the Transgene sub-licence. However, the Directors currently plan to continue the Company's operations on the basis referred to above, together with the existing net assets, and the Directors expect that such activities will raise sufficient funds for the Company to operate as a going concern for a period of twelve months from the date of this report.

In light of the fact that sufficient funding from the activities referred to above is not yet contractually established or in place, there is inherent uncertainty regarding the going concern basis. In certain circumstances, this uncertainty may require the Company to realise assets and extinguish liabilities other than in the normal course of business and at amounts different from those stated in the financial report.

<b>Gain of control of entities</b>	<b>Not Applicable</b>
<b>Loss of control of entities having material effect</b>	<b>Not Applicable</b>
<b>Dividends</b>	<b>Not Applicable</b>
<b>Details of aggregate share of profits (losses) of associates and joint venture entities</b>	<b>Not Applicable</b>
<b>Material interests in entities which are not controlled entities</b>	<b>Not Applicable</b>

## **Compliance Statement**

1. This report has been prepared in accordance with Australian Accounting Standards.
2. This report is based on accounts that are in the process of being audited. At this time the accounts are not, and nor is it believed that they are likely to be, subject to dispute or qualification. The Audit Report to the Financial Statements for 2009 contained a statement under the heading of "*Inherent Uncertainty Regarding Continuation as a Going Concern*". As at the date of the release of this Appendix 4E, as the directors have noted in the Accounting Policies section, there is inherent uncertainty regarding the going concern basis. If at the time of issuing the audit report, these circumstances still exist, then the auditors expect to issue an emphasis of matter opinion similar to the prior year.

## **Annual General Meeting**

The Notice of Annual General Meeting is scheduled to be provided to shareholders in October 2010 to ensure the AGM is held by 30 November 2010.