

Preliminary Final Report of SciGen Limited for the Twelve Months Ended 31 December 2008

(ABRN 101 318 852)

This Preliminary Final Report is provided to the Australian Stock Exchange (ASX) under ASX Listing Rule 4.3A.

Current Reporting Period: Twelve months ended 31 December 2008

Previous Corresponding Period: Twelve months ended 31 December 2007

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SCIGEN LIMITED

APPENDIX 4E – PRELIMINARY FINAL REPORT

Results For Announcement To The Market For the Twelve Months Ended 31 DECEMBER 2008

Revenue and Net Loss

The table below allows a comparison of the business performance for the 12 months ended 31 December 2008 with the 12 months ended 31 December 2007.

| | <u>Current financial period</u> | <u>Previous financial period</u> |
|--|---|---|
| | <u>12 Months ended 31/12/08 US\$000</u> | <u>12 Months ended 31/12/07 US\$000</u> |
| Revenue from ordinary activities | 13,995 | 8,444 |
| Loss from ordinary activities after related income tax | (7,836) | (4,063) |
| Net loss for the period attributable to members | (7,454) | (3,950) |

All the following analysis is calculated by comparing the 12 months ended 31 December 2008 with 12 months ended 31 December 2007:

| | | Percentage Change % | | Amount US\$ '000 |
|--|----|---------------------------|----|---------------------|
| Revenue from ordinary activities | Up | 65.7% | To | 13,995 |
| Loss from ordinary activities after related income tax | Up | 92.9% | To | (7,836) |
| Net loss for the period attributable to members | Up | 88.7% | To | (7,454) |

Revenue

Revenue continues to increase year on year as the Company continues to establish itself and its products in its markets.

Net Loss

Net loss was higher than last year due to an exchange loss incurred in the current year of US\$0.9m as compared to an exchange gain of US\$2.3m in the prior year. Additionally the interest charge continues to rise as a result of expenditure for the construction of the facilities in Israel, India & China.

Dividend

The Company does not propose any dividend for the year.

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Consolidated Income Statement
For the Twelve Months Ended 31 December 2008

| | Note | 12 Months Ended 31 December 2008 US\$ '000 | 12 Months Ended 31 December 2007 US\$ '000 |
|---|-------------|---|---|
| Revenue from ordinary activities | 3(a) | 13,995 | 8,444 |
| Other income (net) | | 420 | 741 |
| Changes in inventories | | (1,142) | 214 |
| Purchases | | (6,054) | (4,237) |
| Employee benefits expense | | (4,466) | (3,899) |
| Depreciation & amortization expenses | | (257) | (318) |
| Borrowing costs | | (2,766) | (2,174) |
| Professional & consultancy fees | | (1,076) | (986) |
| Business development expenses | | (3,684) | (2,237) |
| Insurance premiums | | (246) | (198) |
| Rental expenses | | (447) | (335) |
| Administrative expenses | | (323) | (467) |
| Other (expenses)/income from ordinary activities | | (1,766) | 1,469 |
| Loss From Ordinary Activities Before Income Tax Expense | | <u>(7,812)</u> | <u>(3,983)</u> |
| Income tax expense relating to ordinary activities | | (24) | (80) |
| Loss From Ordinary Activities After Related Income Tax | | <u>(7,836)</u> | <u>(4,063)</u> |
| Minority Interest | | 382 | 113 |
| Total Changes in Equity not resulting from transactions with owners as owners | | <u>(7,454)</u> | <u>(3,950)</u> |
| Loss per security | | | |
| | | (US ¢) | (US ¢) |
| <i>Basic loss per share</i> | 9 | (0.0135) | (0.0072) |
| <i>Diluted loss per share</i> | 9 | (0.0135) | (0.0069) |

The above consolidated income statement should be read in conjunction with the accompanying notes, the Report and Financial Statements for the twelve months ended 31 December 2008, and any public announcements made by SciGen Ltd in accordance with the continuous disclosure requirements.

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Consolidated Balance Sheet
As At 31 December 2008

| | Note | As At 31 December 2008 US\$ '000 | As At 31 December 2007 US\$ '000 |
|--------------------------------------|-------------|---|---|
| Current Assets | | | |
| Cash and cash equivalents | | 6,092 | 4,912 |
| Trade and other receivables | | 7,985 | 4,981 |
| Inventories | | 1,260 | 1,513 |
| Total Current Assets | | 15,337 | 11,406 |
| Non-Current Assets | | | |
| Property, plant & equipment | | 48,359 | 36,188 |
| Intangibles | 5 | 29,968 | 25,539 |
| Lease prepayments | | 1,299 | 1,257 |
| Investment property | | 256 | 319 |
| Long-term prepayments | | 226 | 231 |
| Deferred tax assets | | 12 | 15 |
| Total Non-Current Assets | | 80,120 | 63,549 |
| Total Assets | | 95,457 | 74,955 |
| Current Liabilities | | | |
| Trade and other payables | | 16,132 | 8,055 |
| Interest bearing liabilities | | 7 | 16 |
| Total Current Liabilities | | 16,139 | 8,071 |
| Non-Current Liabilities | | | |
| Trade and other payables | | 4,684 | 2,490 |
| Interest bearing liabilities | | 61,774 | 43,816 |
| Total Non-Current Liabilities | | 66,458 | 46,306 |
| Total Liabilities | | 82,597 | 54,377 |
| Net Assets | | 12,860 | 20,578 |
| Equity | | | |
| Share capital | 6 | 42,530 | 42,530 |
| Reserves | 7 | (1,763) | 1,131 |
| Accumulated losses | 8 | (33,703) | (26,249) |
| | | 7,064 | 17,412 |
| Minority Interest | | 5,796 | 3,166 |
| Total Equity | | 12,860 | 20,578 |

The above consolidated balance sheet should be read in conjunction with the accompanying notes, the Report, the Financial Statements for the twelve months ended 31 December 2008, and any public announcements made by SciGen Ltd in accordance with the continuous disclosure requirements.

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Consolidated Statement of Changes in Equity
As at 31 December 2008

| | Share capital US\$'000 | Foreign currency translation reserve US\$'000 | Share option reserves US\$'000 | Accumulated losses US\$'000 | Sub-total US\$'000 | Minority interest US\$'000 | Total equity US\$'000 |
|--|------------------------------|---|---|-----------------------------------|-----------------------|----------------------------------|-----------------------------|
| Balance at 1 January 2007 | 42,530 | (262) | 197 | (22,299) | 20,166 | 1,443 | 21,609 |
| Exchange difference arising on consolidation of foreign subsidiaries | - | 479 | - | - | 479 | - | 479 |
| Net loss for the year | - | - | - | (3,950) | (3,950) | (113) | (4,063) |
| Total recognized expense and income for the year | - | 479 | - | (3,950) | (3,471) | (113) | (3,584) |
| Contribution by minority shareholders of a subsidiary | - | - | - | - | - | 1,836 | 1,836 |
| Share-based payment | - | - | 717 | - | 717 | - | 717 |
| Balance at 31 December 2007 | 42,530 | 217 | 914 | (26,249) | 17,412 | 3,166 | 20,578 |
| Balance at 1 January 2008 | 42,530 | 217 | 914 | (26,249) | 17,412 | 3,166 | 20,578 |
| Exchange difference arising on consolidation of foreign subsidiaries | - | (3,579) | - | - | (3,579) | - | (3,579) |
| Net loss for the year | - | - | - | (7,454) | (7,454) | (382) | (7,836) |
| Total recognized expense for the year | - | (3,579) | - | (7,454) | (11,033) | (382) | (11,415) |
| Contribution by minority shareholders of a subsidiary | - | - | - | - | - | 3,012 | 3,012 |
| Share-based payment | - | - | 685 | - | 685 | - | 685 |
| Balance at 31 December 2008 | 42,530 | (3,362) | 1,599 | (33,703) | 7,064 | 5,796 | 12,860 |

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Consolidated Statement of Cash Flows
For the Twelve Months Ended 31 December 2008

| | 12 Months to 31 December 2008 <u>US\$ '000</u> | 12 Months to 31 December 2007 <u>US\$ '000</u> |
|--|---|---|
| Cash Flows from Operating Activities | | |
| Loss after income taxes | (7,836) | (4,063) |
| Adjustments for: | | |
| Depreciation of property, plant and equipment | 68 | 94 |
| Depreciation of investment property | - | 9 |
| Amortization of intangible assets | 143 | 171 |
| Amortization of lease prepayments | 46 | 42 |
| Loss on disposal of property, plant and equipment | 4 | 71 |
| Interest income | (439) | (831) |
| Interest expense | 2,766 | 2,177 |
| Share-based payment | 685 | 717 |
| Income tax expense | 24 | 80 |
| | <u>3,297</u> | <u>2,530</u> |
| Operating loss before working capital changes | (4,539) | (1,533) |
| (Increase)/Decrease in working capital | | |
| Inventories | 253 | (981) |
| Other receivables | (295) | (2,630) |
| Trade receivables | (2,947) | (58) |
| Payables and accruals | 2,577 | 4,278 |
| Cash (used in)/generated from operations | (4,951) | (924) |
| Income taxes paid | (18) | (80) |
| Net cash (outflow)/inflow from operating activities | <u>(4,969)</u> | <u>(1,004)</u> |
| Cash Flows from Investing Activities | | |
| Interest received | 135 | 123 |
| Purchase of property, plant & equipment | (12,179) | (16,853) |
| Purchase of intangible assets | (2,854) | (5,906) |
| Purchase of land use rights | - | (45) |
| Net cash outflow from investing activities | <u>(14,898)</u> | <u>(22,681)</u> |
| Cash Flows from Financing Activities | | |
| Interest paid | (46) | (3) |
| Repayment of bank loans | (10) | (33) |
| Proceeds from bank loans | - | 18 |
| Capital contribution by minority interests of a subsidiary | 3,012 | 1,836 |
| Loans from ultimate holding company | 17,977 | 20,254 |
| Net cash inflow from financing activities | <u>20,933</u> | <u>22,072</u> |
| Net increase/(decrease) in cash and cash equivalents | 1,066 | (1,613) |
| Cash and cash equivalents at beginning of the year | 4,912 | 6,614 |
| Translation difference in cash and cash equivalents | 114 | (89) |
| Cash and cash equivalents at end of the year | <u>6,092</u> | <u>4,912</u> |

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Consolidated Statement of Cash Flows
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Notes to the Consolidated Financial Statements
For the Twelve Months Ended 31 December 2008

1. **GOING CONCERN**
2. **BASIS OF PREPARATION**
3. **LOSS FROM ORDINARY ACTIVITIES BEFORE INCOME TAX**
4. **COMMENTARY ON RESULTS**
5. **INTANGIBLE ASSETS**
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Notes to the Consolidated Financial Statements For the Twelve Months Ended 31 December 2008

1. Going Concern

The consolidated financial statements of the Company and its subsidiaries have been prepared on a going concern basis, the validity of which depends on the financial and other support from the ultimate holding company, Bioton S.A., to enable the Group and the Company to operate as a going concern and to settle its debts as and when it falls due for the next twelve months.

During the year ended 31 December 2008, the Group incurred a loss of US\$7,836,000 (2007: US\$4,063,000) and had negative operating cash flows of US\$4,969,000. At the year end the Group had negative net current assets of US\$802,000 (2007: positive US\$3,335,000). Additional loans were provided by Bioton amounting to US\$17,977,000. As at 31 December 2008, the Group has a loan from Bioton of US\$61,644,000 (2007: US\$43,667,000).

Bioton during the year has been negotiating to refinance its borrowings and it is currently sourcing for additional funds. Upon successful conclusion of these negotiations, Bioton has confirmed that it will have the ability and willingness to continue to support the operational and investment cash requirements of the Group.

Accordingly, the financial statements of the Group have been prepared assuming that the Group will continue as a going concern and do not include any adjustments relating to recoverability and classification of recorded asset amounts or to amounts and classification of liabilities that might result if the going concern basis is found to be inappropriate.

2. Basis of Preparation

This preliminary final report has been prepared in accordance with Singapore Financial Reporting Standards.

The accounting policies adopted are consistent with those of the previous financial year and the corresponding interim reporting period.

The preliminary final report is presented in United States dollars, which is the functional currency of the Company.

United States Dollars Presentation

Transactions in foreign currencies during the financial year are converted into United States dollars at the rates of exchange prevailing at the transaction dates. Foreign currency monetary assets and liabilities are translated into United States dollars at the rate of exchange prevailing at the balance sheet date. Exchange differences arising are taken into the consolidated income statement.

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For the purpose of the consolidation of foreign subsidiaries, whose operations are an integral part of the Company's operations, the foreign subsidiaries' balance sheet and profit and loss are translated as follows:-

- Assets, liabilities and contributed equity are translated using closing rates at reporting date;
- Income and expenses are translated using the actual or average rates;
- Retained profits or losses are translated at cumulative average rates; and
- Exchange differences are recognised as a separate component of equity (translation reserve).

3. Loss from Ordinary Activities Before Income Tax

| | 12 Months Ended 31 December 2008 <u>US\$ '000</u> | 12 Months Ended 31 December 2007 <u>US\$ '000</u> |
|---|---|---|
| Loss from ordinary activities before income tax includes the following items of revenue and expenses: | | |
| <i>(a) Revenue</i> | | |
| <i>Revenue from operating activities</i> | | |
| Sales of goods | 13,860 | 8,321 |
| <i>Revenue from outside the operating activities</i> | | |
| Interest income | 135 | 123 |
| <i>Revenue from ordinary activities</i> | 13,995 | 8,444 |
| <i>(b) Other Income</i> | | |
| Negative goodwill | - | (63) |
| Others | 116 | 96 |
| Deemed interest income on non-current payables | 304 | 708 |
| | 420 | 741 |
| <i>(c) Expenses</i> | | |
| Expenses include: | | |
| Cost of goods sold | 7,196 | 4,023 |
| Loss on disposal of property, plant and equipment | 4 | 71 |
| Bad & doubtful trade debts | 16 | 2 |
| Net foreign exchange loss/(gain) | 925 | (2,242) |

The cost of the licence rights are amortised and charged to the statement of financial performance over the estimated period of right of use, which range from 8 to 20 years.

The amortisation commences from the date the product is marketed, following the successful registration of the products in any country according to the licence agreements.

4. Commentary on Results

The Company's activities during the year continued to focus on collaborative research & development of biotechnology derived pharmaceutical products and the registration, marketing and sales of biopharmaceutical

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products – namely recombinant Human Growth Hormone (SciTropin™), SciGen's 3rd generation hepatitis B vaccine (Sci-B-Vac™), GCSF (Scilosyte™) & recombinant Human Insulin (SciLin™).

Year on year revenue increased due to higher sales in Australia, India, Thailand & Vietnam.

During the year, registration of products was granted in the following regions (show by ✓).

| Country | SciTropin (BTG) | SciTropin (Sandoz) | Sci-B-Vac | GCSF | SciLin |
|-------------|-------------------------|--------------------|------------|------|------------|
| Australia | Registered ^a | Registered | - | - | - |
| Hong Kong | De-Registered | - | Registered | - | Registered |
| India | Registered ^b | ✓ | Registered | - | Registered |
| Indonesia | - | - | - | - | Registered |
| Israel | - | - | Registered | - | - |
| Korea | Registered ^c | - | - | - | - |
| Pakistan | - | - | - | - | ✓ |
| Philippines | Registered | ✓ | Registered | ✓ | Registered |
| Singapore | Registered | - | Registered | - | - |
| Thailand | - | - | - | - | Registered |
| Vietnam | Registered ^b | - | Registered | - | Registered |

^a Trademark was changed to Zomacton and registration is transferred to Ferring in Australia, Philippines, and Singapore.

^b On going process for the change in trademark and after which registration shall be transferred to Ferring.

^c Registration is still under SciGen, however, after June 2009, the registration shall be transferred to Ferring.

5. Intangible Assets

| | <u>Licences</u> US\$ '000 | <u>Computer software</u> US\$ '000 | <u>Development costs</u> US\$ '000 | <u>Total</u> US\$ '000 |
|---|------------------------------|---------------------------------------|---------------------------------------|---------------------------|
| <u>Cost</u> | | | | |
| At 1 January 2007 | 20,190 | 56 | 443 | 20,689 |
| Additions | 5,983 | 14 | 669 | 6,666 |
| Disposals/write-off | (874) | - | - | (874) |
| Reclassification to property, plant and equipment | - | - | (443) | (443) |
| At 1 31 December 2007 | 25,299 | 70 | 669 | 26,038 |
| Additions | 3,448 | - | 1,142 | 4,590 |
| Translation differences | (3) | - | (14) | (17) |
| At 31 December 2008 | 28,744 | 70 | 1,797 | 30,611 |
| <u>Accumulated amortization</u> | | | | |
| At 1 January 2007 | 885 | - | - | 885 |
| Amortisation charge for the year | 169 | 2 | - | 171 |
| Disposals/write-off | (557) | - | - | (557) |
| At 31 December 2007 | 497 | 2 | - | 499 |
| Amortisation charge for the year | 117 | 26 | - | 143 |
| Translation differences | - | 1 | - | 1 |
| At 31 December 2008 | 614 | 29 | - | 643 |
| Net Book Value | | | | |
| At 31 December 2007 | 24,802 | 68 | 669 | 25,539 |

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At 31 December 2008

| | | | |
|--------|----|-------|--------|
| 28,130 | 41 | 1,797 | 29,968 |
|--------|----|-------|--------|

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6. Contributed Equity

| | <u>2008</u> <u>US\$ '000</u> | <u>2007</u> <u>US\$ '000</u> |
|------------------------------|---------------------------------|---------------------------------|
| At 1 January and 31 December | 42,530 | 42,530 |

7. Reserves

| | <u>2008</u> <u>US\$ '000</u> | <u>2007</u> <u>US\$ '000</u> |
|--|---------------------------------|---------------------------------|
| <u>Reserves</u> | | |
| <i>1. Share option reserve</i> | | |
| At 1 January | 914 | 197 |
| Share-based payment | 685 | 717 |
| At 31 December | <u>1,599</u> | <u>914</u> |
| <i>2. Foreign currency translation reserve</i> | | |
| At 1 January | 217 | (262) |
| Foreign currency translation reserves movement during the year | (3,579) | 479 |
| At 31 December | <u>(3,362)</u> | <u>217</u> |
| Total Reserves | | |
| At 1 January | <u>1,131</u> | <u>65</u> |
| At 31 December | <u>(1,763)</u> | <u>1,131</u> |

8. Accumulated Losses

| | <u>12 Months</u> <u>Ended</u> <u>31 December</u> <u>2008</u> <u>US\$ '000</u> | <u>12 Months</u> <u>Ended</u> <u>31 December</u> <u>2007</u> <u>US\$ '000</u> |
|--|---|---|
| Balance at beginning of financial year | (26,249) | (22,299) |
| Net loss for the year | (7,454) | (3,950) |
| Balance at end of financial year | <u>(33,703)</u> | <u>(26,249)</u> |

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9. Loss Per Share

| | 12 Months Ended 31 December 2008 <u>US\$ '000</u> | 12 Months Ended 31 December 2007 <u>US\$ '000</u> |
|--|--|--|
| Basic and diluted loss per share is based on: | | |
| (i) Net loss attributable to ordinary shareholders | <u>(7,454)</u> | <u>(3,950)</u> |
| | Number of shares (‘000) | (‘000) |
| (ii) Weighted average number of ordinary shares at end of the financial year | <u>552,270</u> | <u>552,270</u> |

The effect of the exercise of share options on the weighted average number of ordinary shares in issue are as follows:

| | Number of shares (‘000) | (‘000) |
|---|----------------------------|----------------|
| Weighted average number of: | | |
| - Ordinary shares used in the calculation of basic loss per share | 552,270 | 552,270 |
| - Potential ordinary shares issuable under share options | <u>-</u> | <u>18,566</u> |
| Weighted average number of ordinary issued and potential shares assuming full conversion at end of the year | <u>552,270</u> | <u>570,836</u> |

Options granted to the director are considered to be anti-dilutive potential ordinary shares. Therefore, they have not been included in the determination of diluted loss per share.

10. Net Tangible Liabilities Per Share

| | 2008 <u>(US¢ per share)</u> | 2007 <u>(US¢ per share)</u> |
|------------------------------------|--------------------------------|--------------------------------|
| Net tangible liabilities per share | <u>(3.098)</u> | <u>(0.898)</u> |

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11. Segment Information

Segment Revenues

| | External Sales | | Inter-Segment | | Total | |
|----------------------------------|--|--|--|--|--|--|
| | 12 mths ended 31 Dec 2008 <u>US\$ '000</u> | 12 mths ended 31 Dec 2007 <u>US\$ '000</u> | 12 mths ended 31 Dec 2008 <u>US\$ '000</u> | 12 mths ended 31 Dec 2007 <u>US\$ '000</u> | 12 mths ended 31 Dec 2008 <u>US\$ '000</u> | 12 mths ended 31 Dec 2007 <u>US\$ '000</u> |
| <i>Singapore</i> | 25 | 265 | 1,027 | 1,038 | 1,052 | 1,303 |
| <i>Australia</i> | 3,729 | 3,696 | - | - | 3,729 | 3,696 |
| <i>India</i> | 4,966 | 1,552 | - | - | 4,966 | 1,552 |
| <i>Korea</i> | 1,181 | 686 | - | - | 1,181 | 686 |
| <i>Thailand</i> | 2,038 | 859 | - | - | 2,038 | 859 |
| <i>Others</i> | 1,921 | 1,263 | - | - | 1,921 | 1,263 |
| Total of all segments | | | | | 14,887 | 9,359 |
| Eliminations | | | | | (1,027) | (1,038) |
| Interest income | | | | | 135 | 123 |
| Revenue from ordinary activities | | | | | 13,995 | 8,444 |

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Segment Results

| | 12 mths ended 31 Dec 2008 <u>US\$ '000</u> | 12 mths ended 31 Dec 2007 <u>US\$ '000</u> |
|---|---|---|
| <i>Singapore</i> | (47) | 454 |
| <i>Australia</i> | 382 | 247 |
| <i>India</i> | 449 | 186 |
| <i>Korea</i> | (157) | (511) |
| <i>Thailand</i> | 224 | 110 |
| <i>Others</i> | 202 | (233) |
| Total of all segments | 1,053 | 253 |
| Eliminations | - | - |
| Unallocated | (8,865) | (4,236) |
| Loss from ordinary activities before income tax expenses | (7,812) | (3,983) |
| Income tax expense relating to ordinary activities | (24) | (80) |
| Net Loss for the year after income tax before Minority Interest | (7,836) | (4,063) |
| Minority Interest | 382 | 113 |
| Net Loss for the year after Minority Interest | (7,454) | (3,950) |

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12. Other Significant Information

Significant events that occurred during the financial year were as follows:-

a. Commercialization Agreement for Hepatitis B Vaccine

On 7th January 2008, SciGen Ltd announced that it had entered into a Commercialisation agreement with Julphar for the distribution and marketing of Sci-B-Vac, its third generation hepatitis B vaccine primarily in the Middle East. The countries include all the Arab speaking countries in addition to Malaysia, Bangladesh, Pakistan and Afghanistan.

In the Middle East where the prevalence of hepatitis B is over 8%, such as in Saudi Arabia, and significantly more in Tropical Africa, the market potential offers great opportunities for Sci-B-Vac. Julphar is committed to aggressively pursue these markets.

Sci-B-Vac was presented to all Julphar's delegates and marketing personnel at their annual meeting that took place in November 2007 in Dubai and was enthusiastically received.

b. Good Manufacturing Practices (GMP) Certification for Sci-B-Vac

SciGen Ltd announced that it had been awarded the GMP certification of its manufacturing facility in Rehovot, Israel where its third generation hepatitis B vaccines Sci-B-Vac is manufactured. This comes after having successfully implemented and complied with all the requirements as specified by the World Health Organisation (WHO) and the Ministry of Health of Israel. GMP certification is a prerequisite for the renewal of the health registration those countries where Sci-B-Vac was previously registered prior to the change of manufacturing site and the start of the health regulatory submissions in all parts of the world including the EMEA in Europe, the FDA in the USA and other major health regulatory agencies.

c. Rights to Oral-lyn™ secured

SciGen had entered into a product licensing and distribution agreement pursuant to which SciGen Ltd will produce government approvals for the importation, distribution, marketing and sale of Generex's Oral-lyn™, the Company's proprietary oral insulin spray product, in the Peoples' Republic of China, Hong Kong and the following additional countries: Indonesia, South Korea, Malaysia, the Philippines, Singapore, Thailand and Vietnam.

Pursuant to the terms of the Agreement, SciGen will seek government approvals for the sale of Generex Oral-lyn™ in the territory using SciGen's own recombinant human insulin product. SciGen will supply its recombinant human insulin and Generex will formulate and fill Generex Oral-lyn™ in its appointed manufacturing facility for distribution and marketing in SciGen's assigned territory.

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d. Approval of SciLin™ in the Peoples' Republic of China ("China")

SciGen has secured the first of three formulation approvals of its Recombinant Human Insulin in China. Preparations are underway to secure the license for all other formulations from the Chinese Food & Drug Administration (SFDA) and approval is expected shortly.

The product is presently manufactured by Bioton, SciGen's contract manufacturer and major shareholder, and distributed by Hefei Life Sciences (HLST), SciGen's Chinese distributor. HLST management has a long and successful track record in marketing Insulin in the Chinese market and is one of SciGen's partners, together with Bioton, in a fill & finish facility under construction in Hefei, Hanui Province.

The Insulin market in China is the largest in the Asia Pacific Region with sales of US\$500 million in 2007 increasing at the rate of 25 to 30% per year. The WHO (World Health Organisation) estimates that the Chinese Market will exceed US\$1 billion by 2010. SciGen is now poised to secure a significant share of this market starting in the fourth quarter of this year.

e. Status of the manufacturing facilities in Israel, India & China

The manufacturing facility in Israel, which is expected to produce mainly Sci-B-Vac, had been awarded the Good Manufacturing Practice certification by the World Health Organisation on 23 January 2008. SciGen expects to obtain the Certificate of Pharmaceutical Product for Sci-B-Vac from the World Health Organisation by the first quarter of 2009. A licence to export the low dose Sci-B-Vac had been issued by the Israel Ministry of Health and is valid until June 2013.

Previously, SciGen Biopharma's facility was expected to be completed in 2008 and commercial production and sales were expected to commence in 2009. In view of the current developments in 2008, construction of the facility was temporarily rescheduled in October at the direction of Bioton.

SciGen expects that the regulatory approval and registration and insulin in India will be obtained by the fourth quarter of 2010. If the comparability strategy is accepted and the clinical trials are waived regulatory approval and registration for GSSF in India is expected to be obtained by the first quarter of 2010. If the clinical trials are required, approval should be expected by the second quarter of 2011.

Previously, HSBBC's facility was intended to be used for formulation and filling of insulin. SciGen has decided to split the project into two phases, namely filling and packaging (Phase 1) and formulation of insulin (Phase 2). The plan for commencement of Phase 1 is currently pending approval at HSBBC's Board of Directors meeting, which is expected to be held on shortly.

SCIGEN LIMITED
APPENDIX 4E – PRELIMINARY FINAL REPORT

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For the Twelve Months Ended 31 December 2008

13. Information on Audit or Review

This preliminary final report is based on accounts to which one of the following applies.

- | | |
|--|--|
| <input type="checkbox"/> The accounts have been audited. | <input type="checkbox"/> The accounts have been subject to review. |
| <input checked="" type="checkbox"/> The accounts are in the process of being audited or subject to review. | <input type="checkbox"/> The accounts have not yet been audited or reviewed. |

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