Securities Investors Association (Singapore)
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UEN No: S99SS0111B
GST Reg No: M90367530Y

Issuer: iX Biopharma Ltd.

Security: iX Biopharma Ltd.

Meeting details:
Date: 19 October 2018
Time: 10.00 a.m.
Venue: NUSS Kent Ridge Guild House, Inner Chamber, 9 Kent Ridge Drive, Singapore 119241

Company Description

iX Biopharma Ltd., a specialty pharmaceutical and nutraceutical company, develops, manufactures, and commercializes therapies for the treatment of acute and breakthrough pain, and other health conditions in Australia and Singapore. The company operates through Specialty Pharmaceutical, Chemical Analysis, and Nutraceutical segments. Its lead product candidate is Wafermine, a sublingual ketamine oral wafer that is in phase 2 clinical studies for the management of moderate to severe pain. The company's products also include BnoX, a sublingual buprenorphine wafer for the treatment of moderate to severe pain; Wafesil, a sublingual sildenafil wafer for the treatment of male erectile dysfunction; and Silcap for the treatment of male erectile dysfunction. It also promotes and markets nutritional and supplements products through pharmacies, as well as through online; and development and commercialization of nutraceutical products. The company also provides laboratory services. iX Biopharma Ltd. was founded in 2008 and is headquartered in Singapore.
(Source: http://www.sgx.com/wps/portal/sgxweb/home/company_disclosure/stockfacts?code=42C)

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1. The company raised $30.13 million at the IPO in July 2015 and followed up with a private placement in April 2016 and a rights issue in July 2016 to raise a further $4.85 million and $5.03 million respectively.

Since the listing, the net cash outflow for operating activities were $(6.45) million in 2015, $(9.13) million in 2016, $(4.16) million in 2017 and $(8.36) million in 2018. The research and development expenses from 2015 to 2018 were $(4.51) million, $(5.61) million, $(5.12) million and $(8.03) million respectively.

As at the end of the financial year, the group's cash and cash equivalents stood at $20.7 million.

(i) **KET010:** The bulk of the R&D expenses relate to the Phase 2 study of Wafermine to show its efficacy in patients experiencing acute, post-operative pain after undergoing bony or soft-tissue surgery. **Can management help shareholders understand the R&D budget set aside for the group to complete the End of Phase 2 meeting and the subsequent Phase 3 for the Investigational New Drug application with the U.S. Food & Drug Administration (FDA)? Does the group have sufficient resources to complete the drug trial given that its R&D expenses and the net cash outflow for operating activities are high?**

(ii) Capital raising: Would the group require additional capital before the monetisation of Wafermine?

(iii) Strategic collaborations: Can management also help shareholders understand how it is approaching potential strategic partners for the development and commericialisation of Wafermine? What is the experience of management in out-licensing drugs to suitable partners? How does management ensure that the structure of any out-licensing deal will capture a fair share of value for the group?

(iv) Contingency planning: What are the company's backup plans should Wafermine not be approved by FDA for the current indications?

2. As noted in the Chairman's Statement, the group has also successfully registered Wafesil and Silcap with the TGA in June 2018 and August 2018 respectively and will be launching these two drugs in Australia.

(i) What is the sales & marketing budget (including product education to general practitioners) for the launch of these two drugs in Australia?

(ii) Is the proposed registration of Wafesil and Silcap in Asia and the European Union dependent on the success in the Australia market?

On 21 September 2018, the company announced that the Advisory Committee on Medicines Scheduling had maintained the current classification of sildenafil under Schedule 4 as sildenafil does not satisfactorily meet the Schedule 3 Schedule Policy

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Framework criteria issued by the Australian Health Ministers' Advisory Council. Therefore, the sale of sildenafil will continue to require a doctor's prescription and cannot be sold over the counter (OTC) without a doctor's prescription.

(iii) How has this affected the group's plans for Wafesil and Silcap?

(iv) Pipeline: With the discontinuation of Wafernyl, how does the group source for other molecules or identify new indications so as to continue its drug development efforts?

3. In its IPO in July 2015, the group positioned itself as a "*late-stage specialty pharmaceutical company focused on the development and commercialisation of innovative therapies for the treatment of acute and breakthrough pain, as well as male erectile dysfunction*".

In November 2017, the group launched its nutraceutical product under the new brand Entity. The group has commenced online sale of its products on its website, on third-party e-commerce platforms and in pharmacies in major Australian cities.

(i) Can management help shareholders understand the key success factors for its Entity nutraceutical product range to gain traction in the market?

(ii) What is the sales and marketing budget set aside for Entity? How is the group going to fund this?

(iii) How confident is management in converting the advertising & promotional budget into revenue (and profit) from its Entity products?

(iv) Would the group be liable to litigation relating to false or misleading representations or claims about its nutraceutical products? How is the board/risk management committee/management mitigating this risk?

(v) How does the group set aside funds for contingency plans such as product litigation or has the group purchased product liability insurance?

(vi) As at 31 June 2018, the group has inventories with a carrying value of $528,000. **As the group scales up its nutraceutical business, how much working capital is required?**

(vii) Has the board evaluated if the nutraceutical business alters the risk profile of the group significantly? Would it require shareholders' approval for the group to branch out into this business?

A copy of the questions for the Annual Report for the financial year ended 30 June 2017 and 30 June 2016 could be found here:

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https://sias.org.sg/qa-on-annual-reports/?company=iX%20Biopharma%20Ltd

The company's response could be found here:

2017:
https://sias.org.sg/media/qareport/1508895206_iX_Responses-to-SIAS-Questions_Annual-Report-FY2017.pdf

2016:
https://sias.org.sg/media/qareport/1478156163_iX_Responses-to-SIAS-Questions.pdf