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Biota Holdings Limited
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Biota Holdings Limited today announced a licensing agreement, potentially valued at up to US\$102 million, with Boehringer Ingelheim (BI) to develop and commercialise Biota's proprietary nucleoside analogues for Hepatitis C Virus (HCV) infections. What's the strategic rationale for this agreement and why have you chosen to license the compounds at this early stage of their development?

CEO Peter Cook

We have a very disciplined and commercial approach to product development. The decision to partner the development of a product has to strike a balance between the risk-adjusted value you think you could create by continuing to develop the product yourself, versus the value that's being offered through the deal.

We've had a lot of interest in our HCV intellectual property (IP) and believe the value and opportunity created through this deal represents a very good outcome for our shareholders.

BI is internationally recognised as one of the leaders in the research and development of anti-viral therapeutics. They will contribute development and commercialisation expertise, and we shouldn't lose sight of the fact that BI has the financial capacity to support late-stage trials in Hepatitis C, which are particularly difficult and expensive.

Securing the partnership early in the development process should result in more rapid development of the compounds and increase the potential value of the program.

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What are the terms of the agreement and how do they compare with industry benchmarks for similar deals?

CEO Peter Cook

We'll receive an initial up-front fee, and will be reimbursed for our research costs. We'll also receive payment on delivering certain pre-clinical, clinical, regulatory and commercialisation milestones, and will potentially receive royalties on sales of licensed products subsequently marketed by BI.

The deal is in the same league as other recent global HCV deals. It's always difficult to compare deals because the total dollar value doesn't reflect the product's stage of development alone. For example, the deal we signed about 12 months ago with MedImmune for our Respiratory Syncytial Virus (RSV) compounds had a face value of US\$112 million. Our HCV compounds are appreciably earlier in the drug discovery process, yet we've been able to achieve a comparable value. I'd suggest that reflects the current strong global interest in HCV programs by big pharma, and the potential market for any likely product.

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Can you quantify the up-front technology access fees you'll receive from BI and the development events that would result in Biota's receipt of the full US\$102 million?

CEO Peter Cook

There are confidentiality obligations within the agreement for the protection of both parties, so I'm restricted in the detail I can disclose. But it's fair to assume the format of the deal is consistent with industry practice, and that the size of the up-front and milestone payments reflects the industry norm.

I'd also point out that the BI payments will be fairly transparent in our financial statements, including those for the current first half, which will be released early next calendar year.

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Under the agreement with BI, will you continue to own the HCV IP?

CEO Peter Cook

BI also has IP in the Hepatitis C area. In simple terms, our IP will remain with us and any IP generated during the collaborative period of the program will be jointly owned. Obviously, BI will retain its existing Hepatitis C IP.

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How will you seek to monitor the development and commercialisation of the HCV compounds, and given your ongoing legal case against GlaxoSmithKline (GSK) for failing to use its best endeavours to develop Relenza, how are you seeking to ensure BI uses its best endeavours to develop the HCV compounds?

CEO Peter Cook

There's clarity as to who does what under this agreement. We're responsible for drug discovery research and BI is responsible for the worldwide development of the potential compounds and their commercialisation. What that means is that once the compounds are identified and moved from early-phase clinical into later-stage clinical trials, the project becomes effectively BI's to develop and take to market.

These two aspects of the project will be handled separately but both parties are equally represented on the joint research committee that will oversee and coordinate the activities of the program.

In terms of the use of "best endeavours" in the agreement, it's obviously in both parties' interests that product development be on a sound commercial footing, and that there are performance obligations applying to each party. This agreement clearly spells out those obligations and defines "best endeavours".

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Can Biota undertake research to develop nucleoside analogues outside the HCV field? What's the extent of exclusivity surrounding the agreement and are any non-HCV indications covered by the agreement?

CEO Peter Cook

We can work on other nucleosides for other indications, but not with this group of nucleosides, which is a tricyclic group. This group is exclusive to BI, and is available to BI for potentially additional indications.

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You've previously indicated you expect Biota to report a profit, and be cash flow positive, in the current financial year ending June 2007. Do you remain on track to achieve this?

CEO Peter Cook

We're on track for a profitable and cash positive fiscal 2007. The HCV licensing deal was central to our performance objectives for this year. In addition, we're progressing well with our RSV project with MedImmune, we've completed Phase I trials in our Human Rhinovirus (HRV) project, and we've secured an additional US\$8.5 million under a US National Institutes of Health (NIH) grant for the FLUNET compounds within our LANI (long-acting neuraminidase inhibitor) program. We're also seeing significantly improved royalties from Relenza.

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Thank you Peter.

For more information about Biota, visit www.biota.com.au or call CEO Peter Cook on +61 3 9915 3720 or CFO Damian Lismore on +61 3 9915 3721.

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