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Open Briefing®. pSivida. Alimera Agreement Amendment

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Record of interview:

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pSivida Ltd. (NASDAQ:PSDV, ASX:PSD, Xetra:PSI) announced Monday an amendment to its license and collaboration agreement with Alimera Sciences relating to Medidur™ FA whereby pSivida's share of future profits will decrease from 50% to 20% percent in return for Alimera's payment of up to US$78 million. What is the strategic rationale for this transaction?

MD Dr Paul Ashton
We're in the advantageous position where we've out-licensed several ophthalmic applications of our Medidur™ drug delivery system to different partners and we still have other ophthalmic and non-ophthalmic licensing opportunities. The Medidur™ program for diabetic macular edema (DME) and certain other applications are now fully funded by Alimera. Additional ophthalmic applications of Medidur™ are licensed to and fully funded by Pfizer. We will receive payments as these various products move through development. The payments anticipated from these deals will provide the cash required for the company to reach key milestones for our other programs both in ophthalmology and in oncology, where BrachySil™ for pancreatic cancer is the furthest advanced product.

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You've reduced your share of future profits from Medidur™ FA for DME to 20 percent from 50 percent as a result of this transaction. Why would you enter into a transaction that restricts your future profit upside when you've always been so optimistic about its potential?

MD Dr Paul Ashton
We remain very optimistic about the potential for Medidur. The primary value of this deal to pSivida is not only the 20% profit split, which we will now receive on all products developed under the agreement without having to pay any development costs, but also the cash payments to pSivida, the vast majority of which we expect to receive before sales. This deal gives us the resources to develop other products in our pipeline. Thus, the new agreement provides immediate and near term funding to pSivida and eliminates our obligation to share in development costs, significantly reducing the risk of the Medidur program to pSivida, while giving pSivida a significant interest in the profits.

We now have products in development for several very large ophthalmic markets. The development of these products is funded entirely by our partners, Alimera Sciences and Pfizer. Strategically we are well positioned to capture a significant share of the large and expanding back of the eye market.

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You've ascribed up to US$78 million to this transaction. How likely is it that you will receive it?

MD Dr Paul Ashton
We have received US$12m upfront plus relief of US$20m in estimated R&D costs. In addition we anticipate payments up to US$21m over the next 4 1/2 years and US$25m on approval of Medidur in DME, for which we expect the NDA to be filled in early 2010.

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What if the development costs are higher than US$20 million?

MD Dr Paul Ashton
If the costs are higher, Alimera will pay all of these higher costs.

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What is your cash position after having received the US$12 million up-front payment? What changes will occur in your cash burn rate as a result of this transaction?

MD Dr Paul Ashton
Our cash position as at the end of December 2007 was approximately US$10 million. We now have the US$12 million payment from Alimera and we're receiving quarterly research payments from Pfizer. This year we also expect to receive a further US$1.8m from the recent sales of non-core businesses. The recent Alimera deal, together with the previously announced Pfizer deal, should allow us to be approximately cash flow neutral over the next few years with the subsequent potential for significant revenue streams.

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What other programs of potential value are there within pSivida?

MD Dr Paul Ashton
Alimera is using our Medidur technology to develop products for major back of eye diseases. The recent deal provides for up to US$78m before sales, US$12m of which we have already received, and a profit split once sales begin.

Pfizer is using our Durasert technology to develop products for undisclosed back of the eye diseases. The Pfizer deal provides for up to US$165m in equity investments and development and sales related milestones plus R&D funding, US$12m of which we have already received (US$11.5m as an equity investment and US$0.5m as the first quarterly R&D payment). Once commercialized, we will receive sales based royalties.

In addition to the Pfizer and Alimera deals, there are several ophthalmic and nonophthalmic applications we are advancing. We are also working to commercialise our BioSilicon technology, the first application of which, BrachySil, will shortly commence a Phase IIb clinical trial in pancreatic cancer. Long term, we anticipate BioSilicon™ will have increasing value to pSivida.

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What progress has been made in the Pfizer ophthalmology program?

MD Dr Paul Ashton
The Pfizer collaboration is going well. Since April 2007 we have received US$12m from Pfizer pursuant to our agreement and also under the terms of this agreement we retain the rights to use inventions outside the eye. We are not permitted to disclose any more details on progress.

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What are the primary objectives of the BrachySil™ Phase IIb trials?

MD Dr Paul Ashton
We expect to shortly commence a dose profiling study which will examine both safety and efficacy and generate further data on BrachySil™ as a treatment for pancreatic cancer. The study is expected to last six months, after which we plan to move into a pivotal study.

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What distinguishes your current ambitions in relation to BioSilicon™ from past efforts?

MD Dr Paul Ashton
Previously a lot of our effort had gone into understanding the basic science of BioSilicon, a remarkably elegant and radically new approach to drug delivery. Now that much of the science has been completed, we are able to better focus on using this technology to address the needs of patients (and potential corporate partners). In so doing we expect to be able to move this exciting technology to the commercial stage.

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Thank you Paul.

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efficacy for BrachySil; inability to raise capital; continued losses and lack of profitability; inability to develop or obtain regulatory approval for new products; inability to protect intellectual property or infringement of others' intellectual property; inability to obtain partners to develop and market products; termination of license agreements; competition; inability to pay any registration penalties; costs of international business operations; manufacturing problems; insufficient third-party reimbursement for products; failure to retain key personnel; product liability; inability to manage change; failure to comply with laws; failure to achieve and maintain effective internal control over financial reporting; amortization or impairment of intangibles; issues relating to Australian incorporation; potential delisting from ASX or NASDAQ; possible dilution through exercise of outstanding warrants and stock options or future stock issuances; potential restrictions from capital raises; possible influence by Pfizer; and other factors that may be described in our filings with the Securities and Exchange Commission. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. We do not undertake to publicly update or revise our forwardlooking statements even if experience or future changes make it clear that any projected results expressed or implied in such statements will not be realized.