



PharmaDeals Research

Benchmark Report

Produced for:

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Introduction

Purpose of Report

- To provide Biotech Pharmaceuticals with information for benchmarking purposes, on drug delivery licensing deals for clinical-stage oncology products

Methodology

This benchmark report has been performed by PharmaDeals[®] Research using data drawn from PharmaVentures' proprietary database, PharmaDeals[®] Agreements, containing over 25,000 deals made since 1996.

The deals relating to sustained-release opioid products for the treatment of pain were selected using combinations of search criteria including: "anticancer", "drug delivery", and "licensing". The resulting list of deals was then assessed to identify and select those deals for products at the clinical stage of development.

Presentation of Results

The results are presented in tabular form, using data extracted directly from the PharmaDeals[®] Agreements database. The data are presented in two forms:

- A summary table with draws together the key features of each deal, including available financial details.
- A table containing a detailed description of the deal terms, and any subsequent updates to these deals.

Benchmark Analysis: Drug Delivery Licensing Deals for Clinical-Stage Oncology Products.

Deal Summary

Table 1.1. Summary of deals.

(N/D = Not disclosed, *Total potential deal value)

Date deal announced (Deal no.)	Licensor	Licensee	Product	Indication	Status	Territories	Financials (US\$ M)			
							Total*	Upfront	Equity	Milestones
15/04/2002 (10344)	Ethypharm SA	Biovail Corp.	5-FU (5-fluorouracil) microspheres	Glioblastoma	Phase 2/3	US, Canada, Puerto Rico, Mexico	126	N/D	N/D	65
27/05/2002 (10650)	KS Biomedix Holdings plc (now Xenova Group plc)	Sosei Co. Ltd	TransMID107R(TM) (HNÉ66000/SOT-107/xr 311)	Glioma	Phase 2	Japan	25	2	N/D	N/D
13/01/2005 (18945)	Xenova Group plc	Oxxon Therapeutics, Inc.	DISC-GM-CSF	Metastatic melanoma	Phase 1	Worldwide	83	N/D	N/D	N/D
18/07/2005 (21103)	BioDelivery Sciences International, Inc.	Clinical Development Capital LLC	BEMA(TM) Fentanyl (fentanyl transmucosal)	Cancer pain	Phase 2	Worldwide	7	2	7	N/D
12/10/2005 (21979)	Access Pharmaceuticals, Inc.	ULURU, Inc.	AP5346	Cancer - solid tumours	Phase 1	NA	20.4	8.7	N/D	N/D
18/10/2005 (22038)	Sonus Pharmaceuticals, Inc.	Schering AG	TOCOSOL™ Paclitaxel (paclitaxel)	Solid tumours	Phase 2	Worldwide	239.07	20	167	15.82
			TOCOSOL™ Paclitaxel (paclitaxel)	Metastatic breast cancer	Phase 3					

Date deal announced (Deal no.)	Licensor	Licensee	Product	Indication	Status	Territories	Financials (US\$ M)			
							Total*	Upfront	Equity	Milestones
17/03/2006 (23728)	Inex Pharmaceuticals Corp.	Hana Biosciences, Inc.	Marqibo(TM) (sphingosomal vincristine)	Non-Hodgkin's lymphoma, acute lymphoblastic leukaemia, Burkitt's lymphoma, Hodgkin's disease, small-cell lung cancer, solid tumours	Phase 2	Worldwide	42	11.5	30.5	N/D
			INX-0125, sphingosomal vinorelbine	Solid tumours	IND					
			INX-0076, sphingosomal topotecan	Cancer	Preclinical					
21/12/2005 (24323)	Orexo AB	ProStrakan Group plc	Rapinyl(TM) (fentanyl, OX 20)	Breakthrough cancer pain	Phase 2	Europe	26.43	6.01	20.42	N/D
27/06/2006 (24590)	Sosei Co. Ltd	Mundipharma International Holdings Ltd	AD 923, sublingual formulation of fentanyl	Analgesia	Phase 2	Europe, other markets excluding the US, Japan	31.865	N/D	N/D	N/D
03/08/2006 (24924)	BioDelivery Sciences International, Inc.	Meda AB	BEMA(TM) Fentanyl (fentanyl)	Breakthrough pain in cancer	Phase 3	Europe	10	2.5	7.5	N/D
03/08/2006 (24931)	BioDelivery Sciences International, Inc.	QLT USA, Inc. (of QLT, Inc.)	BEMA(TM) Fentanyl (fentanyl)	Breakthrough pain in cancer	Phase 3	Worldwide, excluding US	3	N/D	N/D	N/D
03/08/2006 (24947)	Medical Discoveries, Inc.	Eucodis GmbH	Formestane	Breast cancer	Phase 1	EU	2.5	N/D	N/D	N/D
20/07/2006 (25067)	US Public Health Service	Protox Therapeutics, Inc.	PRX321, NBI-3001	Primary brain tumours	Phase 2	Worldwide	6	N/D	4	N/D
18/09/2006 (25284)	Cell Therapeutics, Inc.	Novartis AG	Xyotax™ (paclitaxel poliglumex)	Non-small-cell lung cancer, ovarian cancer	Phase 3	Worldwide	285	N/D	270	15
13/01/2005 (18945)	Xenova Group plc	Oxxon Therapeutics, Inc.	TransMID107R(TM) (HNÉ66000/SOT-107/xr 311)	Glioma	Phase 2	Japan	25	N/D	N/D	N/D

Date deal announced (Deal no.)	Licensor	Licensee	Product	Indication	Status	Territories	Financials (US\$ M)			
							Total*	Upfront	Equity	Milestones
18/07/2005 (21103)	BioDelivery Sciences International, Inc.	Clinical Development Capital LLC	DISC-GM-CSF	Metastatic melanoma	Phase 1	Worldwide	83	N/D	N/D	N/D
12/10/2005 (21979)	Access Pharmaceuticals, Inc.	ULURU, Inc.	BEMA(TM) Fentanyl (fentanyl transmucosal)	Cancer pain	Phase 2	Worldwide	7	2	7	N/D
18/10/2005 (22038)	Sonus Pharmaceuticals, Inc.	Schering AG	AP5346	Cancer - solid tumours	Phase 1	NA	20.4	8.7		N/D

Deal Details

Table 1.2. Full deal details.

Date deal announced (Deal no.)	15/04/2002 (10344)
Licensor	Ethypharm SA
Licensee	Biovail Corp.
<p><u>Deal Terms</u></p> <p>Ethypharm and Biovail have entered into a €69 M (US\$61 M) product development and licensing agreement, under which Ethypharm will develop six products for Biovail, using and validating Ethypharm's range of drug delivery technologies, from oral to injectable controlled release. These technologies include Ethypharm's Flashtab™ orodispersible formulations as well as its Spherulites™ multilamellar vesicles. Biovail will have exclusive rights to these products in North America, Puerto Rico and Mexico in exchange for milestones, payable upon regulatory approval, and royalty payments on future sales, while Ethypharm will retain exclusive rights for the rest of the world.</p> <p>The Ethypharm products that are covered by this development and licensing deal, include 5-FU (5-fluorouracil) microspheres for the treatment of glioblastoma, one of the most devastating forms of brain cancer. This 5-FU formulation is in Phase 2b trials and has already received Orphan Drug Status in the US and Europe. Biovail and Ethypharm expect to begin Phase 3 trials for this product in 2003 with the intent of full commercialisation in the US in 2005.</p> <p>Ethypharm and Biovail will also enter into a cross-licensing agreement under which the two companies grant each other non-exclusive licences to use respectively Ethypharm's Flashtab™ and Biovail's CEFORM™, either alone or in combination, to develop novel orodispersible pharmaceutical products.</p> <p>In addition to these commercial deals, Biovail will make an equity investment in Ethypharm. This strategic investment will help finance Ethypharm's growth strategies, and further enhances the commercialisation of its product portfolio in Europe and the rest of the world, while giving Biovail access to complementary drug delivery technologies. Under the terms of the stock purchase agreement, Biovail has invested approximately €74 M (US\$65 M) to acquire 15% of the issued and outstanding shares of Ethypharm. In addition, Biovail has acquired an option to purchase an additional 5% stake in Ethypharm at the same price for a specified period and another 5% interest over a 3 year period at predetermined prices.</p>	

Date deal announced (Deal no.)	27/05/2002 (10650)
Licensor	KS Biomedix Holdings plc (now Xenova Group plc)
Licensee	Sosei Co. Ltd
<p><u>Deal Terms</u></p> <p>KS Biomedix (KSB) has appointed Sosei as the Japanese licensee for its TransMID(TM) product in a US\$25 M licensing deal. TransMID(TM) is a novel biopharmaceutical product in development for the treatment of recurrent high-grade glioma, a terminal brain cancer for which there is no known cure. It is based on the transferrin-mediated delivery of a modified diphtheria toxin (CRM107), which is capable of selectively killing cancer cells. TransMID(TM) received Fast Track Status from the US FDA in August 2001 and Orphan Drug Status in December 2001. In addition, the European Commission granted TransMID(TM) Orphan Designation in March 2002.</p> <p>This is the first TransMID(TM) licensing deal agreed by KSB since it acquired the technology from Intelligene Expressions in July 2001. Japan constitutes around 20% of the total worldwide market for glioma treatments and is the second largest single market in the world after the US.</p> <p>Under the terms of the deal, KSB will receive an upfront payment together with staged development milestone payments and sales-related milestones for a total of up to US\$25 M from Sosei. KSB will also receive royalties on product sales as well as revenue from the sale to Sosei of TransMID(TM) materials manufactured at KSB's Edmonton, Alberta facility. Sosei will be responsible for the development, registration and marketing of TransMID(TM) in Japan. A pivotal Phase 3 trial for the lead product TransMID107-R(TM), for recurrent high-grade glioma, is due to commence in North America and Europe in the second half of calendar year 2002. Marketing submission is scheduled for 2004.</p> <p>Update, 14/02/2005: Xenova acquired KSB in 2003 (Deal no. 13663) and the company's licensee for Transmid(TM) for the Japanese market, Sosei, has been granted Orphan Drug Status for the use of TransMID(TM) in the treatment of glioma by the Ministry of Health, Labour and Welfare (MHLW) in Japan. The achievement of Orphan Drug Designation triggers a milestone payment from Sosei to Xenova.</p> <p>TransMID(TM) is Xenova's lead product candidate and is currently in Phase 3 trials for the treatment of glioblastoma multiforme. TransMID(TM) is pumped directly into the brain tumour via two catheters using CED (Convection Enhanced Delivery) licensed from the US NIH.</p>	



Date deal announced (Deal no.)	13/01/2005 (18945)
Licensor	Xenova Group plc
Licensee	Oxxon Therapeutics, Inc.
<p><u>Deal Terms</u></p> <p>Oxxon Therapeutics has licensed the exclusive worldwide rights to Xenova Group's DISC-HSV (disabled infectious single cycle-herpes simplex virus) and DISC-GM-CSF (granulocyte macrophage colony stimulating factor) vector platforms for use in developing products for certain major cancers and chronic infectious diseases. DISC-GM-CSF, used as a stand-alone product, has been tested in a number of oncology indications including a dose-ranging Phase 1 trial for melanoma. The agreement includes global development, manufacturing and marketing rights to DISC-GM-CSF. Xenova retains the rights to the DISC-PRO vaccine programme for the prophylaxis of herpes virus diseases.</p> <p>The agreement covers the exclusive use of DISC-HSV and DISC-GM-CSF for preventive as well as therapeutic products in selected conditions, and options to obtain rights to additional indications subject to the payment of additional fees. The agreement includes the use of the vector both as part of priming and boosting regimens as stand-alone products. Under the terms of the agreement, Oxxon will pay Xenova an upfront fee spread over 24 months and milestone payments on the first four products to complete commercialisation; these are potentially worth up to £44 M (US\$83 M). Royalties will be paid on future sales of all products derived from the DISC-HSV vector platform.</p> <p>The DISC-HSV vector platform was designed for the safe delivery of heterologous antigens to the immune system in order to stimulate a comprehensive range of immunological responses, including helper and cytotoxic T-cell responses. The viral vector is genetically inactivated through the deletion of a single gene from the genome that is essential for the reproduction of the virus. The DISC-HSV vector has a number of features, which may offer significant advantages over alternative vector systems. These include the ability to target cell types for which other vectors have proved unsatisfactory and the capacity to carry and deliver large amounts of foreign DNA.</p> <p>In addition, these vectors combine the immunological advantages of conventional live-virus vaccines with the safety normally associated with chemically inactivated or subunit vaccines. DISC-HSV vectors also have the potential to generate effective immune responses after direct administration to mucosal surfaces, which may be an important element of protection against pathogens that enter the body at those sites. These characteristics, coupled with the inability of the DISC-HSV vector to replicate within the body and its excellent safety profile, demonstrated in extensive preclinical and clinical trials of DISC-HSV as a vaccine, indicate that the DISC-HSV vector has considerable potential for the development of a number of new products.</p> <p>DISC-GM-CSF is an immunotherapy product that uses the DISC-HSV vector to deliver the GM-CSF gene to tumour cells. GM-CSF is a cytokine and a potent stimulator of immune responses. DISC-GM-CSF has broad potential for use across a wide range of solid tumour types. In preclinical studies, DISC-GM-CSF was shown to be effective in models of breast, renal and colorectal cancer. The product was capable of inducing regression when injected directly into these tumours in vivo, and this regression was mediated by the induction of an antitumour immune response. A Phase 1 dose-escalating safety study was completed at three centres in the UK in patients with metastatic melanoma. DISC-GM-CSF was well tolerated, with no</p>	

serious adverse events reported. Following injection it was not possible to retrieve DISC-GM-CSF from either the injection site or from the patient's serum, showing that the DISC-HSV vector was localised and had not spread beyond the required therapeutic area.

Date deal announced (Deal no.)	18/07/2005 (21103)
Licensor	BioDelivery Sciences International, Inc.
Licensee	Clinical Development Capital LLC
<p><u>Deal Terms</u></p> <p>BioDelivery Sciences International (BDSI) and Arius Pharmaceuticals (a wholly owned subsidiary of BioDelivery Sciences International) have entered into a clinical development and licence agreement with Clinical Development Capital (CDC), pursuant to which CDC will provide up to US\$7 M in funding for Phase 3 clinical trials relating to BDSI's BEMA(TM) Fentanyl product.</p> <p>BEMA(TM) Fentanyl is being targeted for use as a treatment for breakthrough cancer pain, i.e. episodes of severe pain that break through the medication used to control persistent pain associated with the disease. BDSI intends to initiate Phase 3 trials of BEMA(TM) Fentanyl in the second half of 2005. BDSI's BEMA(TM) drug delivery technology consists of a dissolvable, dime-sized polymer disc for application to mucosal (inner lining of cheek) membranes. BEMA(TM) discs are designed to deliver a rapid dose of drug across the mucous membranes for time-critical conditions such as pain. BDSI licenses the BEMA(TM) technology from Atrix Laboratories on an exclusive worldwide basis (Deal no. 17345).</p> <p>Under the terms of the agreement, which is effective as of 14 July 2005, CDC will receive a milestone payment as well as royalty payments based on net sales of BEMA(TM) Fentanyl. CDC's obligation to provide funding is subject to certain conditions set forth in detail in the transaction documents, including the following. BDSI will have the right to enter into partnership, collaboration, licensing or other agreement with a qualified partner. BDSI will also grant to CDC a worldwide royalty-free exclusive right and licence to the product, and a right to sublicense the product. Likewise, CDC will grant BDSI a worldwide exclusive right to license and to sublicense the product both during its development term and after milestone payment and product approval. In connection with CDC entering into the licensing agreement, BDSI will issue to CDC a warrant exercisable for up to 500,000 shares of BDSI common stock, par value US\$0.001 per share. This warrant will stand until the earlier of (i) 5:00 pm Eastern Time on the second anniversary of the approval of the first NDA by the US FDA, (ii) the closing of the sale of BDSI or of its acquisition or merger, or (iii) any liquidation of BDSI.</p> <p>The total development funding provided by CDC will consist of an upfront payment of US\$2 M as partial consideration for the licence granted to CDC and periodic payments amounting to US\$5 M; together, the upfront and periodic payments will not exceed the aggregate development costs of the product. The maximum amount of the periodic payments will be US\$416,666.67 paid monthly over 12 months starting on 10 February 2006 and ending on 10 January 2007. The periodic payments will be reduced proportionately if the number of trial participants falls below 90% of the projected cumulative level, but if the enrolment increases to above 90% the monthly payments will be increased again to US\$416,666.67, and the final payment increased so that aggregate payments total US\$5 M.</p>	

Within 60 days of the approval of a NDA, BDSI will pay to CDC a milestone equal to US\$7 M or the actual amount of development funding provided by CDC; any payments already made by BDSI to CDC as a result of BDSI entering into any other partnership for the product, and passing on any consideration thereby received to CDC, will be offset against the milestone payment.

Royalties will be paid to CDC on a two-tiered system based on worldwide annual net sales of the product. On a country-by-country basis, any royalty obligation will expire on the later of (i) expiry of the last BEMA(TM) patent in the country concerned, or (ii) the first full calendar year following entry of a generic version of the product into that country.

Update, 16/02/2006:

BDSI has received an initial US\$2 M payment under a previously announced clinical development and licence agreement with CDC. This resulted from BDSI achieving certain key milestones in the clinical development of its BEMA(TM) Fentanyl formulation.

Subject to certain conditions, following the initial US\$2 M payment, BDSI will receive monthly payments to fund the trials. All payments received by BDSI from CDC are to be accounted for as deposits to be refunded to CDC upon FDA approval of BEMA(TM) Fentanyl. Under the terms of the agreement, CDC will receive the reimbursement payment and royalty payments based on net sales of BEMA(TM) Fentanyl.

Date deal announced (Deal no.)	12/10/2005 (21979)
Licensor	Access Pharmaceuticals, Inc.
Licensee	ULURU, Inc.
<p><u>Deal Terms</u></p> <p>Access Pharmaceuticals has restructured the company to focus on its oncology therapeutics platform and has completed the sale of its oral care business to ULURU, a private Delaware company formed for the purpose of this acquisition, for up to US\$20.6 M. Access sold its interest in Aphthasol™, all OraDisc(TM) products and all Residerm™ products. In addition, ULURU has licensed Access' nanoparticle hydrogel aggregate technology. Access received US\$8.7 M at the closing of the agreement and may receive up to US\$3.7 M within 12 months after closing, and will receive an additional US\$1 M within 24 months after closing. Additional payments of up to US\$7 M will be made upon the achievement of certain milestones.</p> <p>In addition Access Pharmaceuticals is planning to continue development of its cytotoxic oncology product AP5346 with a Phase 2 trial scheduled to begin in the fourth quarter of 2005.</p> <p>ULURU is an emerging speciality pharmaceutical company dedicated to becoming a leading topical drug delivery and oral care company by using its innovative transmucosal delivery system and hydrogel nanoparticle aggregate technologies and acquiring value-added topical products.</p>	



Date deal announced (Deal no.)	18/10/2005 (22038)
Licensor	Sonus Pharmaceuticals, Inc.
Licensee	Schering AG
<p><u>Deal Terms</u></p> <p>Schering and Sonus Pharmaceuticals have signed an agreement granting Schering an exclusive, worldwide licence to Sonus' TOCOSOL™ Paclitaxel anticancer product.</p> <p>TOCOSOL™ Paclitaxel has shown promising safety and antitumour activity in Phase 2 clinical trials in a variety of solid tumours, and the product is currently in a Phase 3 pivotal study for the potential treatment of metastatic breast cancer. Schering and Sonus expect to submit an NDA for this indication by the end of 2007.</p> <p>Under the terms of the agreement, Schering will make a 15% equity investment in Sonus of US\$15.7 M, consisting of 3.9 million shares at the market closing price on 14 October 2005. For an additional US\$0.125 per underlying share, Schering also acquired 5-year warrants to purchase 975,000 shares of Sonus common stock at an exercise price of US\$4.42.</p> <p>The companies have also executed a licensing agreement, under which Schering will pay Sonus an upfront licence fee of US\$20 M and milestone payments of up to US\$132 M upon the achievement of certain US, EU and Japanese clinical and regulatory milestones. Of this US\$132 M, 61% will be for an indication in metastatic breast cancer and 39% will be for the second indication. For the metastatic breast cancer indication, 50% of payments would be for development and commercialisation in the US, 30% would be for the EU and 20% for Japan.</p> <p>The parties have agreed to a core development programme consisting of the ongoing initial pivotal trial in metastatic breast cancer, planned trials for additional indications and trials to support launch of the product, and have agreed to share equally in the projected US\$50 M cost of this core development programme. For the additional trials, Sonus' contribution would not exceed US\$7.5 M in 2006, US\$10 M in 2007 and US\$5 M in 2008.</p> <p>Upon commercialisation, Schering will pay Sonus royalties of 15% to 30% on net sales within the US, depending on net sales. For sales outside the US, Sonus will receive royalties of 15%. Sonus may also receive one-time sales milestone payments of up to US\$35 M upon reaching specified annual global sales thresholds.</p> <p>The licence agreement is subject to Hart-Scott-Rodino regulatory clearance.</p> <p>TOCOSOL™ Paclitaxel is a vitamin E-based emulsion formulation that allows a dose of paclitaxel to be delivered in a 15 minute infusion. Paclitaxel is a member of the taxane group of anticancer drugs and is the active ingredient in approved drug products that are used to treat many forms of cancer. Use of Sonus' novel TOCOSOL technology enables the delivery by TOCOSOL Paclitaxel of nearly 70% more active paclitaxel compared with that from an equal dose of Taxol™.</p>	

Date deal announced (Deal no.)	17/03/2006 (23728)
Licensor	Inex Pharmaceuticals Corp.
Licensee	Hana Biosciences, Inc.
<p><u>Deal Terms</u></p> <p>Inex Pharmaceuticals has signed a letter of intent to license three products from its targeted chemotherapy pipeline to Hana Biosciences. INEX has granted Hana a worldwide licence to develop and commercialise Marqibo(TM) (sphingosomal vincristine), INX-0125 (sphingosomal vinorelbine) and INX-0076 (sphingosomal topotecan). The two companies expect to close the transaction in the second quarter of 2006 after the completion of legal agreements.</p> <p>Upon closing of the transaction, Hana will pay INEX US\$11.5 M in an upfront payment, consisting of cash and Hana shares. INEX will receive an additional US\$30.5 M if development and regulatory milestones are achieved and will also receive royalties on product sales. Hana will be responsible for all future development of the three products, including all future expenses. INEX will support Hana in the near term to transfer knowledge and expertise and to ensure the products can be advanced as quickly as possible and will also be reimbursed for this support.</p> <p>In addition to supporting Hana with the targeted chemotherapy products, INEX will continue its work with the University of British Columbia on its next-generation drug delivery platform to use with chemotherapy drugs as well as work to complete the spin-off of its targeted immunotherapy assets into Tekmira Pharmaceuticals.</p> <p>Marqibo(TM), INX-0125 and INX-0076 are proprietary drugs using INEX's proprietary sphingosomal drug delivery technology. This technology is designed to provide prolonged blood circulation, tumour accumulation and extended drug release at the cancer site. These characteristics are intended to increase the effectiveness while reducing the side effects of the encapsulated drug.</p> <p>Marqibo(TM) has completed Phase 2 clinical trials and is ready to enter Phase 3 clinical trials in first-line aggressive non-Hodgkin's lymphoma and acute lymphoblastic leukaemia. An IND application has been approved for the commencement of Phase 1 clinical trials for INX-0125 in both the US and Canada and preclinical development is being completed for INX-0076.</p> <p>If the transaction does not close for reasons specific to Hana or INEX, the other party will receive a break-up payment.</p> <p>Update, 08/05/2006: Inex Pharmaceuticals has closed the previously announced transaction to license three products from its Targeted Chemotherapy pipeline to Hana Biosciences. INEX has granted Hana a worldwide licence to develop and commercialise Marqibo(TM) (sphingosomal vincristine), INX-0125 (sphingosomal vinorelbine) and INX-0076 (sphingosomal topotecan).</p>	

Under the terms of the transaction, upon closing, Hana will pay INEX US\$11.5 M in an upfront payment, consisting of cash and Hana shares. The upfront payment consists of US\$1.5 M in cash and 1,118,568 Hana common shares priced at US\$8.94, a 20-day volume weighted average price prior to signing the letter of intent on 17 March 2006.

Update, 30/08/2006:

Inex Pharmaceuticals's partner Hana Biosciences has enrolled the first patient in a Phase 1 human clinical trial evaluating the safety, tolerability and preliminary efficacy of INX-0125 (sphingosomal vinorelbine) as a treatment for advanced solid tumours.

Commencement of patient dosing for this trial triggers a US\$1.0 M payment from Hana to INEX.

After INEX pays third-party obligations of approximately US\$0.2 M the company will forward the remainder of the Hana milestone payment to former INEX noteholders as provided in the agreement with noteholders announced 20 June 2006. This payment will reduce INEX's future contingent payments to the noteholders from US\$24.4 M to US\$23.6 M.

On 20 June 2006 INEX reported that it had signed a definitive note purchase and settlement agreement with all of the holders of certain convertible promissory notes issued by a wholly-owned subsidiary of INEX and guaranteed by INEX. The notes were owned by institutional investors.

Future payments to the former noteholders are contingent on INEX receiving milestone or royalty payments from Hana and other consideration received by INEX should it complete the corporate reorganisation that will be voted upon by INEX shareholders on 20 September 2006.

Date deal announced (Deal no.)	21/12/2005 (24323)
Licensor	Orexo AB
Licensee	ProStrakan Group plc
<p><u>Deal Terms</u></p> <p>Orexo and ProStrakan Group have entered into a licensing agreement under which ProStrakan as of 2 January 2006, receives exclusive rights to register and market Rapinyl(TM) (fentanyl, OX 20), Orexo's patented product for management of breakthrough cancer pain, on the European market.</p> <p>In return for these rights, Orexo will receive an upfront licence fee payment of €5 M (approximately SEK47 M, US\$6.01 M) in addition to other licence fees and payments based on development, regulatory and sales milestones, which total up to €17 M (approximately SEK160 M, US\$20.42 M). When ProStrakan introduces Rapinyl(TM) to the European market, the agreement also provides for double-digit royalties upon commercial sales. Furthermore, the licensing agreement provides Orexo with the right to market Rapinyl(TM) on the Nordic market in parallel with ProStrakan.</p> <p>Rapinyl is an oral, fast-dissolving tablet of fentanyl for the treatment of breakthrough cancer pain. It is based on Orexo's unique proprietary technology for sublingual administration. This novel pharmaceutical preparation provides rapid absorption of the active substance and a fast onset of action.</p> <p>The marketing rights for Rapinyl were licensed to Kyowa Hakko Kogyo in 2003 for the Japanese market (Deal no. 17759), and to Endo Pharmaceuticals in 2004 for the North American market (Deal no. 17595).</p> <p>Orexo is a product focused drug delivery company that develops proprietary pharmaceuticals to address areas of unmet therapeutic need. The company exploits its multidisciplinary capabilities to assess areas of therapeutic need that can be met by developing proprietary pharmaceuticals based on well documented pharmacologically active compounds that incorporate Orexo's proprietary drug delivery technologies.</p> <p>ProStrakan Group is a European speciality pharmaceutical company that is engaged in the research, development and commercialisation of prescription medicines for the treatment of unmet therapeutic needs in major markets. With R&D facilities based in the UK and France, the company also markets a range of products in major EU markets through its commercial operations based in the UK, Germany, France and Spain.</p>	

Date deal announced (Deal no.)	27/06/2006 (24590)
Licensor	Sosei Co. Ltd
Licensee	Mundipharma International Holdings Ltd
<p><u>Deal Terms</u></p> <p>Sosei has entered into a licensing agreement with Mundipharma for the development and commercialisation of AD 923, Sosei's novel sublingual fentanyl spray for cancer breakthrough pain, in Europe and other international markets, excluding the US and Japan.</p> <p>AD 923 has been specifically designed to provide rapid onset of analgesia in a device that is easy to use by either the patient or the patient's care giver. An additional benefit is the lockout system that prevents inadvertent overdosage. Sosei has concluded a range of studies that confirm the potential of this novel product for which the next development milestone will be the start of Phase 3 trials.</p> <p>Under the terms of the agreement, Sosei will be responsible for developing and registering AD 923, and Mundipharma will be responsible for manufacture, marketing and sales within the licensed territories. Sosei has, however, retained the option to co-promote AD 923 in the UK and Germany. A joint committee will be established to oversee all activities covered under the agreement. Under the terms of the agreement, Sosei will receive up to £17.5 M (US\$31.856 M), including upfront and milestone payments and double-digit royalties on product sales.</p> <p>Sosei will evaluate its options for commercialisation of AD 923 in the US and Japan. This will include the possibility for own sales or co-promotion in these territories.</p>	



Date deal announced (Deal no.)	03/08/2006 (24924)
Licensor	BioDelivery Sciences International, Inc.
Licensee	Meda AB
<p><u>Deal Terms</u></p> <p>BioDelivery Sciences International (BDSI), a speciality biopharmaceutical company focused on acute-care products, including pain therapies, and Meda, a European speciality pharmaceutical company, have entered into a collaboration to develop and commercialise BDSI's flagship BEMA(TM) Fentanyl product in Europe. BEMA(TM) Fentanyl is a Phase 3 product being developed by BDSI for the treatment of breakthrough cancer pain. BEMA(TM) is an acronym for Bioerodible Mucoadhesive, and consists of a patented oral BEMA(TM) disc, which delivers the drug through the mucosal surface (inner cheek) by placing the disc between the cheek and gum.</p> <p>This agreement follows BDSI's acquisition of the non-US rights to the BEMA(TM) Technology from QLT USA (Deal no. 24931)</p> <p>Under the terms of the agreement, BDSI will grant Meda rights to the European development and commercialisation of BEMA(TM) Fentanyl, in exchange for an upfront fee of US\$2.5 M, certain milestone payments, which could total US\$7.5 M, and double-digit royalties to be received by BDSI on product sales.</p> <p>Meda will manage the clinical development and regulatory submissions in all of Europe. Upon regulatory approval, Meda will exclusively commercialise BEMA(TM) Fentanyl in Europe. BDSI will retain all development and commercial rights in the US, Japan, Australia and other territories outside Europe.</p> <p>Meda concentrates on marketing and market-adapted product development. Acquisitions and long-term partnerships are fundamental factors that drive the company's strategy.</p> <p>BDSI is a speciality pharmaceutical company that is focused on developing innovative products to treat acute conditions such as pain. The company uses its licensed and patented drug delivery technologies to develop and commercialise clinically-significant new products using proven therapeutics.</p>	

Date deal announced (Deal no.)	03/08/2006 (24931)
Licensor	BioDelivery Sciences International, Inc.
Licensee	QLT USA, Inc. (of QLT, Inc.)
<p><u>Deal Terms</u></p> <p>BioDelivery Sciences International, (BDSI), a speciality biopharmaceutical company focused on acute-care products, has purchased from QLT USA all of the non-US rights to the BEMA(TM) drug delivery technology, including all patent rights and related IP. Before this transaction, BDSI had licensed BEMA(TM) from QLT USA on a worldwide, exclusive basis (Deal no. 17345). This deal was originally signed between Arius Pharmaceuticals, which was acquired by BDSI (Deal no. 17542) and Atrix, which merged with QLT in June 2004 (Deal no. 16963). Besides the rights to the BEMA(TM) technology outside of the US, the agreement gives BDSI an option to purchase the US BEMA(TM) technology patents within 12 months.</p> <p>The aggregate purchase price for the non-US portion of the BEMA(TM) technology is US\$3 M, to be paid over time as follows: (1)US\$1 M paid at closing, (2) US\$1 M by the end of first quarter 2007 and (3) US\$1 M to be paid within 30 days of US FDA approval of the first non-US BEMA(TM)-related product. As part of the transaction as it relates to the non-US portion of the former QLT USA/BDSI licence, no further milestone payments or ongoing royalties will be due to QLT USA. In addition BDSI will have the option to purchase the remaining US asset for US\$7 M. These payments will also be paid over time.</p> <p>BEMA(TM) is an acronym for ÔBioerodible MucoadhesiveÕ, and consists of a patented oral BEMA(TM) disc, which delivers the drug through the mucosal surface (inner cheek) by placing the disc between the cheek and gum. BEMA(TM)Fentanyl is now in Phase 3 trials for the treatment of breakthrough cancer pain (see related Deal no. 24924).</p> <p>QLT is a global biopharmaceutical company specialising in developing treatments for eye diseases as well as dermatological and urological conditions.</p>	

Date deal announced (Deal no.)	03/08/2006 (24947)
Licensor	Medical Discoveries, Inc.
Licensee	Eucodis GmbH
<p><u>Deal Terms</u></p> <p>Medical Discoveries and Eucodis have entered into a licensing agreement for Medical Discoveries' formestane cream, a topical steroidal treatment for breast cancer.</p> <p>The agreement provides Eucodis, an Austrian biotechnology company, with exclusive European development rights in exchange for an upfront licence fee and milestone payments totalling approximately US\$2.5 M. Eucodis maintains responsibility for costs associated with formestane cream's Phase 2 trial which is set to commence in 2007. The data collected from these trials will meet the requirements for submission to the world's leading regulatory bodies, the US FDA and the EMEA. At the conclusion of the Phase 2 trial, a steering committee comprised of representatives from both companies will determine the clinical and commercial roadmap for the Phase 3 trial and international commercial launch. In the event that Medical Discoveries and Eucodis jointly conduct the Phase 3 trial, each company will share equal responsibility for the costs incurred. If Eucodis maintains commercial rights for the EU or if formestane cream is out-licensed, Medical Discoveries will receive a royalty package.</p> <p>Formestane is an aromatase inhibitor, previously marketed as an intramuscular depot injection for adjuvant treatment of breast cancer. Formestane cream represents a novel treatment option based on the inhibition of local production of oestrogen, which is a key signal of tumour growth and progression in more than 90% of breast cancer cases.</p>	



Date deal announced (Deal no.)	20/07/2006 (25067)
Licensor	US Public Health Service
Licensee	Protox Therapeutics, Inc.
<p><u>Deal Terms</u></p> <p>Protox Therapeutics has acquired a Phase 2 clinical-stage programme for the treatment of cancer from Neurocrine Biosciences and the US Public Health Service (PHS). The targeted therapeutic toxin PRX321, formerly known as NBI-3001, has received both Fast Track Designation and Orphan Drug Status from the US FDA for primary brain tumours.</p> <p>PRX321 is a targeted therapeutic toxin in which a cytokine, IL-4, is linked to a Pseudomonas exotoxin, a potent substance that can destroy cancer cells. The IL-4 portion of the compound binds to IL-4 receptors found on the surface of various types of cancer cells.</p> <p>The PRX321 programme was acquired by Protox in two separate transactions. In the first transaction, Protox licensed exclusive worldwide rights to IL-4 fusion toxin technology (INxin(TM)) from PHS. In the second transaction, regulatory and product assets were purchased from Neurocrine in order to facilitate the continued development of PRX321 (Deal no. 25084).</p> <p>The IL-4 fusion toxin was originally discovered and developed by Dr Raj Puri, from the Center for Biologics Evaluation and Research of the FDA and colleagues from the National Cancer Institute (NCI) of the US NIH. Subsequent development and clinical studies were sponsored by Neurocrine and additional research continues at the FDA and the National Cancer Institute (NCI) of the US NIH under the direction of Dr Puri.</p> <p>Protox has committed to pay PHS and Neurocrine, for the licence and corresponding assets, up to US\$2 M over the next 3 years. In addition, Protox will pay PHS up to US\$4 M in future milestone payments (based on the compound receiving FDA approval for at least three indications), as well as royalties on commercial sales.</p> <p>Protox Therapeutics is a product-focused development-stage company and a leader in advancing novel, targeted protein toxin therapeutics for treatment of cancer and other proliferative diseases.</p>	



Date deal announced (Deal no.)	18/09/2006 (25284)
Licensor	Cell Therapeutics, Inc.
Licensee	Novartis AG
<p><u>Deal Terms</u></p> <p>Cell Therapeutics has entered into an exclusive worldwide licensing agreement with Novartis for the development and commercialisation of Xyotax(TM) (poliglumex paclitaxel), an investigational agent in Phase 3 clinical trials for the treatment of women with non-small-cell lung cancer (NSCLC) and other cancers.</p> <p>Total product registration and sales milestones for Xyotax(TM) under the agreement could reach as much as US\$270 M. Novartis has also agreed to make a US\$15 M equity investment in the company. Cell Therapeutics will have the option of co-detailing Xyotax(TM) in the US under the direction of Novartis, under an agreement to be entered into if Cell Therapeutics exercises the option. The closing of the transaction is subject to antitrust regulatory clearance and certain other closing conditions.</p> <p>Xyotax(TM) is a biologically enhanced chemotherapeutic that links paclitaxel, the active ingredient in Taxol[®], to a biodegradable polyglutamate polymer, resulting in a NCE. The investigational medicine is currently in Phase 3 clinical trials to test whether the single agent Xyotax(TM) provides improved overall survival compared with paclitaxel in women with NSCLC and poor performance status.</p> <p>The agreement also provides Novartis with an option to develop and commercialise pixantrone based on agreed terms. Pixantrone is an investigational agent designed to potentially increase antitumour activity and decrease the potential for cardiac toxicity associated with the currently marketed anthracyclines. If Novartis exercises its option on pixantrone under certain conditions, Novartis would pay Cell Therapeutics a US\$7.5 M fee and up to US\$104 M in registration- and sales-related milestones.</p> <p>Update, 19/10/2006: Cell Therapeutics has received the required antitrust regulatory clearance for and has closed on the Securities Purchase Agreement announced on 18 September 2006 between Cell Therapeutics and Novartis. In addition, the licence and co-development agreement between Cell Therapeutics and Novartis became effective upon receipt of the required antitrust regulatory clearance.</p>	