



Royalty Rate Analysis

HIV Therapeutic

August 26, 2011

Developer's NAIC: 611310

Science/Technology Fields: Pharmaceutical; Virology; Therapeutics

Arena NAIC: 325412

Technology Type: Product

Supply Chain: Design and Development

International Patent Classification: A61P 31/00

Geographic Region: Global

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<i>Description of Technology</i>
This type of technology is a therapeutic for HIV infection with potential to act as an HIV vaccine.

<i>Examples of Relevant Deals</i>		
Parties	Key Terms	Date
<p>Licensors: Oklahoma Medical Research Foundation</p> <p>And</p> <p>Licensee: Bridge Therapeutic Products</p>	<p>Exclusive patent and technology license to make, have made, use, lease, and sell services and products for inactivation of HIV viruses in biologicals with rights to sublicense.</p> <p>Royalty Rate: 6% net sales</p> <p>Territory: Worldwide</p> <p>Duration: 15 years after first commercial sale</p> <p>Other Financial Terms: Up-front fee of \$50,000. Milestone payments of \$250,000 upon filing for New Drug Application and FDA Product License Application and \$500,000 upon approval of either application. Minimum annual royalties as follows: \$120,000.00: 3rd Year \$150,000.00: 4th \$250,000.00: 5th and each year thereafter. \$3 million worth of licensee's stock given to licensor upon signing of agreement.</p>	January 1, 1998
<p>Licensors: Cira Technologies</p> <p>And</p> <p>Licensee: NeoProbe</p>	<p>Exclusive option and patent license to make, have made, use and a treatment for HIV infected humans with rights to sublicense.</p> <p>Royalties: 6% of net sales</p> <p>Territory: Worldwide</p> <p>Duration: 10 years from first commercial sale</p> <p>Other Financial Terms: No royalties are due the licensor until total net sales of licensed product exceed the amount of licensee's out-of-pocket research and development expenses for preclinical and clinical research conducted up to the time of filing of an NDA or BLA with the FDA, which is up to a total of \$2 million.</p>	April 1, 1998
<p>Licensors: Yale University</p> <p>AND</p>	<p>Exclusive patent and technology license to make, have made, use, sell and practice the invention related to HIV therapy with rights to sublicense.</p> <p>Royalty Rate: 7% of net sales</p>	March 28, 2003

<p>Licensee: Oncorx, Inc.</p>	<p>Territory: Worldwide</p> <p>Duration: Life of patent(s)</p> <p>Other Financial Terms: Milestone payments of \$250,000 upon completion of phase II clinical trials, \$250,000 upon filing of a New Drug Application or foreign registration filing, and \$500,000 upon FDA approval and any New Drug Application approval. \$100,000 to be paid to licensor 18 months after execution date and minimum annual royalties of \$50,000.</p>	
<p>Licensor: CBR Institute for Biomedical Research, Inc</p> <p>AND</p> <p>Licensee: Advanced Genetic Technologies, Inc.</p>	<p>Non-exclusive patent and technology license to use, make, have made and sell licensed product of monoclonal antibodies for HIV disease applications.</p> <p>Royalty Rate: 2% of net sales up to \$200 million and 3% of net sales over \$200 million.</p> <p>Territory: Worldwide</p> <p>Duration: 20 years</p> <p>Other Payment Terms: Up-front payment of \$15,000. Milestone payments as follows: Initiation of Phase I clinical trial: \$50,000 Initiation of Phase II clinical trial: \$100,000 Initiation of Phase III clinical trial: \$250,000 U.S. FDA marketing approval: \$750,000</p> <p>Annual maintenance fees as follows: 1st Anniversary of commercial sale: \$2,500 2nd Anniversary: \$5,000 3rd Anniversary: \$5,000 4th Anniversary: \$10,000 5th Anniversary: \$10,000 Thereafter : \$10,000</p> <p>Minimum annual royalties to be credited against earned royalties as follows: 1st & 2nd Anniversary of first commercial sale: \$50,000 3rd & 4th Anniversary: \$60,000 5th Anniversary: \$70,000 6th and each subsequent Anniversary: \$200,000</p>	<p>January 1, 2007</p>
<p>Licensor: University of North Carolina at Chapel Hill and Niigata University of Pharmacy</p> <p>AND</p> <p>Licensee: Panacos Pharmaceuticals, Inc.</p>	<p>Exclusive patent and technology license to make, have made, use, sell and offer compounds embodying the invention for any and all human therapeutic use for the treatment of HIV with rights to sublicense.</p> <p>Royalty Rate: Tiered 2.5% of net sales less than \$100 million and 3% net sales over \$100 million.</p> <p>Territory: Worldwide</p> <p>Duration: Life of Patent</p> <p>Other Financial Terms: Milestone payments of \$15,000 for each Investigational New Drug application, \$50,000 upon</p>	<p>January 20, 2009</p>

	completion go Phase II Clinical Trials for each product, \$75,000 for filing a New Drug Application for each product, and \$150,000 upon first commercial sale.	
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Relative deals reveal royalty rates for HIV therapeutics are between 2.5-7% with the average rate being between 5-6%. The majority of the deals described milestone payments as well as minimum annual royalties, suggesting that these terms are common in license agreements for HIV therapeutics.¹ Milestone payments for regulatory approval may also be feasible.

<i>Expert Opinions on Industry Standard Terms</i>		
Expert	Affiliation and Title	Key Terms
Anonymous	Director, Technology Transfer Biomedical Licensing Large United States University	This expert explained that the range of 3% to 8% is appropriate for HIV related therapeutics, however most deals would be in the higher range. If the licensor is a university, up-front fees will be minimal given the technology is likely early stage and technical risk is high. Major payments will come from commercial introduction and FDA approval. Such milestone payments are common and are usually within the mid hundreds of thousands. The expert further mentioned that the financial terms in deals for HIV therapeutics really relate to the maturity of the technology. ²
[name omitted for public sample report]	President and Chief Executive Officer and Director Biopharmaceutical Company	Royalty rates around 6% are average for preclinical HIV therapeutic technologies. Milestone payments would be in the high hundreds of thousands of dollars, increasing upwards to millions of dollars once reaching FDA approval and commercial introduction. ³
[name omitted for public sample report]	Director, Business Development Pharmaceutical Consulting and Research Company	A rate of between 5% and 7% is certainly within the appropriate range for HIV therapeutic developments. Infectious disease agents are an attractive candidate for acquiring companies as they can get to commercialization faster and recoup their ROI given proof of concept is demonstrated more quickly. Therefore, the licensor would receive royalties faster than in other therapeutic areas and should be considered when outlining financial terms. Additionally, licensees are wary of high up-fronts has there is a high risk of failure in navigating through regulatory approval. Milestone payments are common and increase as the technology progresses through clinical trials and FDA approval. There are few players in the HIV space, but that space is very competitive and this competitiveness could be leveraged via a structured bidding process. HIV therapeutics that are more preventative in nature have a

¹ Gladstone Restaino, Leslie. "Perspectives on Successful Biotechnology Licensing: Part 2- Focus on Licensing." Innovaro web site. http://pharmalicensing.com/public/articles/view/1142248609_441554a13cfa4/perspectives-on-successful-biotechnology-licensing-part-2-focus-on-licensing (accessed August 24, 2011)

² Anonymous Technology Transfer Expert in Biomedical Licensing from a Large United States University in a phone conversation with Claire Casola on August 18, 2011.

³ [footnote omitted for public sample report]

		larger audience and could have significant public health implications. This could draw interest from the World Health Organization and the Bill & Melinda Gates Foundation. ⁴
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Experts opinions seemed to reveal that an average rate of between 5% and 6% is appropriate for HIV therapeutic technologies. All experts agreed that milestone payments (typically within the hundreds of thousands range) are standard in license agreements for HIV therapeutics and increase as the technology progresses through the approval process and into commercial introduction. According to Dr. John Bonfiglio from Oragenics, such increases in milestone payments can be as high as in the low millions.

<i>Industry Average Royalty Rate</i>
5.5% with minimum payments and a milestone payment on regulatory approval.

Based on relative deals, expert opinions, and research data, the industry average royalty rate for HIV treatment technologies appears to be around 5.5%.^{5,6,7}

The market shows the need for more effective HIV treatment methods is increasing, as global spending on HIV research and activities reaches over \$25 billion and treatments could be provided for 6.7 million people.⁸ Such market data can be used to help identify the licensee's market share, potential revenues, and narrow down financial terms within a license agreement.

It is important to note that in situations where an HIV treatment is used for public non-commercial use or in urgent situation, royalties paid to patent holder will be lower and in fact the European Union puts the maximum royalty at 4%.⁹

⁴ [footnote omitted for public sample report]

⁵ "Global BioPharma Royalty Rates and Deal Terms Surgery." 2010. Licensing Executives Society web site (subscription required). <http://www.lesusacanada.org/Login.aspx?ReturnUrl=%2f2009biopharmrates.aspx> (accessed August 24, 2011).

⁶ Zaharoff, Howard. "Setting Values and Royalty Rated for Medical and Life Sciences." November 2004. Morese Barnes-Brown Pendleton web site. http://www.mbbp.com/resources/iptech/royalty_rates.html (accessed August 24, 2011).

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⁸ "Needs and Costs; HIV/AIDS." Global Health web site. http://www.globalhealth.org/hiv_aids/needs/ (accessed August 25, 2011).

⁹ "Intellectual Property and Access to HIV/AIDS Treatment Case Studies." *Interagency Coalition on AAIDS and Development*. AIDS Law web site. <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=698> (accessed August 24, 2011).