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\$525M Gets Emtriva Interest From Emory For Gilead, Royalty Pharma

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Gilead Sciences Inc. and Royalty Pharma bought out Emory University's royalty interest in emtricitabine - or Emtriva - for \$525 million.

The companies will make a one-time cash payment to Emory in exchange for all royalties due on worldwide net sales of the product.

Foster City, Calif.-based Gilead will pay 65 percent of the payment - or \$341.25 million - to Emory, while New York-based Royalty Pharma will pay 35 percent - or \$183.75 million.

"Gilead was one of five interested parties, and it was an extremely competitive process that really went down to the wire," said Michael Mandl, executive vice president of Atlanta-based Emory University. "At the end of the day, the combination of price and the quality of the contract with Gilead and Royalty Pharma was the most fair and accurate for us."

Emory initiated the process in January as part of the university's efforts to make new, focused investments in its own research programs. A competitive bidding process drove up the price of the Emtriva royalties, which Emory has held since three of its scientists, Dennis Liotta, Raymond Schinazi and Woo-Baeg Choi, invented emtricitabine. Liotta and Schinazi began their work in AIDS in the mid-1980s when they established the first HIV laboratory at Emory.

Emtricitabine moved away from that laboratory in 1996, when Durham, N.C.-based Triangle Pharmaceuticals Inc. licensed the product. Gilead acquired Triangle in early 2003, and received approval of Emtriva later that year for HIV infection in combination with other antiretroviral agents. (See *BioWorld Today*, July 3, 2003.)

The product had worldwide sales of \$57.6 million last year, but only \$12.1 million for the second quarter of 2005. Truvada - a product approved in August 2004 that contains Emtriva and Gilead's other HIV drug Viread - is taking over those sales. It brought in \$67.9 million in 2004, and \$123.1 million in the second quarter. Viread (tenofovir disoproxil fumarate) had 2004 sales of \$782.9 million, and second-quarter 2005 sales of \$209.1 million.

Notably, Gilead released news after the market closed on Tuesday that it was starting two randomized, double-blind Phase III trials of tenofovir disoproxil fumarate in hepatitis B patients. One study will enroll 300 patients, while the other will enroll 240 patients, who will be randomized between tenofovir DF and Gilead's Hepsera. The primary endpoint of both trials is the proportion of patients with a complete response at week 48.

As the company works to expand the indications for Viread, it also is focused on Truvada and its potential use in combination with other HIV products. Gilead is working in a joint venture with New York-based Bristol-Myers Squibb Co. to develop a triple fixed-dose combination product comprised of Truvada and BMS's Sustiva. (See *BioWorld Today*, Dec. 21, 2004.)

If successful, that product would substantially increase the sales potential of emtricitabine. Emory's U.S. patents for the product expire in 2021.

"We decided that this was clearly something we knew was of great value," Mandl told *BioWorld Today*, adding that Emory did not need to sell emtricitabine. "Our attitude was if we got the right price, we'd sell. If we didn't, that would be fine, too."

As the developer of Emtriva, Gilead had a clear interest in buying the royalties from Emory. Royalty Pharma, on the other hand, is a company whose main business is to purchase revenue streams. The company owns royalty interests in biopharmaceuticals, such as Amgen Inc.'s Neupogen and Neulasta, Genentech Inc. and Biogen Idec Inc.'s Rituxan, and Chiron Corp.'s TOBI.

Emory and inventors of emtricitabine may acquire up to a 25 percent interest in the proceeds payable by Royalty Pharma (about \$46 million worth), if they do so within 30 days of closing. Lazard and Citigroup, both of New York, acted as financial advisers to Gilead, and Emory and the inventors, respectively. The transaction is expected to close the end of this month.

Upon closing, Gilead will begin paying a share of the emtricitabine royalties to Royalty Pharma, and another share to London-based GlaxoSmithKline plc. GSK is entitled to a royalty of emtricitabine sales due to a prior patent dispute settlement with Emory.

Gilead also will make a one-time \$15 million payment to Emory for amending and restating their original license agreement, bringing total gross proceeds to the university to \$540 million. That payment was not laid out in the original deal, but one agreed upon recently by both parties.

"It's something we've been talking with them about for several months on a parallel track," Mandl said.

While Emory plans to reinvest its share of the proceeds into the university's research and discovery programs, a "minority interest" of the money will go to emtricitabine's three inventors, two of whom still remain at the university.

Emory University and the inventors of both Viread (tenofovir disoproxil fumarate) and Emtriva have waived their rights to a royalty on sales of Truvada in Gilead Access Program countries, so the product can be offered at a no-profit price in places hit hard by the epidemic. Viread's inventors are Antonin Holy, of the Academy of Sciences of the Czech Republic in Prague, and Erik DeClercq, of Katholic University in Leuven, Belgium.

In addition to its three HIV products - Truvada, Viread and Emtriva - Gilead has four other marketed products: AmBisome for systemic fungal infections, Hepsera for hepatitis B, Tamiflu for influenza A and B, and Vistide for cytomegalovirus retinitis in patients with AIDS.

Gilead declined to comment on Tuesday, citing a quiet period prior to releasing its second-quarter results. For the quarter ended June 30, total revenues were \$495.3 million, up 55 percent, compared to total revenues of \$319.7 million for the second quarter of 2004. Net income for the second quarter was \$196 million, or 41 cents per diluted share, topping the consensus analyst estimate of 36 cents per share. That compares to net income of \$111.5 million, or 24 cents per diluted share, for the second quarter of 2004.

As of June 30, Gilead had cash, cash equivalents and marketable securities of about \$1.8 billion.

The company's stock (NASDAQ:GILD) rose \$1.05 Tuesday to close at \$46.60.