



## **CYPRESS BIOSCIENCE, INC. AND FOREST LABORATORIES, INC. TO COMMENCE THE SECOND PHASE III CLINICAL TRIAL FOR MILNACIPRAN IN THE FOURTH QUARTER**

San Diego, California, September 9, 2004 – Cypress Bioscience, Inc. (NASDAQ: CYPB) announced today that it expects its partner, Forest Laboratories (NYSE: FRX) to initiate the second Phase III trial evaluating milnacipran for the treatment of Fibromyalgia Syndrome (“FMS”) during the fourth quarter of this year.

Cypress is currently running the first Phase III trial for milnacipran, which was commenced in October 2003. Enrollment in this trial is expected to be completed by the end of the year, with results available in the third quarter of 2005. As originally agreed, Forest Laboratories would run the second Phase III clinical trial for milnacipran, with the assistance of Cypress. In light of the increased expense and risk associated with running two parallel trials, Cypress and Forest are discussing an arrangement whereby, for this trial only, Cypress would initially share in some of the costs of the trial, with Forest reimbursing Cypress with a premium under certain circumstances. Assuming positive results in both pivotal trials, the Phase III program could be completed in 2006.

Dr. Jay D. Kranzler, Chairman of the Board and Chief Executive Officer of Cypress said, “The timely start of the second Phase III trial is consistent with our goal, shared by Forest, to maintain leadership in the development of drugs for FMS.”

### **About Milnacipran**

Milnacipran is a novel compound which exerts its effect by inhibiting the reuptake of both norepinephrine and serotonin, two neurotransmitters known to play an essential role in regulating pain and mood. It has been approved for the treatment of non-pain indications in 32 countries and has been used safely by more than 3 million patients during more than six years of commercial availability outside the U.S.

### **About Fibromyalgia**

Fibromyalgia is considered one of a group of related chronic pain syndromes characterized by both physical and psychiatric symptoms that include conditions such as irritable bowel syndrome (IBS), chronic tension headache, non-cardiac chest pain, and certain types of lower back pain. FMS is estimated to affect six to twelve million people in the United States. FMS is most often diagnosed in the primary care setting and in addition is the second most commonly diagnosed condition in rheumatology clinics in the United States after osteoarthritis.

For more information about FMS, please visit [www.FMSresource.com](http://www.FMSresource.com).

### **About Cypress Bioscience, Inc.**

Cypress is committed to be the innovator and leader in providing products that improve the treatment of Functional Somatic Syndromes, including Fibromyalgia Syndrome (FMS), and other related pain and Central Nervous System conditions. Cypress’ strategy involves acquiring/in-licensing central nervous system active compounds and developing them for novel indications.

In August 2001, Cypress licensed from Pierre Fabre Medicament its first product for clinical development, milnacipran. The license agreement provides Cypress with an exclusive license to develop and sell any products with the compound milnacipran as an active ingredient for any indication in the United States and Canada. On January 9, 2004, Cypress entered into a collaboration agreement with Forest Laboratories for the development and marketing of milnacipran. In October 2003, Cypress began initiating its Phase III clinical trials for the use of milnacipran as a potential treatment for FMS. Cypress

is continuing to evaluate various potential strategic transactions, including the potential acquisition of products and companies, and other alternatives that Cypress believes may enhance stockholder value.

For more information about Cypress, please visit the Company's web site at [www.cypressbio.com](http://www.cypressbio.com).

*This press release, as well as Cypress' SEC filings and web site at <http://www.cypressbio.com>, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 including statements about the potential and effectiveness of milnacipran to treat FMS and other related Functional Somatic Syndromes, the potential development of milnacipran for other chronic pain syndromes, and entering into a strategic transaction. Actual results could vary materially from those described as a result of a number of factors, including those set forth in Cypress Annual Report on Form 10-K, the most recent Quarterly Report on Form 10-Q and any subsequent SEC filings. In addition, there is the risk that we and Forest Laboratories may not be able to successfully develop or market milnacipran or any other products for the treatment of FMS and other related Functional Somatic Syndromes, and, as a result, would not receive any milestone or royalty payments from Forest Laboratories; that we and Forest Laboratories may encounter regulatory or other difficulties in the development of milnacipran for FMS, including delays in completing Phase III trials, including a delay in the commencement of the second Phase III clinical trial; that we may not be able to protect our patents or proprietary technology; that milnacipran may not significantly improve the treatment of FMS or any other related Functional Somatic Syndrome; that we may not be successful in identifying, licensing and developing any additional products, technologies or companies and even if we complete any such transaction, it may not enhance stockholder value. Cypress undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this press release, except as required by law.*

**For additional information please contact**

For Cypress Bioscience:  
Sabrina Martucci Johnson, Chief Financial Officer  
Mary Gieson, Investor Relations  
(858) 452-2323

###