DURECT Corporation Announces Acquisition of Southern BioSystems, Inc

CUPERTINO, Calif., April 30 /PRNewswire/ —
DURECT Corporation (Nasdaq: DRRX) announced today that it has acquired Southern BioSystems, Inc. (“SBS”), a privately held company located in Birmingham, Alabama. SBS develops, manufactures and sells biodegradable polymer and non-polymer drug delivery systems. SBS also provides bulk supply of biodegradable polymer for seven FDA approved products sold by five customers.

Under the terms of the acquisition, DURECT is issuing 1,350,560 shares of common stock, and will issue up to 724,856 additional shares of common stock upon the exercise of outstanding SBS options and warrants, in exchange for all of SBS’s outstanding equity interests. DURECT is also assuming approximately $1.7 million in debt. As a result of the acquisition, SBS is a wholly owned subsidiary of DURECT. DURECT will register the shares issued in connection with the acquisition for resale with the Securities and Exchange Commission in the fourth quarter of 2001. The terms of the transaction may require DURECT to increase the total number of shares of DURECT common stock issued to former SBS equity holders at the time the registration statement is filed, if necessary, so that the total consideration received by the former SBS equity holders, on a fully diluted basis, is valued at approximately $25 million, based on the price of DURECT common stock in the period of time before the registration statement is filed. The transaction is intended to qualify as a tax-free reorganization and is being accounted for using the purchase method of accounting.

As part of this acquisition, DURECT has acquired intellectual property, including 3 issued U.S. patents, covering SBS’s proprietary drug delivery technologies. SBS has three drug delivery platforms, the SABER(TM) delivery system, microspheres and drug-loaded implants, as well as ongoing product development programs. The SABER(TM) technology is a patented and versatile depot technology with a simple manufacturing process. SABER(TM) is intended to be injected subcutaneously as a liquid, via a needle and syringe, and remains in a highly viscous liquid form following injection to conform to body shape. SBS has existing collaborations and active human therapeutic development programs in place with a number of pharmaceutical companies, including Purdue Pharma L.P., AstraZeneca, Alcon and others. SBS also has several animal therapeutic collaborations in place.

“This acquisition continues our strategy to expand the breadth of our drug delivery capabilities. With this acquisition, we have added three additional drug delivery platforms, the SABER(TM) delivery system, microspheres and drug-loaded implants, which will allow us to move additional products into development. These technology platforms, which enable delivery of drugs from days to months, are very complementary to our existing DUROS(R) business, which has a therapeutic delivery profile from months to a year,” stated Dr. James E. Brown, CEO of DURECT.

“We are pleased to be associated with a core team of technical experts at the forefront of depot technology development,” stated Dr. Felix Theeuwes,

Chairman and Chief Scientific Officer of DURECT. “We believe that the SABER(TM) technology has the potential to make significant impacts in the treatment of chronic debilitating diseases and may in the future enable many biotechnology drugs to reach the marketplace in a superior dosage form. Ultimately, this could lead to improved therapy for patients. The SABER platform is a highly lipophilic, non-polymer depot that has shown reduced initial drug release upon injection and improved release profile, and may provide a less painful administration when compared to alternative polymer based products on the market today such as human growth hormone or leuprolide for prostate cancer. As a result of this acquisition, we will initiate development on additional protein-based therapeutic candidates.”

“We are very excited with the added expertise that DURECT brings to the SBS technology business. Given the resource base at DURECT in product development, clinical expertise, manufacturing, and financing, we look forward to expanding our development efforts and accelerating our business plan for both partner and internal development programs,” said Dr. Wallace Smith, Chief Executive Officer of SBS.

As a result of this acquisition, DURECT plans to increase spending on additional research and development programs. DURECT expects the increased spending to have a neutral impact to DURECT’s future break-even profitability, which is anticipated for 2004.

About DURECT Corporation:

DURECT Corporation is pioneering the development and commercialization of pharmaceutical systems to deliver the right drug to the right site in the right amount at the right time. DURECT’s pharmaceutical systems combine technology innovations from the medical device and drug delivery industries with proprietary pharmaceutical and biotechnology drug formulations. These capabilities can enable new drug therapies or optimize existing therapies based on a broad range of compounds, including small molecule pharmaceuticals as well as biotechnology molecules such as proteins, peptides and genes.

DURECT’s lead product in development, DUROS sufentanil, is designed to deliver sufentanil on a continuous basis for 3 months for the treatment of chronic pain. Sufentanil is a FDA approved opioid that is currently used in hospitals as an anesthetic. Chronic pain is a significant problem associated with chronic diseases, including cancer and various neurological and skeletal disorders. DUROS sufentanil is intended for patients whose chronic pain is stable, opioid responsive and results from a variety of malignant and non-malignant causes. Annual sales of opioids for the treatment of chronic pain exceed $1 billion.

In addition to DUROS sufentanil, DURECT’s second product in development, DUROS hydromorphone, continuously delivers hydromorphone to the spine. DURECT is also selling FDA cleared catheters for the delivery of fluids to the inner ear. DURECT also manufactures, sells and distributes the ALZET(R) osmotic pump product for use in laboratory research.

Founded in 1998, DURECT is headquartered in Cupertino, CA. The company's World Wide Web site can be accessed at http://www.www.durect.com. The company's World Wide Web site for ALZET osmotic pumps and IntraEAR can be accessed at http://www.alzet.com and http://www.intraear.com, respectively. To join DURECT's email alert service, please register by selecting "Email Alerts" on the main Investor Relations web page at http://www.www.durect.com.

DUROS is a registered trademark of ALZA Corporation.

About Southern BioSystems, Inc.:

Southern BioSystems, Inc. ("SBS") researches, develops and manufactures controlled-release drug delivery products to help clients commercialize human and veterinary pharmaceuticals. SBS has three drug-delivery platforms: the proprietary SABER(TM) delivery system, microspheres and drug-loaded implants.

SABER(TM) is a biodegradable highly viscous liquid that can be formulated for oral, parenteral dermal or other routes of administration. SBS has the capabilities to formulate microspheres for oral, parenteral dermal or other routes of administration. SBS also develops drug-loaded implants and, through its subsidiary Birmingham Polymers, also manufactures biodegradable polymers.

The company's World Wide Web site can be accessed at http://www.southernbiosystems.com.

SABER(TM) is a trademark of Southern BioSystems, Inc., a subsidiary of DURECT Corporation.

The statements in this press release regarding DURECT's products in development, product development plans, expected product benefits, anticipated spending or financial results are forward-looking statements involving risks and uncertainties that could cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, DURECT's ability to develop, manufacture and commercialize its products, complete successful clinical trials, obtain product approvals from regulatory agencies, build a manufacturing facility, manage its growth and costs, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in the company's S-1 registration statement, filed with the SEC on September 22, 2000, 424(b) prospectus filed with the SEC on September 28, 2000, Quarterly Report on Form 10Q for the quarter ended September 30, 2000 filed with the SEC on November 14, 2000 and Annual Report on Form 10K for the fiscal year ended December 31, 2000 filed with the SEC on March 30, 2001.

Contact: Schond L. Greenway, Director, Investor Relations of DURECT Corporation, 408-777-1417, schond.greenway@durect.com

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CONTACT: Schond L. Greenway, Director, Investor Relations of DURECT Corporation, 408-777-1417, schond.greenway@durect.com/