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DURECT Corporation Reports Second Quarter 2002 Financial Results

CUPERTINO, Calif., Jul 29, 2002 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended June 30, 2002.

(Photo: http://www.newscom.com/cgi-bin/prnh/20020717/DRRXLOGO)

DURECT's net loss for the three months ended June 30, 2002 was \$9.9 million or 21 cents per share, compared to \$21.0 million or 45 cents per share for the same period in 2001. DURECT's results for the three months ended June 30, 2002 included other non-cash charges for the amortization of intangible assets and stock-based compensation of \$820,000, compared to \$1.4 million for the same period in 2001. The Company's net loss for the three months ended June 30, 2001 included a one-time, non-cash charge of \$14.0 million for acquired in-process research and development associated with the acquisition of Southern BioSystems, Inc.

"We are pleased with the steady progress in our business. The recent announcement of the initiation of our pivotal Phase III program for our lead product in development, the CHRONOGESIC (sufentanil) Pain Therapy System is an exciting and important milestone for DURECT. We believe the CHRONOGESIC therapy, once approved, will be a significant improvement over currently available long-term pain therapies on the market today," stated Dr. Jim Brown, President and Chief Executive Officer of DURECT. "We also continue to make progress on our other internal development programs and we are happy to report that we have initiated enrollment of patients in a Phase I clinical study to investigate the delivery of cromolyn sodium for the treatment of asthma and allergic rhinitis using one of our proprietary biodegradable drug delivery platforms."

"We also continue to look for opportunities to collaborate with other biotech and pharmaceutical companies to develop and commercialize innovative pharmaceutical systems products utilizing our platform drug delivery technologies in the areas of chronic diseases," stated Dr. Felix Theeuwes, Chairman and Chief Scientific Officer of DURECT. "Earlier today we announced that we have entered into an agreement with Voyager Pharmaceutical Corporation for the development and commercialization of a Voyager patented product for the treatment of Alzheimer's disease. We are excited that Voyager has selected our DURIN technology for use in its proprietary treatment."

Research and development expenses were \$8.2 million in the three months ended June 30, 2002, compared to \$5.3 million for the same period in 2001. The increase was primarily attributable to expanded research and development activities, especially related to continued preparation for the company's pivotal Phase III clinical trials for its lead product, CHRONOGESIC, which commenced at the end of second quarter of 2002. The increase was also attributable to continued investments in the research and development of other pharmaceutical systems based on SABER and DURIN technologies and the hiring of additional research and development.

Selling, general and administrative expenses were \$2.4 million in the three

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months ended June 30, 2002, compared to \$2.2 million for the same period in 2001. The increase was primarily due to the modest expansion of corporate infrastructure to support the growth in all areas of DURECT's business.

At June 30, 2002, DURECT had cash, cash equivalents and investments of \$58.4 million, including \$2.9 million in restricted investments.

DURECT expects its net loss for the third quarter of 2002 to be in the range of \$11.0 million to \$11.5 million or 23 to 24 cents per share. DURECT's estimates include non-cash charges for the amortization of intangible assets and stock-based compensation of approximately \$800,000 for the third quarter of 2002.

DURECT Corporation (www.www.durect.com) is pioneering the development and commercialization of pharmaceutical systems for the treatment of chronic debilitating diseases and enabling biotechnology-based pharmaceutical products. DURECT's goal is to deliver the right drug to the right site in the right amount at the right time. DURECT's lead product in development, the CHRONOGESIC(TM) (sufentanil) Pain Therapy System is a 3-month product for the treatment of chronic pain. DURECT owns three proprietary drug delivery platform technologies, including the SABER(TM) Delivery System (a patented and versatile depot injectable useful for protein delivery), the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system) and the DURIN(TM) Biodegradable Implant (drug-loaded implant system).

NOTE: CHRONOGESIC(TM) is a trademark of DURECT Corporation. SABER(TM), MICRODUR(TM) and DURIN(TM) are trademarks of Southern BioSystems, Inc., a wholly owned subsidiary of DURECT Corporation. Other trademarks referred to belong to their respective owners.

The statements in this press release regarding DURECT's products in development, expected product benefits, product development and clinical trials plans and projected future financial results, are forward-looking statements involving risks and uncertainties that can 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 research, develop, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, timely enroll patients and clinical sites in connection with its clinical studies, effectively administer its clinical trials, manage its growth and expenses, finance its activities and operations, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in DURECT's Annual Report on Form 10-K for the fiscal year ended December 31, 2001 filed with the SEC on March 28, 2002, under the heading "Factors that may affect future results," and other periodic reports filed with the SEC.

CHRONOGESIC is under development by DURECT and has not been submitted or approved for commercialization by the US Food and Drug Administration or other health authorities.

> DURECT CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share amounts)

> > Three months ended

Six months ended

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	June 30,		June 30,	
	2002 (unaudited)	2001 (unaudited)		2001 (unaudited)
Revenue, net	\$1,772	\$1,687	\$3,396	\$3,086
Cost of goods sold (1)	785	974	1,564	1,585
Gross profit	987	713	1,832	1,501
Operating expenses: Research and develop Selling, general and	-	5,333	16,173	9,474
administrative Amortization of	2,441	2,157	4,764	4,035
intangible assets Stock-based	335	461	670	735
compensation (1) Acquired in-process research	468	919	1,037	1,854
and development		14,030		14,030
Total operating expenses	11,422	22,900	22,644	30,128
Loss from operations	(10,435)	(22,187)	(20,812)	(28,627)
Other income (expense): Interest income Interest expense Net other income	598 (78) 520	(84)	1,309 (161) 1,148	2,864 (145) 2,719
Net loss	\$(9,915)	\$(20 , 990)	\$(19,664)	\$(25,908)
Net loss per share, basic diluted Shares used in computing		\$(0.45)	\$(0.41)	\$(0.57)
basic and diluted net loss per share	48,076	46,325	47,929	45,726
(1) Stock-based compensat: related to the following				
Cost of goods sold Research and development Selling, general and administrative Total stock-based	\$17 330	\$65 613	\$46 724	\$87 1,294
	138	306	313	560
compensation	\$485	\$984	\$1,083	\$1,941

DURECT CORPORATION CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	June 30, 2002 (unaudited)	December 31, 2001 (1)
Assets Current assets: Cash, cash equivalents and short-term investments Inventories and other current assets	\$52,939 4,389	\$55,204 5,007
Total current assets	57,328	60,211
Property and equipment, net Intangible assets, net Long-term investments and other non-	12,886 9,507	13,136 10,178
current assets	5,497	21,418
Total assets	\$85,218	\$104,943
Liabilities and stockholders' equity Current liabilities: Accounts payable and accrued		
liabilities Long-term obligations, current	\$4,140	\$5,065
portion Total current liabilities	665 4,805	683 5,748
Long-term obligations, noncurrent portion	1,932	2,147
Stockholders' equity	78,481	97,048
Total liabilities and stockholders' equity	\$85,218	\$104,943

(1) Derived from audited financial statements.

SOURCE DURECT Corporation



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