DURECT Corporation Announces Third Quarter 2003 Financial Results

CUPERTINO, Calif., Nov. 6 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today its financial results for the three months ended September 30, 2003.

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

DURECT's net loss for the three months ended September 30, 2003 was $6.4 million or 13 cents per share, compared to $9.1 million or 19 cents per share for the same period in 2002. DURECT's results for the three months ended September 30, 2003 included non-cash charges for the amortization of intangible assets and stock-based compensation of $217,000, compared to $688,000 for the same period in 2002. Cash used in operating activities was $4.3 million for the three months ended September 30, 2003, compared to $6.0 million for the same period in 2002.

"With respect to our CHRONOGESIC(R) product, we are currently exploring additional mechanisms to prevent a premature shutdown of the system, and have already generated feasibility data relating to these mechanisms," stated Dr. James E. Brown, President and CEO of DURECT. "While we were disappointed with the delay in the restart of our clinical trials, we remain committed to bringing this product to commercialization. We believe that the market for CHRONOGESIC continues to grow and remains very attractive. Additionally, in previous clinical trials, patients using the CHRONOGESIC product showed an improvement in pain scores, exhibited reduced side effects and preferred CHRONOGESIC over their existing chronic pain medication. We are confident that our CHRONOGESIC therapy, once approved, will be a significant improvement over currently available long-term pain therapies on the market today."

Dr. Brown added, "We also continue to make significant progress in the development of our other products. Today, we are pleased to announce that we have completed the first study in humans of our post-operative pain relief depot product. This pain relief product is based on our patented SABER(TM) delivery technology and is intended to provide local analgesia following surgery for up to three days, which coincides with the period of the greatest need for post surgical pain control in most patients. We were very pleased with the good biocompatibility we observed with the SABER depot in this study. In addition, the results from the study showed that the extent of absorption of the drug was 100% and the rate of absorption of drug from the depot was continuous for three days as intended. These data are promising with respect to the development of our pain depot product and further increased our confidence in the capabilities of the SABER technology platform.

"Finally, we are also pleased to report on a significant milestone with respect to our collaboration with Pain Therapeutics using our SABER gel-cap technology to deliver certain opioid drugs. Pain Therapeutics recently announced a development program for a novel long-acting formulation of oxycodone that utilizes our SABER gel-caps, targeted to decrease the potential for oxycodone abuse."

Total revenues were $3.0 million for the three months ended September 30, 2003, compared to $1.8 million for the same period in 2002. The increase in total revenues was primarily attributable to higher collaborative research and development revenue recognized from DURECT's agreements with various strategic partners as the Company continued to make progress on the collaboration projects and higher net product sales from DURECT's product lines.

Research and development expenses were $5.4 million for the three months ended September 30, 2003, compared to $7.6 million for the same period in 2002. The decrease in the three months ended September 30, 2003 was primarily attributable to the lower development costs related to DURECT's lead product CHRONOGESIC, partially offset by a slight increase in research and development expenses under the Company's collaborative arrangements and for our post-operative pain product. DURECT incurred higher research and development costs related to our Phase III clinical trial for CHRONOGESIC in the same period in 2002. The decrease in the research and development expenses in the three months ended September 30, 2003 was also the result of lower personnel expenses due to the reduction in force in the fourth quarter of 2002.

Selling, general and administrative expenses were $2.1 million in the three months ended September 30, 2003, compared to $2.2 million for the same period in 2002. The decrease was primarily attributable to continued cost savings in the existing corporate infrastructure to support all areas of DURECT's business.

At September 30, 2003, DURECT had cash and investments of $92.0 million, including $3.3 million in restricted investments, compared with cash and investments of $86.7 million at June 30, 2003. This increase was primarily due to the net proceeds of approximately $9.5 million received in July 2003 from the sale of additional $10.0 million aggregate principal amount of convertible notes, offset by cash used in operating activities in the three months ended September 30, 2003. At September 30, 2003, DURECT had $60.0 million in aggregate principal amount of Convertible Notes due 2008.

DURECT expects its net loss for the fourth quarter of 2003 will range from $7.0 million to $7.5 million or 14 to 15 cents per share. DURECT's estimates include non-cash charges for the amortization of intangible assets and stock-based compensation of approximately $350,000 to $400,000 for the fourth quarter of 2003.

About DURECT Corporation

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. In addition to its rights to the CHRONOGESIC product, 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).

The statements in this press release regarding DURECT's products in development, product development plans and projected 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 complete the design, development, and manufacturing process development of its products, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, manage its growth and expenses, manage relationships with third parties, 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, 2002 filed with the SEC on March 14, 2003 and other periodic reports filed with the SEC under the heading "Factors that may affect future results."

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)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2003	2002	2003	2002
Product revenue, net	$1,723	$1,515	$4,945	$4,805
Collaborative research and development and other revenue	1,227	268	3,786	374
Total revenues	2,950	1,783	8,731	5,179
Operating expenses:				
Cost of revenues	711	706	1,840	2,224
Research and development	5,366	7,571	16,220	23,744
Selling, general and administrative	2,141	2,225	6,603	6,989
Amortization of intangible assets	339	335	1,009	1,005
Stock-based compensation(A)	(122)	353	(141)	1,436
Total operating expenses	8,435	11,190	25,531	35,398
Loss from operations	(5,485)	(9,407)	(16,800)	(30,219)
Other income (expense):				

Interest income	123	428	732	1,737
Interest expense	(1,068)	(71)	(1,371)	(232)
Net other income (expense)	(945)	357	(639)	1,505
Net loss	$(6,430)	$(9,050)	$(17,439)	$(28,714)
Net loss per share, basic and diluted	$(0.13)	$(0.19)	$(0.35)	$(0.60)
Shares used in computing basic and diluted net loss per share	50,624	48,161	50,347	48,006
(A) Stock-based compensation related to the following:				
Cost of revenues	$3	$15	$14	$61
Research and development	34	219	(225)	943
Selling, general and administrative	(159)	119	70	432
	$(122)	$353	$(141)	$1,436

DURECT CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEET
(in thousands)

	September 30, 2003 (unaudited)	December 31, 2002 (A)
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$65,348	$42,800
Inventories and other current assets	4,477	4,241
Total current assets	69,825	47,041
Property and equipment, net	9,602	11,625
Goodwill	6,399	4,716
Intangible assets, net	3,327	4,121
Long-term investments and other non-current assets	29,965	5,468
Total assets	$119,118	$72,971
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$5,788	$4,568
Long-term obligations, current portion	453	617
Total current liabilities	6,241	5,185
Long-term obligations, noncurrent portion	62,621	1,604
Stockholders' equity	50,256	66,182

Total liabilities and stockholders' equity	$119,118	$72,971

(A) Derived from audited financial statements.

SOURCE DURECT Corporation

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