DURECT Corporation Reports Third Quarter 2002 Financial Results

CUPERTINO, Calif., Nov. 12 /PRNewswire-FirstCall/ —
DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended September 30, 2002.

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

DURECT's net loss for the three months ended September 30, 2002 was $9.1 million or 19 cents per share, compared to $8.9 million or 19 cents per share for the same period in 2001. DURECT's results for the three months ended September 30, 2002 included non-cash charges for the amortization of intangible assets and stock-based compensation of $688,000, compared to $1.3 million for the same period in 2001.

"Yesterday we achieved a major milestone at DURECT with the agreement with Endo Pharmaceuticals to collaborate on the development and commercialization of our CHRONOGESIC(TM) product for the U.S. and Canada," stated Dr. James Brown, President and Chief Executive Officer of DURECT. "We selected Endo as our partner because of their strong commitment to be a focused leader in the pain field. They have built a team of sales and marketing executives with established track records for successfully launching new pharmaceutical products. We have developed a great relationship between the two organizations and are confident that together with Endo we will add substantial value for patients and shareholders of both our companies."

"Today we also announced that we amended our development and commercialization agreement with ALZA Corporation under which DURECT holds exclusive rights to develop, commercialize and manufacture products using ALZA's patented DUROS(R) technology in selected fields of use," stated Dr. Felix Theeuwes, Chairman and Chief Scientific Officer of DURECT. "Under the amended agreement, DURECT's maintenance of exclusivity in our licensed fields is no longer subject to minimum annual requirements for development spending or the number of products we have under development. These changes to the agreement align more closely the interests of DURECT and ALZA and further strengthen the collaboration between the two companies. We are focused on making progress on all of our development programs. We continue to look for opportunities to collaborate with other biotech and pharmaceutical companies to develop and commercialize innovative pharmaceutical system products utilizing our platform drug delivery technologies in the areas of chronic diseases."

Research and development expenses were $7.6 million in the three months ended September 30, 2002, compared to $7.2 million for the same period in 2001. The increase was primarily attributable to expanded research and development activities, especially related to initiation of the company's pivotal Phase III clinical trial for its lead product, CHRONOGESIC in June 2002. The clinical trials are temporarily on hold pending agreement between DURECT and the Food and Drug Administration (FDA) regarding additional monitoring and data collection. These protocol changes requested by the FDA were not in relation to any observed safety issue or adverse event.

Independent from the adjustments to the protocol, DURECT is implementing some necessary design and manufacturing enhancements to the CHRONOGESIC product. DURECT anticipates that the changes to the existing clinical protocol, and the implementation of these design and manufacturing enhancements, will delay the restart of clinical trials until the second half of 2003. The increase in research and development expenses was also attributable to continued research and development of other pharmaceutical systems based on SABER and DURIN technologies.

Selling, general and administrative expenses were $2.2 million in the three months ended September 30, 2002, compared to $2.3 million for the same period in 2001. The slight decrease was primarily due to cost efficiency achieved in existing corporate infrastructure.

At September 30, 2002, DURECT had cash, cash equivalents and investments of $52.0 million, including $2.9 million in restricted investments.

DURECT expects its net loss for the fourth quarter of 2002 to be in the range of $9.0 million to $9.5 million or 19 to 20 cents per share. DURECT's estimates include non-cash charges for the amortization of intangible assets and stock-based compensation of approximately $600,000 for the fourth quarter of 2002.

DURECT expects its net loss will range from $27.0 million to $29.0 million or 54 to 58 cents per share for the fiscal year of 2003. DURECT's estimates include non-cash charges for the amortization of intangible assets, stock-based compensation and depreciation of approximately $4.0 million for the year of 2003. Total cash burn for 2003 is expected to be in the range of $23.0 million to $25.0 million.

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 November 2001, DURECT completed a pilot phase III program for the CHRONOGESIC(TM) (sufentanil) Pain Therapy System, 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 and 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, 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, 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)

	Three months ended September 30,		Nine months ended September 30,	
	2002 (unaudited)	2001 (unaudited)	2002 (unaudited)	2001 (unaudited)
Revenue, net	$1,783	$1,841	$5,179	$4,928
Cost of goods sold (1)	721	963	2,285	2,548
Gross profit	1,062	878	2,894	2,380
Operating expenses:				
Research and development	7,571	7,206	23,744	16,680
Selling, general and administrative	2,225	2,305	6,989	6,339
Amortization of intangible assets	335	555	1,005	1,290
Stock-based compensation (1)	338	750	1,375	2,605
Acquired in-process research and development	--	--	--	14,030
Total operating expenses	10,469	10,816	33,113	40,944
Loss from operations	(9,407)	(9,938)	(30,219)	(38,564)
Other income (expense):				
Interest income	428	1,096	1,737	3,960
Interest expense	(71)	(92)	(232)	(238)
Net other income	357	1,004	1,505	3,722

Net loss	$(9,050)	$(8,934)	$(28,714)	$(34,842)
Net loss per share, basic and diluted	$(0.19)	$(0.19)	$(0.60)	$(0.76)
Shares used in computing basic and diluted net loss per share	48,161	46,906	48,006	46,120
(1) Stock-based compensation related to the following:				
Cost of goods sold	$15	$31	$61	$118
Research and development	219	503	943	1,798
Selling, general and administrative	119	247	432	807
Total stock-based compensation	$353	$781	$1,436	$2,723

DURECT CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	Sept. 30, 2002 (unaudited)	Dec. 31, 2001 (1)
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$45,511	$55,204
Inventories and other current assets	3,914	5,007
Total current assets	49,425	60,211
Property and equipment, net	12,242	13,136
Goodwill	4,716	4,716
Intangible assets, net	4,456	5,462

Long-term investments and other non-current assets	6,514	21,418
Total assets	$77,353	$104,943
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$5,116	$5,065
Long-term obligations, current portion	643	683
Total current liabilities	5,759	5,748
Long-term obligations, noncurrent portion	1,848	2,147
Stockholders' equity	69,746	97,048
Total liabilities and stockholders' equity	$77,353	$104,943

(1) Derived from audited financial statements.

SOURCE:
DURECT Corporation

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