DURECT Corporation Reports Second Quarter 2001 Financial Results

CUPERTINO, Calif., July 30 /PRNewswire/ —
DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended June 30, 2001.

The company's net loss attributable to common stockholders for the three months ended June 30, 2001 was $7.0 million or 15 cents per share (excluding a one-time, non-cash charge) compared to $5.2 million, or 65 cents per share, for the three months ended June 30, 2000. DURECT incurred 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. that was completed during the quarter. Including the one-time non-cash charge for acquired in-process research and development, the company's net loss was $21.0 million. DURECT's results for the period also include non-cash charges for the amortization of intangible assets and stock-based compensation of $1.4 million compared to $1.6 million for the same period in 2000.

"We are pleased with the company's progress over the quarter. We have completed our Phase II clinical trial for Chronogesic(TM) and completed construction of our commercial manufacturing facility. Each of these accomplishments represents a significant step towards initiating our Phase III clinical trial, and towards bringing our products to market. In addition, we received clearance for a special 510(k) pre-market notification with the FDA for our next generation ear delivery catheter. The cleared catheter is used by the Naval Medical Center San Diego as part of a blinded, placebo controlled study evaluating the use of gentamicin for the treatment of Meniere's disease," stated James E. Brown, CEO of DURECT. "We also announced our acquisition of Southern BioSystems. 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."

The increase in net loss in the second quarter of 2001 compared to the same quarter in 2000, excluding the one-time charge for acquired in-process research and development, was primarily due to increased research and development activity and selling, general and administrative expenses. The increase in research and development expenses was primarily attributable to the company's Phase II clinical trial for its lead product, Chronogesic(TM). The increase in selling, general and administrative expenses was primarily due to an increase in general and administrative personnel and related expenses necessary to support DURECT's growth. The increase in operating expenses was partially offset by increased interest income resulting from higher average outstanding cash and investment balances.

At June 30, 2001, the company had cash and investments of $94.2 million compared to $106.1 million at December 31, 2000.

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 CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEET
(in thousands)

	June 30, 2001 (unaudited)	December 31, 2000 (1)
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$68,715	$104,432
Inventories and other current assets	5,794	4,881
Total current assets	74,509	109,313
Property and equipment, net	10,527	4,472
Intangible assets, net	11,186	5,175
Long-term investments and other non- current assets	25,476	1,652
Total assets	$121,698	$120,612
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$4,947	$3,846
Other current liabilities	667	407
Total current liabilities	5,614	4,253
Other long term liabilities	2,498	1,105
Stockholders' equity	113,586	115,254
Total liabilities and stockholders' equity	$121,698	$120,612

(1) Derived from audited financial statements.

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

	Three months ended June 30,		Six months ended June 30,	
	2001 (unaudited)	2000 (unaudited)	2001 (unaudited)	2000 (unaudited)
Revenue, net	$1,687	$998	$3,086	$1,081
Cost of goods sold (1)	974	575	1,585	611
Gross profit	713	423	1,501	470
Operating expenses:				
Research and development	5,315	2,983	9,409	5,242
Research and development to related party	18	171	65	433
Selling, general and administrative	2,157	1,003	4,035	1,973
Amortization of intangible assets	461	233	735	302
Stock-based compensation (1)	919	1,367	1,854	2,499
Acquired in-process research and development	14,030	--	14,030	--
Total operating expenses	22,900	5,757	30,128	10,449
Loss from operations	(22,187)	(5,334)	(28,627)	(9,979)
Other income (expense):				
Interest income	1,281	540	2,864	828
Interest expense	(84)	(33)	(145)	(55)
Net other income	1,197	507	2,719	773
Net loss	(20,990)	(4,827)	(25,908)	(9,206)
Accretion of cumulative dividends on Series B convertible preferred stock	--	326	--	653
Net loss attributable to common stockholders	$(20,990)	$(5,153)	$(25,908)	$(9,859)
Net loss per common share, basic and diluted	$(0.45)	$(0.65)	$(0.57)	$(1.35)
Shares used in computing basic and diluted net loss per share	46,325	7,958	45,726	7,279

Pro forma net loss attributable to common stockholders excluding acquired in-process research & development	$(6,960)	$(11,878)
Pro forma net loss per share, basic and diluted excluding acquired in-process research & development	$(0.15)	$(0.26)
Shares used in computing pro forma net loss per share	46,325	45,726

(1) Stock-based compensation related to the following:

Cost of goods sold	$65	$21	$87	$21
Research and development	613	960	1,294	1,665
Selling, general and administrative	306	407	560	834
	$984	$1,388	$1,941	$2,520

The statements in this press release regarding DURECT's products in development, product development plans, or expected product benefits, 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, successfully complete clinical trials, obtain product and manufacturing approvals from regulatory agencies, and validate and qualify a manufacturing facility, 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 10-Q for the quarter ended April 30, 2001 filed with the SEC on May 11, 2001 and Annual Report on Form 10-K for the fiscal year ended December 31, 2000 filed with the SEC on March 30, 2001.

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