DURECT Corporation Announces Second Quarter 2004 Financial Results and Update on Its Development Programs

CUPERTINO, Calif., July 21 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended June 30, 2004 and an update on its development programs.

Our net loss for the three months ended June 30, 2004 was $7.4 million or 14 cents per share, compared to $5.1 million or 10 cents per share for the same period in 2003. Our results for the three months ended June 30, 2004 included non-cash charges for the amortization of intangible assets and stock-based compensation of $443,000, compared to $470,000 for the same period in 2003. Cash used in operating activities was $6.3 million for the three months ended June 30, 2004, compared to $3.6 million for the same period in 2003.

“Over the last three years, we have developed several robust and patent-protected platform technologies. Together with our collaborative partners where applicable, we have steadily advanced a pipeline based on these technologies including Remoxy(TM) (ORADUR(TM) oral oxycodone gel-cap), our SABER(TM)-based post-operative pain depot, and a DURIN-based Alzheimer’s disease treatment. These programs are either in the clinic or anticipated to enter the clinic by the end of this year,” stated James E., Brown, DVM, President and CEO of DURECT.

Dr. Brown added, “With regard to our CHRONOGESIC product, our plan had been to resume clinical trials by the end of 2004. After a series of promising results in vitro and in vivo with our most recent CHRONOGESIC system design, we had initiated the process of clinical manufacturing. Unfortunately, we have learned recently from an animal study that we have not yet solved the pre-mature shutdown problem (stop in the delivery of drug before the intended full duration of delivery). Therefore, based on this information, we will not be resuming clinical trials with our CHRONOGESIC product in 2004. We continue to work to address this issue in order to bring this product to market. We have made significant investments into CHRONOGESIC and our sufentanil infrastructure, and we plan to move forward with this investment.”

Dr. Brown continued, “DURECT has evolved as a company, with a breadth of technologies and a pipeline that we believe provides diversification to diminish development and commercial risk to build lasting shareholder value.”

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    First Half 2004 Developments

    CHRONOGESIC(R) (sufentanil) Pain Therapy Product
    -- We expect a delay in the resumption of the CHRONOGESIC clinical program
       previously anticipated to begin during the second half of 2004.

    Post-Operative Pain Depot
    -- We are preparing for a Phase II clinical trial for our post-operative
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pain relief depot product, anticipated to begin by the end of the year. Our post-operative pain relief depot product is a sustained release injectible using the patented SABER(TM) delivery system and bupivicaine designed to provide 2-3 days of post-surgical pain relief.

Remoxy(TM)

-- Our collaborative partner, Pain Therapeutics, Inc., recently announced positive Phase I pharmacokinetics and anti-abuse clinical results for Remoxy(TM), a novel long-acting oral formulation of oxycodone based on DURECT's ORADUR technology.
-- Pain Therapeutics has announced their plans to initiate Phase III studies for Remoxy by year-end.

Alzheimer's Disease Product

-- Significant progress has been made with our on-going collaboration with Voyager Pharmaceutical Corporation to develop a treatment for Alzheimer's disease using our DURIN(TM) drug delivery platform, which is the subject of several pending patent applications on a worldwide basis.
-- During the first half of 2004, Voyager completed an interim analysis of a proof of concept clinical study that supported advancing the DURIN-based product further in development.
-- Voyager plans to initiate Phase I clinical studies on the DURIN-based product by the end of the year.

Tinnitus (Inner Ear Disorders) Treatment

-- During the second quarter of 2004, we announced an exclusive license agreement for NeuroSystec Corporation to develop, market and sell products for the treatment of certain inner ear disorders including chronic tinnitus (ringing in the ears) based on our technologies. The first potential product is currently in pre-clinical development. We will receive certain milestone payments related to the development and commercialization of products under this agreement, as well royalties based on product sales.

Financial Results

Total revenues were $3.1 million for the three months ended June 30, 2004, compared to $3.2 million for the same period in 2003. The slight decrease in total revenues was primarily attributable to lower collaborative research and development revenue recognized from our strategic partners, offset by higher product sales from our product lines.

Research and development expenses were $6.0 million for the three months ended June 30, 2004, compared to $5.3 million for the same period in 2003. The increase in the three months ended June 30, 2004 was primarily attributable to the higher development costs related to CHRONOGESIC, our SABER post-operative pain depot product and other products under development.

Selling, general and administrative expenses were $2.3 million for the three months ended June 30, 2004, compared to $2.2 million for the same period in 2003. The increase was primarily attributable to higher expenses to comply with the Sarbanes-Oxley Act.

Interest income was $289,000 for the three months ended June 30, 2004, compared with $368,000 for the same period in 2003. The decrease in interest income was primarily the result of lower yields in our cash and investments in the three months ended June 30, 2004. Interest expense was $1.1 million for the three months ended June 30, 2004 as compared to $179,000 for the same period in 2003. The increase during the three months ended June 30, 2004 was primarily the result of the interest expense on the $60.0 million convertible notes we issued in June and July of 2003.

At June 30, 2004, we had cash and investments of $73.8 million, including $2.8 million in restricted investments, compared with cash and investments of $80.3 million at March 31, 2004.

We expect our net loss for the third quarter of 2004 will range from $7.0 million to $8.0 million or 14 to 16 cents per share. Our total cash burn for the fiscal year 2004 is expected to be in the range of $25.0 million to $27.0 million, which includes interest payments of $3.8 million for the convertible notes. We expect our net loss will range from $30.0 million to $32.0 million or 58 to 62 cents per share for the fiscal year of 2004.

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.

NOTE:

CHRONOGESIC(R), SABER(TM), ORADUR(TM) and DURIN(TM) are trademarks of DURECT Corporation. Remoxy(TM) is a trademark of Pain Therapeutics, Inc.

The statements in this press release regarding DURECT's products in development, product development plans, anticipated clinical trials 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, 2003 filed with the SEC on March 11, 2004, DURECT's Quarterly Report on Form 10-Q and other periodic reports filed with the SEC under the heading "Factors that may affect future results."

CHRONOGESIC, our post operative pain product, Remoxy and other products mentioned above are under development and have not been submitted or approved for commercialization by the US Food and Drug Administration or other health authorities.

DURECT CORPORATION

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

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Product revenue, net	$1,760	$1,715	$3,125	$3,222
Collaborative research and development and other revenue	1,320	1,485	3,340	2,559
Total revenues	3,080	3,200	6,465	5,781
Operating expenses:				
Cost of revenues	867	534	1,432	1,129
Research and development	6,040	5,282	11,449	10,854
Selling, general and administrative	2,339	2,219	4,563	4,462
Amortization of intangible assets	308	335	643	670
Stock-based compensation(1)	135	135	170	(19)
Total operating expenses	9,689	8,505	18,257	17,096
Loss from operations	(6,609)	(5,305)	(11,792)	(11,315)
Other income (expense):				
Interest income	289	368	593	609
Interest expense	(1,113)	(179)	(2,224)	(303)
Net other income (expense)	(824)	189	(1,631)	306
Net loss	$(7,433)	$(5,116)	$(13,423)	$(11,009)
Net loss per common share, basic and diluted	$(0.14)	$(0.10)	$(0.26)	$(0.22)
Shares used in computing basic and diluted net loss per share	51,396	50,294	51,260	50,209
(1) Stock-based compensation related to the following:				
Cost of revenues	$(2)	$3	$1	$11
Research and development	126	(23)	153	(259)
Selling, general and administrative	11	155	16	229
	$135	$135	$170	$(19)

DURECT CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	June 30, 2004	December 31, 2003 (1)
Assets		
Current assets:		
Cash and cash equivalents	$7,680	$21,203
Short-term investments	44,154	39,511
Accounts receivable, net	2,321	1,968
Inventories	1,914	1,902

Prepaid expenses and other current assets	1,340	1,480
Total current assets	57,409	66,064
Property and equipment, net	8,250	9,316
Goodwill	6,399	6,399
Intangible assets, net	2,351	2,994
Long-term investments	19,231	21,334
Restricted investments	2,782	3,119
Other non-current assets	2,929	3,181
Total assets	$99,351	$112,407
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, accrued liabilities and deferred revenue	$4,568	$4,551
Long-term obligations, current portion	463	463
Total current liabilities	5,031	5,014
Long-term obligations, noncurrent portion	62,146	62,278
Stockholders' equity	32,174	45,115
Total liabilities and stockholders' equity	$99,351	$112,407

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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