DURECT Corporation Announces First Quarter 2008 Financial Results

CUPERTINO, Calif., May 7 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended March 31, 2008. Total revenues were $6.4 million for the three months ended March 31, 2008, compared to $5.7 million for the same period in 2007. Net loss for the three months ended March 31, 2008 was $7.8 million, compared to a net loss of $8.8 million for the same period in 2007.

At March 31, 2008, DURECT had cash and investments of $53.4 million, compared to cash and investments of $62.0 million at December 31, 2007; these figures include restricted investments of $1.0 million at March 31, 2008 and at December 31, 2007.

“We continued to make progress towards our product development and corporate objectives during the first quarter,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We continued to advance our POSIDUR(TM), ELADUR(TM), TRANSDUR(TM)-Sufentanil and Remoxy(TM) programs, including support of Pain Therapeutics and King Pharmaceuticals in their preparation of the New Drug Application (NDA) filing for Remoxy(TM) as well as starting commercial production of certain key components that are integral to Remoxy. We also continued to be active in business development and strengthened our intellectual property position by acquiring additional patents that may be strategic to our business.”

Recent Highlights:

— Remoxy and other Abuse-Resistant Opioids. In the first quarter of 2008, DURECT continued to execute on its activities supporting the filing of the Remoxy NDA, and we began to manufacture commercial lots of certain key components that are included in Remoxy to meet the anticipated production requirements of King Pharmaceuticals. Our collaborator, Pain Therapeutics, has stated that they expect to file the NDA for Remoxy in the second quarter of 2008. In 2007, our collaborators King Pharmaceuticals and Pain Therapeutics announced that the pivotal Phase III trial for Remoxy successfully met its primary endpoint ($p<0.01$) that was prospectively defined by the U.S. Food and Drug Administration (FDA) during the Special Protocol Assessment (SPA) process. In addition, the study achieved statistically significant results in secondary endpoints such as Quality of Analgesia ($p<0.01$) and Global Assessment ($p<0.01$). No drug related safety issues were noted in the study.

Remoxy is an abuse-resistant, long-acting form of oxycodone based on our ORADUR(TM) technology intended for the treatment of chronic pain.

In addition to Remoxy, there are three other ORADUR-based abuse-resistant opioids covered in our collaboration with Pain Therapeutics. Pain Therapeutics has previously announced positive results from a Phase I clinical trial for one of these drug candidates, and Pain Therapeutics has stated that it expects to file an

Investigational New Drug application (IND) for a new abuse-resistant opioid in 2008.

— POSIDUR (SABER-Bupivacaine) Post-Operative Pain Relief Depot. We continue to be in dialogue with the FDA regarding the Phase III program. Upon completion of our discussions with the FDA, we plan to commence that program. As preparation for our Phase III program, we held an investigators meeting on April 25, 2008 with physicians attending the Arthroscopy Association of North America 2008 Annual Meeting in Washington. We have also recently conducted a survey, using independent consultants, among providers and insurers/payers to explore coverage and pricing for POSIDUR. In 2007, we announced positive results from a 122 patient Phase IIb clinical trial in which POSIDUR at a dose of 5 mL demonstrated statistically significant reductions in post-operative pain (by approximately 30% versus placebo) and in total consumption of supplemental opioid analgesic medications (approximately 3x less versus placebo) in patients undergoing inguinal hernia repair. A poster (http://www.www.durect.com/pdf/Posidur_AHS_2008_Poster.pdf) describing this study was presented at a meeting of the American Hernia Society on March 25, 2008.

POSIDUR is our post-operative pain relief depot that utilizes our patented SABER(TM) technology to deliver bupivacaine to provide up to three days of pain relief after surgery. POSIDUR is licensed to Nycomed for commercialization in Europe and select other countries, and DURECT has retained commercialization rights in the US, Canada and Asia.

— ELADUR (TRANSDUR(TM)-Bupivacaine). In the first quarter of 2008, we continued to conduct manufacturing scale-up and processing to secure Phase II and Phase III supplies, and to develop our clinical and regulatory strategy. We have previously announced positive results from a 60 patient Phase IIa clinical trial of patients suffering from post-herpetic neuralgia. In this study, ELADUR showed improved pain control versus placebo during the 3-day continuous treatment period. In addition, ELADUR appeared to be well tolerated overall, and patients treated with ELADUR and placebo exhibited similar safety profiles. A poster describing this study is being presented at the 27th Annual Scientific Meeting of the American Pain Society on May 8, 2008 and will be accessible shortly thereafter on our website (http://www.www.durect.com/wt/durect/page_name/Publications).

ELADUR is our proprietary transdermal patch intended to provide bupivacaine for a period of up to three days from a single application. We retain full commercial rights to this drug candidate.

— TRANSDUR-Sufentanil. Endo Pharmaceuticals, our licensee for commercialization in the US and Canada, is continuing to conduct Phase II studies with TRANSDUR-Sufentanil designed to evaluate the conversion of patients on oral opioids to TRANSDUR-Sufentanil.

TRANSDUR-Sufentanil is our proprietary transdermal patch intended to provide sufentanil to chronic pain sufferers for a period of up to seven days from a single application.

— Business Development Activities. We continue to be active on the business development front and have multiple late stage programs that are the subject of partnering discussions with third parties. These

include ELADUR (worldwide), TRANSDUR-Sufentanil (ex-US and Canada), POSIDUR (Asia), as well as various other programs, some of which are internally funded and some of which are funded by third parties under feasibility agreements.

— Expansion of patent portfolio. In the first quarter of 2008, we acquired from a third party a portfolio of worldwide patents relating to drug delivery technologies. This portfolio consists of approximately 49 issued and pending U.S. patents and patent applications as well as their international counterparts. Taken together with a similar portfolio acquisition in the fourth quarter of 2007, we have significantly increased our patent estate, which we believe will benefit our business by broadening our drug delivery technology base and strengthening our intellectual property position.

About DURECT Corporation

DURECT Corporation is an emerging specialty pharmaceutical company developing pharmaceutical systems based on its proprietary drug delivery platform technologies. The Company currently has a number of late-stage pharmaceutical products in development addressing large markets in pain management, with a number of research programs underway targeting chronic disease and other therapeutic areas. For more information, please visit http://www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding the anticipated filing of an NDA for Remoxy, our anticipated commencement of the Phase III program for POSIDUR, commercial production of Remoxy, our possible entry into future collaborative agreements as well as other statements regarding DURECT's products in development, product development plans, anticipated regulatory, clinical and development milestones and timing thereof, future clinical trial results, our business development intentions, the potential benefits to our business from our above referenced acquisition of patents and DURECT's emergence as a specialty pharmaceutical company 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 (and that of its third party collaborators where applicable) abilities to obtain approvals from regulatory agencies with respect to its development activities and products, design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of the referenced product candidates, consummate collaborative agreements relating to our product candidates and technologies, manufacture and commercialize the referenced product candidates, obtain marketplace acceptance of the referenced product candidates and manage and obtain capital to fund its growth, operations and expenses and the breadth, validity and enforceability of the acquired patents referenced above. Further information regarding these and other risks is included in DURECT's Form 10-K on March 13, 2008 under the heading "Risk Factors."

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

	Three Months Ended March 31,	
	2008	2007
Collaborative research and development and other revenue	$4,269	$3,458
Product revenue, net	2,169	2,268
Total revenues	6,438	5,726
Operating expenses:		
Cost of revenues (1)	822	860
Research and development (1)	9,634	10,352
Selling, general and administrative (1)	3,879	3,538
Amortization of intangible assets	11	7
Total operating expenses	14,346	14,757
Loss from operations	(7,908)	(9,031)
Other income (expense):		
Interest and other income	568	978
Interest expense	(455)	(714)
Net other income	113	264
Net loss	$(7,795)	$(8,767)
Net loss per share, basic and diluted	$(0.11)	$(0.13)
Shares used in computing basic and diluted net loss per share	74,113	69,231

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

Cost of revenues	$35	$34
Research and development	1,607	1,156
Selling, general and administrative	775	668
Total stock-based compensation	$2,417	$1,858

DURECT CORPORATION
CONDENSED BALANCE SHEET
(in thousands)

	As of March 31, 2008	As of December 31, 2007 (1)

	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$33,913	$37,589
Short-term investments	12,979	19,710
Accounts receivable (net of allowances of $60 and $49, respectively)	3,434	3,622
Inventories	2,437	1,963
Prepaid expenses and other current assets	1,824	1,904
Total current assets	54,587	64,788
Property and equipment, net	7,323	7,658
Goodwill	6,399	6,399
Intangible assets, net	194	180
Long-term investments	5,473	3,697
Restricted Investments	1,018	1,020
Other long-term assets	277	278
Total assets	$75,271	$84,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,210	$1,834
Accrued liabilities	4,946	5,499
Contract research liability	989	1,946
Deferred revenue, current portion	5,330	5,728
Convertible subordinated notes	23,599	23,599
Other short-term liabilities	841	482
Total current liabilities	36,915	39,088
Deferred revenue, non-current portion	7,958	9,268
Other long-term liabilities	1,044	1,083
Stockholders' equity	29,354	34,581
Total liabilities and stockholders' equity	$75,271	$84,020

(1) Derived from audited financial statements.

SOURCE DURECT Corporation
05/07/2008
CONTACT: Matthew J. Hogan, Chief Financial Officer of DURECT Corporation, +1-408-777-4936
Photo: NewsCom: http://www.newscom.com/cgi-bin/prnh/20020717/DRRXLOGO
AP Archive: http://photoarchive.ap.org
PRN Photo Desk, photodesk@prnewswire.com
Web site: http://www.www.durect.com