DURECT Corporation Announces Second Quarter 2008 Financial Results

CUPERTINO, Calif., Aug. 5 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended June 30, 2008. Total revenues were $6.3 million for the three months ended June 30, 2008, compared to $13.4 million for the same period in 2007. Net loss for the three months ended June 30, 2008 was $8.6 million, compared to a net loss of $0.5 million for the same period in 2007. Revenues and net loss were favorably impacted in the second quarter of 2007 by the achievement of an $8.0 million milestone under our Nycomed collaboration related to the clinical development of POSIDUR(TM).

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

At June 30, 2008, DURECT had cash and investments of $47.6 million, compared to cash and investments of $62.0 million at December 31, 2007; these figures include restricted investments of $1.0 million at June 30, 2008 and at December 31, 2007.

“The major event for us since the end of the first quarter was the filing of the New Drug Application (NDA) for Remoxy(TM), which represents the first NDA filing for a product candidate based on one of DURECT’s platform technologies,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We also continued to make progress in our dialogue with the FDA with respect to POSIDUR(TM) and, relevant to ELADUR(TM), received orphan drug designation for bupivacaine for post-herpetic neuralgia. In addition, our balance sheet has been strengthened by the elimination of all of our $23.6 million of convertible debt which was exchanged into common stock per the original terms of our indenture.”

Recent Highlights:

— Remoxy and other Abuse-Resistant Opioids. In June 2008, an NDA for Remoxy (ORADUR(TM)-based oxycodone) was submitted to the U.S. Food and Drug Administration (FDA). Pursuant to Prescription Drug User Fee Act (PDUFA) guidelines, the FDA is expected to determine whether to accept the NDA for filing within 90 days. At that time Pain Therapeutics (the NDA sponsor) will also learn if the NDA filing was granted priority review. A priority review designation is given to drugs that offer real advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes the FDA to review a NDA is reduced from 12 months to approximately 6 months. In addition, during the second quarter of 2008 DURECT made its first shipment of certain key components that are included in Remoxy to meet the production requirements of King Pharmaceuticals, which has rights to commercialize Remoxy upon approval.

Remoxy, an investigational drug, is a long acting oral formulation of oxycodone intended to treat moderate to severe pain. Based on DURECT's ORADUR technology, which is covered by issued and pending patent applications owned by DURECT, Remoxy is designed to resist common methods of prescription drug misuse and abuse.

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 they have stated that they expect to file an Investigational New Drug application (IND) for a new abuse-resistant opioid in 2008.

— POSIDUR (SABER(TM)-Bupivacaine) Post-Operative Pain Relief Depot. We continue to be in dialogue with the FDA regarding the Phase III program and believe we are making progress in defining our plans.

POSIDUR is our post-operative pain relief depot that utilizes our patented SABER 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). The FDA recently granted to DURECT orphan drug designation for bupivacaine for relief of persistent pain associated with post-herpetic neuralgia (PHN). Bupivacaine is the active pharmaceutical ingredient in ELADUR, DURECT's investigational transdermal drug patch. If ELADUR is the first bupivacaine product approved for PHN, under the 1983 Orphan Drug Act, ELADUR will receive seven years of market exclusivity following its approval by the FDA. In the second quarter of 2008, we continued to develop our clinical and regulatory strategy, and to conduct manufacturing scale-up and processing activities to secure Phase II and Phase III supplies.

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

— TRANSDUR-Sufentanil. Endo Pharmaceuticals, our licensee for commercialization of TRANSDUR-Sufentanil in the US and Canada, has stated that they expect to have data from a Phase II study by the end of 2008 and expect to hold an End-of-Phase II meeting with the FDA in late 2008 or early 2009.

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 in business development 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.

— Elimination of Convertible Notes. In June 2008, the remaining $23.6 million in 6.25% Convertible Notes were exchanged at their maturity date into

approximately 7.5 million shares of common stock, per the original terms of the indenture.

Earnings Conference Call

A live audio webcast of a conference call to discuss second quarter 2008 results will be broadcast live over the internet at 9:00 a.m. Eastern Time on August 6 and is available by accessing DURECT's homepage at http://www.www.durect.com and clicking "Investor Relations." If you are unable to participate during the live webcast, the call will be archived on DURECT's website under Audio Archive in the "Investor Relations" section.

About DURECT Corporation

DURECT is an emerging specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including Remoxy(TM), POSIDUR(TM), ELADUR(TM), and TRANSDUR(TM)-Sufentanil. DURECT's proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as abuse deterrence, improved convenience, compliance, efficacy and safety for small molecule and biologic drugs. For more information, please visit http://www.www.durect.com.

NOTE: POSIDUR(TM), SABER(TM), ORADUR(TM), TRANSDUR(TM), and ELADUR(TM) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. Remoxy, POSIDUR, ELADUR and TRANSDUR-Sufentanil are drug candidates under development and have not been approved for commercialization by the US Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release regarding the anticipated acceptance by the FDA of the NDA for Remoxy, the possibility of a priority review designation for the Remoxy NDA, the potential FDA approval or benefits of Remoxy, the anticipated Phase II trial data and End-of-Phase II meeting for TRANSDUR-Sufentanil, the potential of ELADUR to receive seven years of market exclusivity as an orphan drug, our possible entry into future collaborative agreements as well as other statements regarding DURECT's products in development, product development plans, product designs and benefits, anticipated regulatory, clinical and development milestones and timing thereof, future clinical trial results, our business development intentions, 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, avoid infringing patents held by other parties and securing and defending patents of our own, and manage and obtain capital to fund its growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q on May 8, 2008 under the heading "Risk Factors."

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

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Collaborative research and development and other revenue	$3,867	$11,408	$8,136	$14,866
Product revenue, net	2,436	2,024	4,605	4,292
Total revenues	6,303	13,432	12,741	19,158
Operating expenses:				
Cost of revenues (1)	982	778	1,804	1,638
Research and development (1)	9,898	9,630	19,532	19,982
Selling, general and administrative (1)	4,074	3,683	7,953	7,221
Amortization of intangible assets	12	8	23	15
Total operating expenses	14,966	14,099	29,312	28,856
Loss from operations	(8,663)	(667)	(16,571)	(9,698)

Other income (expense):				
Interest and other income	368	908	936	1,886
Interest and other expense	(304)	(720)	(759)	(1,434)
Net other income (expense)	64	188	177	452
Net loss	$(8,599)	$(479)	$(16,394)	$(9,246)
Net loss per share, basic and diluted	$(0.11)	$(0.01)	$(0.22)	$(0.13)
Shares used in computing basic and diluted net loss per share	75,430	69,364	74,772	69,298

(1) Includes stock-based compensation related to the following:

Cost of revenues	$31	$33	$66	$67
Research and development	1,360	1,097	2,967	2,253
Selling, general and administrative	674	555	1,449	1,223
Total stock-based compensation	$2,065	$1,685	$4,482	$3,543

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of June 30, 2008 (unaudited)	As of December 31, 2007 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$31,445	$37,589
Short-term investments	10,859	19,710
Accounts receivable (net of allowances of $47 and $49, respectively)	3,080	3,622
Inventories	2,653	1,963
Prepaid expenses and other current assets	1,723	1,904
Total current assets	49,760	64,788
Property and equipment, net	6,988	7,658
Goodwill	6,399	6,399
Intangible assets, net	182	180
Long-term investments	4,259	3,697
Restricted Investments	1,018	1,020
Other long-term assets	274	278
Total assets	$68,880	$84,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$749	$1,834
Accrued liabilities	6,812	5,499
Contract research liability	678	1,946
Deferred revenue, current portion	5,768	5,728

Convertible subordinated notes	-	23,599
Other short-term liabilities	425	482
Total current liabilities	14,432	39,088
Deferred revenue, non-current portion	6,649	9,268
Other long-term liabilities	982	1,083
Stockholders' equity	46,817	34,581
Total liabilities and stockholders' equity	$68,880	$84,020

(1) Derived from audited financial statements.

SOURCE DURECT Corporation
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