DURECT Corporation Announces Third Quarter 2007 Financial Results

CUPERTINO, Calif., Nov. 1 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended September 30, 2007. Total revenues were $4.9 million for the three months ended September 30, 2007, compared to $5.1 million for the same period in 2006. Net loss for the three months ended September 30, 2007 was $7.9 million, compared to a net loss of $8.6 million for the same period in 2006. Cash used in operating activities was $1.0 million for the three months ended September 30, 2007, compared to $3.1 million in the three months ended September 30, 2006. At September 30, 2007, we had cash and investments of $66.6 million, including $1.3 million in restricted investments, compared with cash and investments of $81.6 million at December 31, 2006. Cash flow in the third quarter of 2007 and the cash and investments balance at September 30, 2007 reflect the $8.0 million POSIDUR milestone payment from Nycomed that was recognized as revenue in the second quarter but was received in the third quarter.

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

“Our third quarter efforts focused on advancing our product development pipeline and improving our balance sheet. Toward that end, we recently reported positive results from our POSIDUR Phase IIb hernia study, King Pharmaceuticals and Pain Therapeutics completed enrollment in the Remoxy(TM) pivotal Phase III trial and Endo initiated their Phase II program with our TRANSDUR(TM)-Sufentanil patch,” stated James E. Brown, D.V.M., President and CEO of DURECT. “In addition, we took proactive steps to generate early conversions of our convertible notes to decrease our outstanding debt and to meter out the issuance of the underlying shares.”

Recent Company Highlights:

* POSIDUR. In July 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. This Phase IIb trial was designed to be the study upon which we and our collaborator Nycomed would base our decision for advancing POSIDUR into Phase III clinical trials. These successful results triggered an $8 million milestone payment by Nycomed to DURECT under the parties’ collaborative agreement. We have held an end-of-Phase II meeting with the U.S. Food & Drug Administration (FDA) and are in dialogue with the FDA regarding the Phase III program. Hospira, our manufacturer of POSIDUR, has produced supplies for ICH stability, validation and Phase III clinical trials.

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.

* Remoxy. According to our licensee, Pain Therapeutics, and its sublicensee, King Pharmaceuticals, the Remoxy Phase III pivotal study is fully enrolled and top-line results of this study are expected in the fourth quarter of 2007. This pivotal Phase III trial is being conducted in accordance with a Special Protocol Assessment (SPA) with the FDA.

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

* TRANSDUR(TM)-Sufentanil. According to its public disclosures, Endo Pharmaceuticals, our licensee for commercialization in the US and Canada, commenced its Phase II program in June 2007.

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

* ELADUR(TM) (TRANSDUR-Bupivacaine). We have completed enrollment of patients and expect to report results in 2007 from a Phase IIa trial designed to assess safety as well as the magnitude, duration and characteristics of analgesic activity of ELADUR in approximately 50 patients with Post-Herpetic Neuralgia (PHN).

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

* Reduction in Convertible Notes. We reduced the balance of our outstanding convertible notes from $37.3 million at June 30, 2007 to $23.6 million as of October 31, 2007 ($33.1 million at September 30, 2007) by paying a small premium over the future interest payments due on these notes in order to induce early conversion.

* Inclusion in New NASDAQ(R) Index. Effective September 25, 2007, we were selected as an inaugural member in the NASDAQ NeuroInsights(R) Neurotech Index (ticker: NERV). The Neurotech Index tracks the stock performance of 32 companies which meet certain minimum market criteria and were identified by NeuroInsights as being significantly involved in researching, developing, manufacturing and marketing pharmaceuticals, biologics, medical devices and diagnostics for the brain and nervous system.

Earnings Conference Call

A live audio webcast of a conference call to discuss third quarter 2007 results will be broadcast live over the internet at 4:30 p.m. Eastern Time and is available by accessing DURECT’s homepage at 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 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 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.

DURECT Forward-Looking Statement

The statements in this press release regarding our products in development, product development plans, anticipated data announcements from the ELADUR Phase IIa trial and the Remoxy pivotal Phase III trial, discussions with the FDA and other anticipated regulatory, clinical and development milestones and timing thereof, future clinical trial results and our intended 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, our (and that of our third party collaborators where applicable) abilities to design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of the product candidate, obtain product and manufacturing approvals from regulatory agencies, manufacture and commercialize the product candidate and manage and obtain capital to fund our growth, operations and expenses. Further information regarding these and other risks is included in our Form 10-Q filed on August 8, 2007 under the heading “Risk Factors.”

DURECT CORPORATION

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

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Collaborative research and development revenue	$2,992	$3,158	$9,858	$10,264
Milestone revenue	-	-	8,000	-
Product revenue, net	1,940	1,976	6,232	6,189
Total revenues	4,932	5,134	24,090	16,453
Operating expenses:				
Cost of revenues (1)	780	666	2,418	2,265
Research and development (1)	8,858	9,930	28,840	25,643
Selling, general and administrative (1)	3,135	3,346	10,356	9,540

Amortization of intangible assets	8	22	23	416
Total operating expenses	12,781	13,964	41,637	37,864
Loss from operations	(7,849)	(8,830)	(17,547)	(21,411)
Other income (expense):				
Interest and other income	906	957	2,792	2,841
Interest expense	(716)	(710)	(2,150)	(2,719)
Debt conversion expense	(223)	-	(223)	(2,287)
Net other income (expense)	(33)	247	419	(2,165)
Net loss	$(7,882)	$(8,583)	$(17,128)	$(23,576)
Net loss per share, basic and diluted	$(0.11)	$(0.12)	$(0.25)	$(0.36)
Shares used in computing basic and diluted net loss per share	69,655	68,688	69,414	64,943

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

Cost of revenues	31	$20	$98	$47
Research and development	1,038	774	3,291	2,084
Selling, general and administrative	497	368	1,720	1,011
Total stock-based compensation	$1,566	$1,162	$5,109	$3,142

DURECT CORPORATION
Condensed Balance Sheet
(in thousands, except per share amounts)

	As of September 30, 2007 (unaudited)	As of December 31, 2006 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$36,030	$41,554
Short-term investments	27,314	28,297
Accounts receivable	5,437	2,152
Inventories	2,027	2,052
Prepaid expenses and other current assets	1,989	1,744
Total current assets	72,797	75,799
Property and equipment, net	7,918	7,451
Goodwill	6,399	6,399

Intangible assets, net	88	111
Long-term investments	1,983	10,472
Restricted Investments	1,283	1,284
Other non-current assets	280	969
Total assets	$90,748	$102,485
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$606	$864
Accrued liabilities	7,051	4,522
Contract research liability	1,536	1,624
Interest payable on convertible notes	604	97
Deferred revenue, current portion	5,239	5,348
Equipment financing obligations, current portion	37	34
Bonds payable, current portion	210	210
Other short-term liabilities	149	-
Convertible subordinated notes due 2008	33,145	-
Total current liabilities	48,577	12,699
Bond payable and equipment financing obligations, noncurrent portion	578	606
Convertible subordinated notes due 2008	-	37,337
Deferred revenue, noncurrent portion	10,578	14,507
Other long-term liabilities	780	304
Stockholders' equity	30,235	37,032
Total liabilities and stockholders' equity	$90,748	$102,485

(1) Derived from audited financial statements

SOURCE DURECT Corporation
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