DURECT Corporation Announces Third Quarter 2008 Financial Results

CUPERTINO, Calif., Nov. 3 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended September 30, 2008. Total revenues were $6.6 million for the three months ended September 30, 2008, compared to $4.9 million for the same period in 2007. Net loss for the three months ended September 30, 2008 was $9.2 million, compared to a net loss of $7.9 million for the same period in 2007.

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

At September 30, 2008, we had cash and investments of $38.9 million, compared to cash and investments of $62.0 million at December 31, 2007; these figures include restricted investments of $1.0 million at September 30, 2008 and at December 31, 2007.

Based on our financial results in the first three quarters of 2008, the receipt of a $20 million upfront license fee from Alpharma in the fourth quarter of 2008 and a review of projections for the remainder of 2008, we are now revising our financial guidance for cash burn in 2008 from $32-36 million to approximately $10-12 million. Assuming that none of the other business development opportunities that we are currently pursuing close this year, we anticipate ending 2008 with more than $50 million in cash and investments.

“The first major event for us since the end of the second quarter was the granting of Priority Review status by the FDA of the New Drug Application (NDA) for REMOXY(R), 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. “The second major event for us was the establishment of a collaboration with Alpharma to develop and commercialize our ELADUR(TM) bupivacaine pain patch. We believe that licensing of this program to Alpharma, a company with proven development and commercialization capabilities, will benefit the program, and has also enabled us to substantially lower our cash burn rate for 2008 and strengthen our financial resources.”

Recent Highlights:

— REMOXY and other Abuse-Resistant Opioids. On June 10, 2008, an NDA for REMOXY (ORADUR(R)-based oxycodone) was submitted to the U.S. Food and Drug Administration (FDA). In August, this NDA filing was accepted and granted Priority Review by the FDA. The FDA typically grants Priority Review to drug candidates that have the potential to demonstrate significant improvements compared to marketed products. The FDA goal for completing review of a drug with Priority Review is six months from the date the application was submitted (i.e., December 10, 2008). REMOXY will be the subject of an FDA public advisory committee meeting scheduled for November 13, 2008.

REMOXY, an investigational drug, is a long acting oral formulation of oxycodone intended to treat moderate to severe pain. Based on DURECT’s

ORADUR(R) technology, which is covered by issued and pending patents owned by us, 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 with one of these drug candidates, and has stated that it commenced a Phase I clinical study with a third abuse-resistant opioid drug candidate in August 2008.

— POSIDUR(TM) (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 that program. In parallel with these discussions, we and our European collaborator, Nycomed, continue to advance development of this drug candidate. As one element in advancing the program, because an orthopedic surgical model will be part of our proposed studies for regulatory approval, we are commencing a 60-patient Phase IIb study in Australia using a 5 mL dose in shoulder surgery intended to allow us to confirm aspects of our clinical study design and conduct. Additionally, Nycomed is commencing Phase IIb studies in surgical models in Europe. These studies will contribute to the total number of patient exposures that will ultimately be required by the FDA and the European Medicines Agency (EMEA) as part of the product approval process in the U.S. and Europe.

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 we have retained commercialization rights in the US, Canada and Asia.

— ELADUR (TRANSDUR(TM)-Bupivacaine). In September 2008, we entered into a development and license agreement with Alpharma Ireland Ltd., an affiliate of Alpharma, Inc., granting such party the exclusive worldwide rights to develop and commercialize ELADUR. Alpharma, Inc. is a global specialty pharmaceutical company with a growing branded franchise in the U.S. pain market.

This Agreement became effective in October 2008 after passing clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Under this agreement, Alpharma paid us an upfront license fee of $20 million in the fourth quarter of 2008, with possible additional payments of up to $93 million upon the achievement of predefined development and regulatory milestones spread over multiple clinical indications and geographical territories as well as possible additional payments of up to $150 million in sales based milestones. If ELADUR is commercialized, DURECT would also receive royalties on product sales. Alpharma will control and fund the further development of the program.

ELADUR is our proprietary transdermal patch intended to deliver bupivacaine for a period of up to three days from a single application.

— 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 early 2009.

TRANSDUR-Sufentanil is our proprietary transdermal patch intended to deliver 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 programs that are the subject of partnering discussions with third parties.

Earnings Conference Call

A live audio webcast of a conference call to discuss third quarter 2008 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on November 3 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(R), 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(R), 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 DURECT's future cash balances and other financial results, the potential FDA approval or benefits of REMOXY, the planned and potential Phase IIb and Phase III trials of POSIDUR, anticipated trials and other requirements for regulatory approval of POSIDUR, potential payments from Alpharma for development and commercialization of ELADUR, the anticipated Phase II trial data and End-of-Phase II meeting for TRANSDUR-Sufentanil, 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 August 8, 2008 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,	
	2008	2007	2008	2007
Collaborative research and development and other revenue	$4,341	$2,992	$12,477	$17,858
Product revenue, net	2,293	1,940	6,898	6,232
Total revenues	6,634	4,932	19,375	24,090
Operating expenses:				
Cost of revenues (1)	870	780	2,674	2,418
Research and development (1)	11,423	8,858	30,955	28,840
Selling, general and administrative (1)	3,825	3,135	11,778	10,356
Amortization of intangible assets	12	8	35	23
Total operating expenses	16,130	12,781	45,442	41,637
Loss from operations	(9,496)	(7,849)	(26,067)	(17,547)
Other income (expense):				
Interest and other income	349	906	1,285	2,792
Interest and other expense	(14)	(716)	(773)	(2,150)
Debt conversion expense	-	(223)	-	(223)
Net other income (expense)	335	(33)	512	419
Net loss	$(9,161)	$(7,882)	$(25,555)	$(17,128)
Net loss per share, basic and diluted	$(0.11)	$(0.11)	$(0.33)	$(0.25)

Shares used in computing basic and

diluted net loss per share	81,779	69,655	77,124	69,414

(1) Includes stock-based

compensation related to the

following:

Cost of revenues	$44	$31	$110	$98
Research and development	1,300	1,038	4,267	3,291
Selling, general and administrative	619	497	2,068	1,720
Total stock-based compensation	$1,963	$1,566	$6,445	$5,109

DURECT CORPORATION
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(unaudited)

	As of September 30, 2008 (unaudited)	As of December 31, 2007 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$23,085	$37,589
Short-term investments	13,452	19,710
Accounts receivable (net of allowances of $120 and $49, respectively)	3,773	3,622
Inventories	2,830	1,963
Prepaid expenses and other current assets	1,380	1,904
Total current assets	44,520	64,788
Property and equipment, net	6,484	7,658
Goodwill	6,399	6,399
Intangible assets, net	170	180
Long-term investments	1,334	3,697
Restricted Investments	1,046	1,020
Other long-term assets	278	278
Total assets	$60,231	$84,020

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	$754	$1,834
Accrued liabilities	6,226	5,499
Contract research liability	871	1,946
Deferred revenue, current portion	6,034	5,728
Convertible subordinated notes	-	23,599
Other short-term liabilities	425	482
Total current liabilities	14,310	39,088

Deferred revenue, non-current portion 5,339 9,268

Other long-term liabilities	934	1,083
Stockholders' equity	39,648	34,581

Total liabilities and stockholders' equity $60,231 $84,020

(1) Derived from audited financial statements.

SOURCE DURECT Corporation
11/03/2008
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