DURECT Corporation Announces First Quarter 2009 Financial Results

CUPERTINO, Calif., May 6 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended March 31, 2009. Total revenues were $6.2 million for the three months ended March 31, 2009, compared to $6.4 million for the same period in 2008. Net loss for the three months ended March 31, 2009 was $8.7 million, compared to a net loss of $7.8 million for the same period in 2008.

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

At March 31, 2009, DURECT had cash and investments of $47.0 million, compared to cash and investments of $52.7 million at December 31, 2008; these figures include restricted investments of $0.8 million at March 31, 2009 and $1.0 million at December 31, 2008.

“The most significant events for DURECT during the first quarter were interactions with the U.S. Food & Drug Administration (FDA),” stated James E. Brown, D.V.M., President and CEO of DURECT. “A successful end-of-Phase II meeting with the FDA was conducted for TRANSDUR(TM)-Sufentanil, and we also recently received FDA feedback on our POSIDUR program, enabling us to construct our Phase III development plans. In addition, we are awaiting a mid-year meeting by King Pharmaceuticals with the FDA to clarify the status of the REMOXY(R) New Drug Application (NDA).”

Recent Highlights:

— Remoxy. Pain Therapeutics, our licensee, received a Complete Response Letter from the FDA in December 2008 indicating that the NDA is not approved in its present form. According to Pain Therapeutics, the FDA indicated that additional non-clinical data will be required to support the approval of REMOXY but the FDA has not requested or recommended additional clinical efficacy studies prior to approval. Our understanding is that Pain Therapeutics and its commercialization collaborator, King Pharmaceuticals, and their outside technical advisors have been evaluating the FDA Complete Response Letter and there are plans to meet with the FDA in mid-2009, which should provide our collaborators with a more reliable context with which to make projections about REMOXY.

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 patents and pending patent applications owned by us, REMOXY is designed to resist common methods of prescription drug misuse and abuse.

— POSIDUR(TM) (SABER(TM)-Bupivacaine). We have recently received detailed feedback from the FDA on our proposed Phase III program. We are pursuing a target label for POSIDUR that would allow POSIDUR to be used for a broad range of surgeries. Based on FDA feedback, in contrast to the two pivotal efficacy studies that we had previously

planned, we now anticipate conducting one pivotal efficacy study and several other supportive clinical studies in additional surgical models to provide greater definition for the settings in which the product should be used and to support our target label. We currently expect that the total number of patient exposures that we will submit to the FDA in an NDA will be approximately 700-800. Under our current development program, approximately 300 human subjects have been exposed to POSIDUR. Assuming the program progresses as we expect, we anticipate that the Phase III program should take approximately two years from initiation to NDA filing. To review the major planned activities for POSIDUR in 2009:

— We expect to have data from our approximately 60 patient Phase IIb clinical study in shoulder surgery this year.

— We plan to conduct a thorough QTc (tQTc) study in 2009. A tQTc study is a cardiac safety test increasingly recommended by the FDA. To date, we have not observed any differences in cardiovascular or central nervous system side effects between the roughly 300 patients dosed to date with POSIDUR versus approximately 150 placebo patients.

— Nycomed is conducting a Phase IIb study in hysterectomy patients and a Phase IIb study in shoulder surgery patients beginning in 2009. Those studies will be conducted in a different manner than U.S. studies and will be suitable for European regulatory approval purposes. We anticipate that these studies will provide data from an additional surgical model (hysterectomy) and will add to our safety database.

— Lastly, we are in discussions with various parties about licensing development and commercialization rights to POSIDUR in the U.S., Canada and Asia.

POSIDUR is our investigational 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(TM) (TRANSDUR(TM)-Bupivacaine). In October 2008, worldwide rights to this program were licensed to Alpharma, which was acquired by King Pharmaceuticals in December 2008. Our main activities since that time have involved interacting with the King team on the program such that specific decisions can be made with respect to the clinical program.

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

— TRANSDUR-Sufentanil. A 74 patient Phase IIb clinical trial of chronic pain patients using TRANSDUR-Sufentanil was completed during 2008 and described by us in the first quarter of 2009. In this trial, all of the primary and secondary objectives were met by showing patients could be successfully converted from oral opioids such as OxyContin(R) and from fentanyl patches such as Duragesic(R) to TRANSDUR-Sufentanil, while also showing a reduction in pain scores on our therapy. A successful end-of Phase II meeting was held with the FDA in February 2009. As a result of that meeting, we believe we understand the anticipated

regulatory pathway for the Phase III program and approval, which we expect will follow a 505(b)2 pathway as discussed with FDA. Effective August 26, 2009, we will receive back from Endo Pharmaceuticals the rights to develop and commercialize TRANSDUR-Sufentanil in the U.S. and Canada. We are in active discussions with several potential partners regarding licensing of the program.

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.

— Other Business Matters. In an effort to conserve cash during the current adverse economic environment, in March we implemented a headcount reduction of 41 positions. This action affected most functional groups, but we believe this should not affect our key corporate goals for the year. Our current headcount is approximately 25% lower than at the start of the year.

Earnings Conference Call

A live audio webcast of a conference call to discuss first quarter 2009 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on May 6 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 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 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 our possible licensing of development and commercialization rights to POSIDUR and TRANSDUR-Sufentanil to third parties, our collaborators' anticipated meeting with the FDA regarding REMOXY, our intended dose, target label and anticipated total patient exposures, our and Nycomed's clinical development plans including tQTc and other clinical studies, potential timing of completion of our Phase IIb clinical trial and Phase III program for POSIDUR and potential agreements with third parties about licensing and development rights to our product candidates 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,

failure of our clinical trials to produce intended results, possible adverse events associated with the use of our drug candidates, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of our drug candidates, DURECT's (and that of its third party collaborators where applicable) difficulty or failure 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 secure and defend 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-K filed on March 10, 2009 under the heading "Risk Factors."

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

	Three months ended March 31,	
	2009	2008
Collaborative research and development revenue	$3,745	$4,269
Product revenue, net	2,415	2,169
Total revenues	6,160	6,438
Operating expenses:		
Cost of revenues (1)	824	822
Research and development (1)	9,903	9,634
Selling, general and administrative (1)	4,257	3,890
Total operating expenses	14,984	14,346
Loss from operations	(8,824)	(7,908)
Other income (expense):		
Interest and other		

income	179	568
Interest expense	(11)	(455)
Net other income	168	113
Net loss	$(8,656)	$(7,795)
Net loss per share, basic and diluted	$(0.11)	$(0.11)
Shares used in computing basic and diluted net loss per share	82,023	74,113

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

Cost of revenues	$78	$35
Research and development	2,281	1,607
Selling, general and administrative	1,171	775
Total stock-based compensation	$3,530	$2,417

DURECT CORPORATION
Condensed Balance Sheet
(in thousands)

	As of March 31, 2009 (unaudited)	As of December 31, 2008 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$23,463	$29,445
Short-term investments	18,191	20,836
Short-term restricted investments	371	624
Accounts receivable	3,392	4,055
Inventories	2,639	3,474
Prepaid expenses and other		

current assets	3,153	1,850
Total current assets	51,209	60,284
Property and equipment, net	5,435	5,971
Goodwill	6,399	6,399
Intangible assets, net	145	157
Long-term investments	4,520	1,362
Long-term restricted Investments	429	425
Other long-term assets	270	276
Total assets	$68,407	$74,874
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$712	$1,018
Accrued liabilities	4,785	5,204
Contract research liability	645	995
Deferred revenue, current portion	8,826	9,235
Other short-term liabilities	408	431
Total current liabilities	15,376	16,883
Deferred revenue, noncurrent portion	19,903	19,771
Other long-term liabilities	667	656
Stockholders' equity	32,461	37,564
Total liabilities and stockholders' equity	$68,407	$74,874

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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