DURECT Corporation Announces Second Quarter 2010 Financial Results

CUPERTINO, Calif., Aug 04, 2010 /PRNewswire via COMTEX/ —

DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended June 30, 2010. Total revenues were $7.3 million for the three months ended June 30, 2010 compared to $4.9 million for the three months ended June 30, 2009. Net loss for the three months ended June 30, 2010 was $6.3 million, compared to a net loss of $7.5 million for the same period in 2009.

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At June 30, 2010, we had cash and investments of $57.2 million, compared to cash and investments of $41.6 million at December 31, 2009.

“The key event in the second quarter was our entry into a strategic collaboration with Hospira covering the development and commercialization of POSIDUR(TM) in the U.S. and Canada,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We continue to advance our pipeline of product candidates. BESST, our pivotal U.S. Phase III clinical study for POSIDUR(TM), continued enrollment during the quarter. King Pharmaceuticals is preparing the NDA resubmission for REMOXY(R) by year-end and initiated a Phase IIb clinical study of ELADUR(TM) in chronic low back pain during the second quarter. Lastly, we recently commenced a Phase I clinical trial in our ORADUR(R)-ADHD program.”

Business Highlights:

-- REMOXY. In July 2009, King met with the FDA to discuss the Complete Response Letter received in December 2008 regarding the REMOXY NDA. According to King, it anticipates that in the fourth quarter of 2010 it will resubmit the NDA for REMOXY intended to address all FDA comments in the Complete Response Letter.

REMOXY, an investigational drug, is a unique long acting oral formulation of oxycodone intended to treat moderate to severe pain. Based on DURECT's ORADUR 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 (SABER(TM)-Bupivacaine) Post-Operative Pain Relief Depot. In June 2010, we entered into an agreement with Hospira, Inc. covering the development and commercialization of POSIDUR in the U.S. and Canada. Under terms of the agreement, Hospira made an upfront payment to us of $27.5 million, with the potential for up to an additional $185 million in performance based milestone payments based on the successful development, approval and commercialization of POSIDUR. For the U.S. and Canada, the two companies will jointly direct and equally fund the remaining development costs for POSIDUR, while Hospira will have exclusive

commercialization rights with sole funding responsibility. In addition, if commercialized, Hospira will pay DURECT a royalty on product sales.

In the second quarter of 2010, we continued to enroll patients in our U.S. pivotal Phase III clinical study known as BESST (Bupivacaine Effectiveness and Safety in SABER Trial). We expect to complete enrollment of BESST, comprising approximately 300 patients, in the first half of 2011.

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 Hospira for commercialization in the U.S. and Canada, and to Nycomed for commercialization in Europe and other defined countries. We have retained commercialization rights in Japan and all other countries not subject to the Nycomed and Hospira licenses.

ELADUR (TRANSDUR(TM)-Bupivacaine). In October 2008, worldwide rights to this program were licensed to Alpharma, which was acquired by King Pharmaceuticals in December 2008. In April 2010, King Pharmaceuticals initiated a Phase IIb trial evaluating the safety and efficacy of ELADUR in patients with chronic low back pain. King expects to enroll approximately 260 patients in this study.

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

TRANSDUR-Sufentanil. In February 2009, a successful end-of-Phase II meeting with the FDA was conducted for this program outlining a potential regulatory pathway for the Phase III program and NDA submission. During 2009, we transitioned the program back to our control. We are in discussions with potential partners regarding licensing development and commercialization rights to this program to which we hold worldwide rights.

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.

ORADUR-ADHD Program. In July 2010, we commenced a Phase I clinical trial in this program with multiple formulations. ORADUR-ADHD applies our proprietary ORADUR technology to a leading active pharmaceutical ingredient for the treatment of attention deficit disorder (ADHD). Under an agreement with Orient Pharma, we are collaborating to perform a clinical development program through a Phase II study intended to produce a data package that will support later stage development of the drug candidate and subsequent licensing by DURECT. We are

responsible for formulation and study design of the pre-defined
-- clinical program, which Orient Pharma will fund and execute.

Earnings Conference Call

A live audio webcast of a conference call to discuss second quarter 2010 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on August 4 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, POSIDUR, ELADUR, and TRANSDUR-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), ELADUR(TM), and DURIN(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 U.S. Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release regarding the anticipated resubmission of the REMOXY NDA, our U.S. pivotal Phase III clinical trial (BESST) for POSIDUR including the anticipated timing of completion of the trial and patient enrollment, potential milestone payments and royalties receivable from Hospira, Phase IIb trial for ELADUR including anticipated patient enrollment numbers and timing thereof, our intention to enter into collaborations with respect to TRANSDUR-Sufentanil and our ORADUR-ADHD Phase I trial, the potential benefits and uses of our drug 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, delays and additional costs due to requirements imposed by regulatory agencies on our drug candidates, unexpected results and adverse events from clinical trials for our drug candidates, our failure to achieve the performance milestones or commercial sales that trigger the referenced payments or royalties under our collaborative agreements, our (and that of our third party collaborators where applicable) difficulty or failure to obtain approvals from regulatory agencies with respect to development activities and products, design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of the referenced drug candidates, consummate collaborative agreements relating to our drug candidates and technologies, manufacture and commercialize the referenced drug candidates, obtain marketplace acceptance of the referenced drug candidates, avoid infringing patents held by other parties and secure and defend patents of our own, and manage and obtain capital to fund our growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q on May 10, 2010 under the heading "Risk Factors."

DURECT CORPORATION

STATEMENT OF OPERATIONS DATA
(in thousands, except per share amounts)
(unaudited)

	Three months ended June 30,

	2010	2009
Collaborative research and development and other revenue	$4,657	$2,606
Product revenue, net	2,656	2,271
Total revenues	7,313	4,877
Operating expenses:		
Cost of product revenues (1)	861	837
Research and development (1)	9,204	7,866
Selling, general and administrative (1)	3,584	3,777
Total operating expenses	13,649	12,480
Loss from operations	(6,336)	(7,603)
Other income (expense):		
Interest and other income	48	106
Interest and other expense	(21)	(11)
Net other income	27	95
Net loss	$(6,309)	$(7,508)
Net loss per share, basic and diluted	$(0.07)	$(0.09)
Shares used in computing basic and diluted net loss per share	86,845	82,138

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

Cost of product revenues	$86	$117
Research and development	1,290	1,327
Selling, general and administrative	663	864
Total stock-based compensation	$2,039	$2,308

	Six months ended June 30,	
	2010	2009
Collaborative research and development and other revenue	$8,473	$6,518
Product revenue, net	6,506	4,686
Total revenues	14,979	11,204
Operating expenses:		
Cost of product revenues (1)	2,239	1,661
Research and development (1)	18,625	17,936
Selling, general and administrative (1)	7,086	8,034
Total operating expenses	27,950	27,631
Loss from operations	(12,971)	(16,427)
Other income (expense):		
Interest and other income	59	285
Interest and other expense	(23)	(22)
Net other income	36	263
Net loss	$(12,935)	$(16,164)
Net loss per share, basic and diluted	$(0.15)	$(0.20)

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Shares used in computing basic and diluted net loss per share	86,801	82,081
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(1) Includes stock-based compensation related to the following:

Cost of product revenues	$170	$195
Research and development	2,567	3,608
Selling, general and administrative	1,332	2,035
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Total stock-based compensation	$4,069	$5,838
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DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of June 30, 2010 (unaudited)	As of December 31, 2009 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$21,273	$8,287
Short-term investments	32,875	32,834
Short-term restricted investments	66	-
Accounts receivable	3,340	1,700
Inventories	2,852	2,799
Prepaid expenses and other current assets	1,773	1,433
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Total current assets	62,179	47,053
Property and equipment, net	2,656	3,808
Goodwill	6,399	6,399
Intangible assets, net	84	108
Long-term investments	2,591	-

Long-term restricted Investments	366	431
Other long-term assets	260	352
Total assets	$74,535	$58,151
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LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$931	$1,019
Accrued liabilities	4,117	5,337
Contract research liability	1,370	990
Deferred revenue, current portion	8,220	4,703
Other short-term liabilities	219	208
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Total current liabilities	14,857	12,257
Deferred revenue, noncurrent portion	38,888	17,543
Other long-term liabilities	396	508
Stockholders' equity	20,394	27,843
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Total liabilities and stockholders' equity	$74,535	$58,151
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(1) Derived from audited financial statements.

SOURCE DURECT Corporation