DURECT Corporation Announces Third Quarter 2004 Financial Results and Update on Its Development Programs

CUPERTINO, Calif., Oct. 25 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended September 30, 2004 and an update on its development programs.

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

Our net loss for the three months ended September 30, 2004 was $7.3 million or 14 cents per share, compared to $6.4 million or 13 cents per share for the same period in 2003. Our results for the three months ended September 30, 2004 included non-cash charges for the amortization of intangible assets and stock-based compensation of $311,000, compared to $217,000 for the same period in 2003. Cash used in operating activities was $4.4 million for the three months ended September 30, 2004, compared to $4.3 million for the same period in 2003.

“We are pleased with the strong progress we have made this quarter. We currently have four developmental programs, using four different proprietary delivery platforms — transdermal (sufentanil patch), oral (ORADUR(TM)-based oxycodone), injectible (SABER(TM)-based post-operative pain depot) and implantable (DURIN(TM)-based Alzheimer’s Disease product) — that are either in the clinic or anticipated to enter clinical development by the end of 2004.

These accomplishments are due to the experience, ingenuity and hard work of our employees who are committed to the development of much-needed products to treat patients suffering from chronic debilitating diseases,” said James E. Brown, President and CEO of DURECT. “DURECT has evolved as a company, with a breadth of technologies and a pipeline that we believe provides diversification to diminish development and commercial risk. We will continue to exploit the value that we have created from our technologies and execute upon the tasks necessary to move these programs forward to build lasting value for shareholders.”

Third Quarter 2004 Developments

Transdermal Sufentanil Pain Product

— We announced the initiation of a Phase I clinical trial for a new proprietary transdermal sufentanil product. The trial consists of a pharmacokinetic study in normal, healthy volunteers in Europe. The objectives of the clinical study are to determine the safety and tolerability of DURECT’s transdermal sufentanil patch as well as evaluate the pharmacokinetics of sufentanil following transdermal administration.

— Our transdermal sufentanil product is intended to provide extended chronic pain relief for up to seven days, as compared to the three days of relief provided with currently available opiate patches. Further, we

anticipate that the small size of our sufentanil patch (less than 1/5th the size of currently marketed |ransdermal fentanyl patches for a therapeutically equivalent dose) may offer improved convenience for patients.

Post-Operative Pain Depot

— We initiated a Phase II clinical study for our post-operative pain relief depot (SABER-bupivacaine). Our post-operative pain relief depot product is a sustained release injectable designed to provide 2-3 days of post-surgical pain relief and is based on our patented SABER delivery system.

— We anticipate that the trial will enroll approximately 65 patients, with an option to enroll an additional 30 patients, for a possible total enrollment of 95 patients in the trial.

— The Phase II trial will be a dose escalation study, conducted in three parts. All parts of the trial will be conducted in Australia as an open label study for the treatment of pain in patients following repair of inguinal hernia. Patients will be administered with SABER-bupivacaine at the completion of surgery, and the trial will evaluate the safety and efficacy of the injection.

— The primary end points for the trial will include a pharmacokinetic evaluation of plasma bupivacaine levels, time to first supplemental analgesic, analysis of the sum of pain intensity and analysis of total pain relief. The information on dose response collected in this study will be used in future Phase III trials to demonstrate the safety and efficacy of the SABER-bupivacaine product.

Remoxy(TM)

— Our development and commercialization partner, Pain Therapeutics, Inc. has announced their plan to initiate Phase III studies for Remoxy(TM) by the end of 2004.

— Pain Therapeutics further announced this quarter that it has received FDA clearance to conduct clinical trials in the U.S. with this product.

— Remoxy is a novel long-acting oral formulation of oxycodone based on DURECT’s ORADUR(TM) technology, a proprietary oral sustained release technology with several potential abuse deterrent properties.

CHRONOGESIC(R) (sufentanil) Pain Therapy Product

— We continue to work on the system design of our CHRONOGESIC(R) product in order to resume clinical trials for this product.

— CHRONOGESIC is an osmotic implant that delivers sufentanil for the treatment of chronic pain.

Alzheimer’s Disease Product

— Significant progress has been made with our on-going collaboration with Voyager Pharmaceutical Corporation to develop a treatment for Alzheimer’s Disease using our DURIN(TM) drug delivery platform.

— Voyager is currently conducting two proof of concept clinical studies utilizing the intended active agent.

— Voyager plans to initiate the Phase I clinical program on the DURIN-based product using the same active agent by the end of 2004.

Financial Results

Total revenues were $3.4 million for the three months ended September 30, 2004, compared to $3.0 million for the same period in 2003. The increase in total revenues was primarily attributable to higher collaborative research and development revenue recognized from our strategic partners and higher product sales from our ALZET(R) and polymer product lines.

Research and development expenses were $6.6 million for the three months ended September 30, 2004, compared to $5.4 million for the same period in 2003. The increase in the three months ended September 30, 2004 was primarily attributable to the higher development costs related to our SABER post-operative pain depot product, transdermal patch product, CHRONOGESIC and other partnered products under development.

Selling, general and administrative expenses were $2.3 million for the three months ended September 30, 2004, compared to $2.1 million for the same period in 2003. The increase was primarily attributable to higher expenses to comply with the Sarbanes-Oxley Act.

Interest income was $326,000 for the three months ended September 30, 2004, compared with $123,000 for the same period in 2003. The increase in interest income was primarily the result of higher yields in our cash and investments in the three months ended September 30, 2004. Interest expense was $1.1 million for the three months ended September 30, 2004 and 2003, which was primarily the result of the interest expense on the $60.0 million convertible notes we issued in June and July of 2003.

At September 30, 2004, we had cash and investments of $69.3 million, including $2.8 million in restricted investments, compared with cash and investments of $73.8 million at June 30, 2004.

We expect our net loss for the fourth quarter of 2004 will range from $7.0 million to $8.0 million or 14 to 16 cents per share. Our total cash burn for the fiscal year 2004 is expected to be in the range of $23.0 million to $25.0 million, which includes interest payments of $3.8 million for the convertible notes.

About DURECT Corporation

DURECT Corporation is a pharmaceutical company focused on the development of pharmaceutical systems based on its proprietary drug delivery platform technologies that treat chronic debilitating diseases and enable biotechnology products. These platform technologies include the SABER(TM) Delivery System (a patented and versatile depot injectable useful for protein and small molecule delivery), the ORADUR(TM) sustained release oral gel-cap technology (an oral sustained release technology with several potential abuse deterrent properties), the DURIN(TM) Biodegradable Implant (drug-loaded implant system) and the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system). DURECT also partners with pharmaceutical companies to develop and commercialize proprietary and enhanced pharmaceutical products based on its

technologies. DURECT has five disclosed on-going development programs of which three are in collaboration with pharmaceutical partners. Additional information about DURECT is available at www.www.durect.com.

NOTE: SABER(TM), ORADUR(TM), DURIN(TM), MICRODUR(TM) and CHRONOGESIC(R) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners.

The statements in this press release regarding DURECT's products in development, product development plans, anticipated clinical trials, potential product benefits and markets, and projected financial results 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 ability to complete the design, development, and manufacturing process development of its products, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, manage its growth and expenses, manage relationships with third parties, finance its activities and operations, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in DURECT's Annual Report on Form 10-K for the fiscal year ended December 31, 2003 filed with the SEC on March 11, 2004, DURECT's Quarterly Report on Form 10-Q and other periodic reports filed with the SEC under the heading "Factors that may affect future results."

CHRONOGESIC, our post operative pain and transdermal products, Remoxy and other products mentioned above are under development and have not been submitted or approved for commercialization by the US Food and Drug Administration or other health authorities.

DURECT CORPORATION

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

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Product revenue, net	$1,776	$1,723	$4,901	$4,945
Collaborative research and development and other revenue	1,589	1,227	4,929	3,786
Total revenues	3,365	2,950	9,830	8,731
Operating expenses:				
Cost of revenues	685	711	2,117	1,840
Research and development	6,571	5,366	18,020	16,220
Selling, general and administrative	2,262	2,141	6,825	6,603
Amortization of intangible assets	303	339	946	1,009
Stock-based compensation(1)	8	(122)	178	(141)
Total operating				

expenses	9,829	8,435	28,086	25,531
Loss from operations	(6,464)	(5,485)	(18,256)	(16,800)
Other income (expense):				
Interest income	326	123	919	732
Interest expense	(1,122)	(1,068)	(3,346)	(1,371)
Net other expense	(796)	(945)	(2,427)	(639)
Net loss	$(7,260)	$(6,430)	$(20,683)	$(17,439)
Net loss per common share, basic and diluted	$(0.14)	$(0.13)	$(0.40)	$(0.35)
Shares used in computing basic and diluted net loss per share	51,670	50,624	51,397	50,347

(1) Stock-based compensation related to the following:

Cost of revenues	$--	$3	$1	$14
Research and development	3	34	156	(225)
Selling, general and administrative	5	(159)	21	70
	$8	$(122)	$178	$(141)

DURECT CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2004	December 31, 2003 (1)
Assets		
Current assets:		
Cash and cash equivalents	$18,245	$21,203
Short-term investments	31,043	39,511
Accounts receivable, net	2,512	1,968
Inventories	1,841	1,902
Prepaid expenses and other current assets	1,280	1,480
Total current assets	54,921	66,064
Property and equipment, net	7,189	9,316
Goodwill	6,399	6,399
Intangible assets, net	2,048	2,994
Long-term investments	17,268	21,334
Restricted investments	2,788	3,119
Other non-current assets	2,779	3,181

Total assets	$93,392	$112,407
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, accrued liabilities and deferred revenue	$5,741	$4,551
Long-term obligations, current portion	473	463
Total current liabilities	6,214	5,014
Long-term obligations, noncurrent portion	61,858	62,278
Stockholders' equity	25,320	45,115
Total liabilities and stockholders' equity	$93,392	$112,407

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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