

DURECT CORP  
Form 10-Q  
August 05, 2010  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2010

OR

**.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 000-31615

**DURECT CORPORATION**

(Exact name of registrant as specified in its charter)

Edgar Filing: DURECT CORP - Form 10-Q

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**94-3297098**  
(I.R.S. Employer  
Identification No.)

**2 Results Way**

**Cupertino, California 95014**

(Address of principal executive offices, including zip code)

**(408) 777-1417**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by a check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of July 31, 2010, there were 86,889,389 shares of the registrant's Common Stock outstanding.

**Table of Contents**

**INDEX**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
Item 1. <u>Financial Statements</u>	3
<u>Condensed Balance Sheets As of June 30, 2010 and December 31, 2009</u>	3
<u>Condensed Statements of Operations For the three and six months ended June 30, 2010 and 2009</u>	4
<u>Condensed Statements of Cash Flows For the six months ended June 30, 2010 and 2009</u>	5
<u>Notes to Condensed Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	33
Item 4. <u>Controls and Procedures</u>	33
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	34
Item 1A. <u>Risk Factors</u>	34
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	50
Item 3. <u>Defaults Upon Senior Securities</u>	50
Item 4. <u>[Removed and Reserved]</u>	50
Item 5. <u>Other Information</u>	50
Item 6. <u>Exhibits</u>	50
(a) Exhibits	
<u>Signatures</u>	51

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****DURECT CORPORATION****CONDENSED BALANCE SHEETS**

(in thousands)

	<b>June 30, 2010 (unaudited)</b>	<b>December 31, 2009 (Note 1)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 21,273	\$ 8,287
Short-term investments	32,875	32,834
Short-term restricted investments	66	
Accounts receivable (net of allowances of \$114 and \$103 at June 30, 2010 and December 31, 2009, respectively)	3,340	1,700
Inventories	2,852	2,799
Prepaid expenses and other current assets	1,773	1,433
<b>Total current assets</b>	<b>62,179</b>	<b>47,053</b>
Property and equipment (net of accumulated depreciation of \$21,505 and \$20,190 at June 30, 2010 and December 31, 2009, respectively)	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
<b>Total assets</b>	<b>\$ 74,535</b>	<b>\$ 58,151</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
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
<b>Total current liabilities</b>	<b>14,857</b>	<b>12,257</b>
Deferred revenue, non-current portion	38,888	17,543
Other long-term liabilities	396	508
Commitments		
Stockholders equity:		
Common stock	9	8
Additional paid-in capital	347,200	341,705
Accumulated other comprehensive income		10
Accumulated deficit	(326,815)	(313,880)

Edgar Filing: DURECT CORP - Form 10-Q

Stockholders' equity	20,394	27,843
Total liabilities and stockholders' equity	\$ 74,535	\$ 58,151

The accompanying notes are an integral part of these financial statements.

**Table of Contents**

**DURECT CORPORATION**  
**CONDENSED STATEMENTS OF OPERATIONS**

(in thousands, except per share amounts)

(unaudited)

	Three months ended		Six months ended	
	June 30,		June 30,	
	2010	2009	2010	2009
Collaborative research and development and other revenue	\$ 4,657	\$ 2,606	\$ 8,473	\$ 6,518
Product revenue, net	2,656	2,271	6,506	4,686
<b>Total revenues</b>	<b>7,313</b>	<b>4,877</b>	<b>14,979</b>	<b>11,204</b>
Operating expenses:				
Cost of product revenues (1)	861	837	2,239	1,661
Research and development (1)	9,204	7,866	18,625	17,936
Selling, general and administrative (1)	3,584	3,777	7,086	8,034
<b>Total operating expenses</b>	<b>13,649</b>	<b>12,480</b>	<b>27,950</b>	<b>27,631</b>
<b>Loss from operations</b>	<b>(6,336)</b>	<b>(7,603)</b>	<b>(12,971)</b>	<b>(16,427)</b>
Other income (expense):				
Interest and other income	48	106	59	285
Interest expense	(21)	(11)	(23)	(22)
<b>Net other income</b>	<b>27</b>	<b>95</b>	<b>36</b>	<b>263</b>
<b>Net loss</b>	<b>\$ (6,309)</b>	<b>\$ (7,508)</b>	<b>\$ (12,935)</b>	<b>\$ (16,164)</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.07)</b>	<b>\$ (0.09)</b>	<b>\$ (0.15)</b>	<b>\$ (0.20)</b>
Shares used in computing basic and diluted net loss per share	86,845	82,138	86,801	82,081

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

Cost of product revenues	\$ 86	\$ 117	\$ 170	\$ 195
Research and development	1,290	1,327	2,567	3,608
Selling, general and administrative	663	864	1,332	2,035
<b>Total stock-based compensation</b>	<b>\$ 2,039</b>	<b>\$ 2,308</b>	<b>\$ 4,069</b>	<b>\$ 5,838</b>

The accompanying notes are an integral part of these financial statements.



**Table of Contents**

**DURECT CORPORATION**  
**CONDENSED STATEMENTS OF CASH FLOWS**

(in thousands)

(unaudited)

	<b>Six months ended</b>	
	<b>June 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (12,935)	\$ (16,164)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,339	1,508
Stock-based compensation	4,069	5,838
Changes in assets and liabilities:		
Accounts receivable	(1,640)	1,719
Inventories	(68)	767
Prepaid expenses and other assets	(248)	(1,279)
Accounts payable	(88)	(172)
Accrued and other liabilities	(102)	(1,482)
Contract research liability	380	(379)
Deferred revenue	24,862	(1,380)
Total adjustments	28,504	5,140
Net cash provided by (used in) operating activities	15,569	(11,024)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(163)	(85)
Purchases of available-for-sale securities	(29,920)	(27,963)
Proceeds from maturities of available-for-sale securities	25,070	18,193
Proceeds from sales of available-for-sale securities	2,207	1,154
Net cash used in investing activities	(2,806)	(8,701)
<b>Cash flows from financing activities</b>		
Payments on equipment financing obligations	(23)	(21)
Net proceeds from issuances of common stock	246	325
Net cash provided by financing activities	223	304
Net increase (decrease) in cash and cash equivalents	12,986	(19,421)
Cash and cash equivalents, beginning of the period	8,287	29,445
Cash and cash equivalents, end of the period	\$ 21,273	\$ 10,024

The accompanying notes are an integral part of these financial statements.



**Table of Contents****DURECT CORPORATION****NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS****Note 1. Summary of Significant Accounting Policies*****Nature of Operations***

DURECT Corporation (the Company) was incorporated in the state of Delaware on February 6, 1998. The Company is a pharmaceutical company developing therapies based on its proprietary drug formulations and delivery platform technologies. The Company has several products under development by itself and with third party collaborators. The Company also manufactures and sells osmotic pumps used in laboratory research, and designs, develops and manufactures a wide range of standard and custom biodegradable polymers and excipients for pharmaceutical and medical device clients for use as raw materials in their products. In addition, the Company conducts research and development of pharmaceutical products in collaboration with third party pharmaceutical and biotechnology companies.

***Basis of Presentation***

The accompanying unaudited financial statements include the accounts of the Company. These financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and therefore, do not include all the information and footnotes necessary for a complete presentation of the Company's results of operations, financial position and cash flows in conformity with U.S. generally accepted accounting principles (U.S. GAAP). The unaudited financial statements reflect all adjustments (consisting only of normal recurring adjustments) which are, in the opinion of management, necessary for a fair presentation of the financial position at June 30, 2010, the operating results for the three and six months ended June 30, 2010 and 2009, and cash flows for the six months ended June 30, 2010 and 2009. The balance sheet as of December 31, 2009 has been derived from audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These financial statements and notes should be read in conjunction with the Company's audited financial statements and notes thereto, included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2009 filed with the SEC.

The results of operations for the interim periods presented are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year.

***Reclassifications***

Certain prior period amounts in the condensed statements of operations have been reclassified to conform to current period presentation. The Company reclassified \$167,000 related to the Company's agreement with Nycomed from research and development expenses to collaborative research and development and other revenue in the six months ended June 30, 2009. Such reclassification did not impact the Company's net loss or financial position.

***Inventories***

Inventories are stated at the lower of cost or market, with cost determined on a first-in, first-out basis.

Inventories consisted of the following (in thousands):

	<b>June 30, 2010 (unaudited)</b>	<b>December 31, 2009</b>
Raw materials	\$ 543	\$ 516
Work in process	827	690
Finished goods	1,482	1,593
Total inventories	\$ 2,852	\$ 2,799



---

**Table of Contents**

**DURECT CORPORATION**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**

***Revenue Recognition***

Revenue from the sale of products is recognized when there is persuasive evidence that an arrangement exists, the product is shipped and title transfers to customers, provided no continuing obligation on the Company's part exists, the price is fixed or determinable and the collectability of the amounts owed is reasonably assured. The Company enters into license and collaboration agreements under which it may receive up-front license fees, research funding and contingent milestone payments and royalties. The Company's deliverables under these arrangements typically consist of granting licenses to intellectual property rights and research and development services. The Company evaluates whether there is stand-alone value for the delivered elements and objective and reliable evidence of fair value to allocate revenue to each element in multiple element agreements. When the delivered element does not have stand-alone value or there is insufficient evidence of fair value for the undelivered element(s), the Company recognizes the consideration for the combined unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is generally ratably over the longest period of involvement. Returns or credits related to the sale of products have not had a material impact on our revenues or net loss.

Upfront payments received upon execution of collaborative agreements are recorded as deferred revenue and recognized as collaborative research and development revenue based on a straight-line basis over the period of the Company's continuing involvement with the third-party collaborator pursuant to the applicable agreement. Such period generally represents the longer of the estimated research and development period or other continuing obligation period defined in the respective agreements between the Company and its third-party collaborators.

Research and development revenue related to services performed under the collaborative arrangements with the Company's third-party collaborators is recognized as the related research and development services are performed. These research payments received under each respective agreement are not refundable and are generally based on reimbursement of qualified expenses, as defined in the agreements. Research and development expenses under the collaborative research and development agreements generally approximate or exceed the revenue recognized under such agreements over the term of the respective agreements. Deferred revenue may result when the Company does not expend the required level of effort during a specific period in comparison to funds received under the respective agreement. For joint control and funding development activities, the Company recognizes revenue from the net reimbursement of the research and development expenses from our partner and records the net payment of research and development expenses to our partner as additional research and development expense.

Milestone payments under collaborative arrangements are recognized as collaborative research and development revenue upon achievement of the milestone events, which represent the culmination of the earnings process related to that milestone as defined in the agreement. Milestone payments are triggered either by the results of our research and development efforts or by events external to us, such as regulatory approval to market a product or the achievement of specified sales levels by a third-party collaborator. As such, the milestones are substantially at risk at the inception of the collaboration agreement, and revenue is only recognized upon the achievement of a milestone event if the Company has no future performance obligations related to that milestone payment.

Revenue on cost-plus-fee contracts, such as under contracts to perform research and development for others, is recognized as the related services are rendered as determined by the extent of reimbursable costs incurred plus estimated fees thereon.

**Table of Contents****DURECT CORPORATION****NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**

The collaborative research and development and other revenues associated with the Company's major third-party collaborators are as follows (in thousands):

<b>Collaborator</b>	<b>Three months ended</b>		<b>Six months ended</b>	
	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
King Pharmaceuticals, Inc. (King)(1)	\$ 2,695	\$ 1,632	\$ 5,270	\$ 3,556
Hospira, Inc. (Hospira)(2)	747		747	
Nycomed Danmark, APS (Nycomed)(3)	595	381	904	930
Pain Therapeutics, Inc. (Pain Therapeutics)	27	46	728	322
Endo Pharmaceuticals, Inc. (Endo)(4)				985
Others	593	547	824	725
Total collaborative research and development and other revenue	\$ 4,657	\$ 2,606	\$ 8,473	\$ 6,518

## Notes:

- Amounts related to the ratable recognition of upfront fees were \$804,000 and \$1.6 million for the three and six months ended June 30, 2010, respectively, compared to \$804,000 and \$1.8 million for the corresponding periods in 2009.
- Amounts related to the ratable recognition of upfront fees were \$302,000 for the three and six months ended June 30, 2010, compared to zero for the corresponding periods in 2009.
- Amounts related to the ratable recognition of upfront fees were \$309,000 and \$617,000 for the three and six months ended June 30, 2010, respectively, compared to \$381,000 and \$763,000 for the corresponding periods in 2009.
- Amounts related to the ratable recognition of upfront fees were zero for the three and six months ended June 30, 2010, respectively, compared to zero and \$875,000 for the corresponding periods in 2009. The Company's agreement with Endo was terminated effective August 26, 2009.

**Comprehensive Loss**

Other comprehensive income (loss) is comprised entirely of unrealized gains and losses on the Company's available-for-sale securities for all periods presented, are included in total comprehensive loss as follows (in thousands).

<b>Three months ended</b>		<b>Six months ended</b>	
<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>
<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>

## Edgar Filing: DURECT CORP - Form 10-Q

Net loss	\$ (6,309)	\$ (7,508)	\$ (12,935)	\$ (16,164)
Net change in unrealized gain on available-for-sale investments	(5)	47	(10)	(28)
Comprehensive loss	\$ (6,314)	\$ (7,461)	\$ (12,945)	\$ (16,192)

**Table of Contents****DURECT CORPORATION****NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)*****Net Loss Per Share***

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding. Diluted net loss per share is computed using the weighted-average number of common shares outstanding and common stock equivalents (i.e., options and warrants to purchase common stock) outstanding during the year, if dilutive, using the treasury stock method for options and warrants.

	<b>Three months ended</b>		<b>Six months ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Outstanding dilutive securities not included in diluted net loss per share				
Options to purchase common stock	19,228	16,361	19,652	16,323
Warrants	1	1	1	1
Total	19,229	16,362	19,653	16,324

***Recent Accounting Pronouncements***

In September 2009, the FASB issued Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements a consensus of the FASB Emerging Issues Task Force* (ASU 2009-13). It updates the existing multiple-element revenue arrangements guidance currently included under ASC 605-25, which originated primarily from the guidance in EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). The revised guidance primarily provides two significant changes: (1) eliminates the need for objective and reliable evidence of the fair value for the undelivered element in order for a delivered item to be treated as a separate unit of accounting, and (2) eliminates the residual method to allocate the arrangement consideration. In addition, the guidance also expands the disclosure requirements for revenue recognition. ASU 2009-13 will be effective for the first annual reporting period beginning on or after June 15, 2010, with early adoption permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. The Company expects to adopt ASU 2009-13 prospectively as of January 1, 2011. The Company is currently assessing the future impact of this new accounting update to its financial statements.

In March 2010, Accounting Standards Codification Topic 605, Revenue Recognition (ASC 605) was amended to define a milestone and clarify that the milestone method of revenue recognition is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, a company can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The Company will adopt this guidance in the third quarter of 2010 on a prospective basis. The Company is currently assessing the future impact of this guidance on its results of operations and financial condition.

**Table of Contents****DURECT CORPORATION****NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)****Note 2. Strategic Agreements*****Agreement with Hospira, Inc.***

In June 2010, the Company and Hospira, Inc. (Hospira) entered into a license agreement to develop and market POSIDUR (SABER-bupivacaine) in the U.S. and Canada. POSIDUR is the Company's investigational post-operative pain relief depot currently in Phase III clinical development in the U.S. that utilizes the Company's 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 other specified countries, and the Company retains commercialization rights in Japan and all other countries not licensed to Hospira and Nycomed.

Under terms of the agreement, Hospira made an upfront payment of \$27.5 million, with the potential for up to an additional \$185 million in performance milestone payments based on the successful development, approval and commercialization of POSIDUR in the U.S. and Canada. 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 upon regulatory approval with sole funding responsibility. In addition, the Company has also granted to Hospira the right to develop and commercialize in the U.S. and Canada, at Hospira's sole cost, other specified local anesthetic products based on the SABER technology, if any, which come into existence under the Agreement. Hospira will be responsible for commercial manufacture of licensed products under the Agreement, provided that the Company will supply to Hospira a specified excipient for use in the manufacture of licensed products pursuant to a supply agreement entered into by the parties. On a product by product basis, Hospira will pay the Company a royalty on sales of each licensed product commercialized under the Agreement for a defined period, after which the license granted to Hospira for such product shall convert to a fully paid-up, non-royalty bearing and perpetual license. The term of the agreement shall be for the duration of Hospira's obligation to pay royalties for product sales under the Agreement. The agreement provides each party with specified termination rights, including the right of Hospira to terminate at will after a specified period and each party to terminate the agreement upon material breach of the agreement by the other party. The agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties and indemnities.

The following table provides a summary of amounts comprising our net share of the research and development costs for POSIDUR under the agreement with Hospira (in thousands):

	<b>Three months ended</b>		
	<b>March 31, 2010</b>	<b>June 30, 2010</b>	<b>Total</b>
Research and development expenses reimbursable by Hospira	\$	\$ 445	\$ 445
Research and development expenses reimbursable by the Company			
Net payable to Hospira	\$	\$	\$
Net receivable from Hospira	\$	\$ 445	\$ 445

No research and development expenses were incurred under this agreement prior to the three month period ended June 30, 2010.

**Table of Contents****DURECT CORPORATION****NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**

The following table provides a summary of collaborative research and development revenue recognized under the agreement with Hospira (in thousands). The cumulative aggregate payments received by the Company as of June 30, 2010 were \$27.5 million under this agreement.

	Three months ended		Six months ended	
	June 30, 2010	2009	June 30, 2010	2009
Ratable recognition of upfront payment (1)	\$ 302	\$	\$ 302	\$
Research and development expenses reimbursable by Hospira	445		445	
<b>Total collaborative research and development revenue</b>	<b>\$ 747</b>	<b>\$</b>	<b>\$ 747</b>	<b>\$</b>

- (1) The Company's estimate of the term of our continuing involvement was based on the later of the research and development period and the term of the Company's manufacturing obligation under the development and license agreement with Hospira.

***Agreement with Alparma Ireland Limited, an affiliate of Alparma Inc. (Alparma) (acquired by King)***

Effective October 2008, the Company and Alparma entered into a development and license agreement granting Alparma the exclusive worldwide rights to develop and commercialize ELADUR, DURECT's investigational transdermal bupivacaine patch. As a result of the acquisition of Alparma by King in December 2008, King has assumed all the rights and obligations of Alparma under the agreement.

The following table provides a summary of collaborative research and development revenue recognized under the agreement with King with regard to ELADUR (in thousands). The cumulative aggregate payments received by the Company as of June 30, 2010 were \$26.6 million under this agreement.

	Three months ended		Six months ended	
	June 30, 2010	2009	June 30, 2010	2009
Ratable recognition of upfront payment (1)	\$ 804	\$ 804	\$ 1,609	\$ 1,818
Research and development expenses reimbursable by King	765	458	1,725	1,369
<b>Total collaborative research and development revenue</b>	<b>\$ 1,569</b>	<b>\$ 1,262</b>	<b>\$ 3,334</b>	<b>\$ 3,187</b>

- (1) The Company's estimate of the remaining term of our continuing involvement was modified in the second quarter of 2009 as a result of an updated development plan.



**Table of Contents****DURECT CORPORATION****NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)*****Agreement with Nycomed***

In November 2006, the Company entered into a development and license agreement with Nycomed, and this agreement was amended in February 2010. Under the terms of the agreement, the Company licensed to Nycomed the exclusive commercialization rights to POSIDUR for the European Union (E.U.) and certain other countries. Nycomed paid an upfront license fee of \$14.0 million in 2006 and a milestone payment of \$8.0 million in 2007, with future potential additional milestone payments of up to \$181.0 million upon achievement of defined development, regulatory and sales milestones. Prior to the February 2010 amendment, the agreement provided for the Company and Nycomed to jointly direct and equally fund with Nycomed a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the E.U. After the amendment, as between Nycomed and the Company, the Company now has final decision-making authority over clinical trials intended for the U.S. registration of POSIDUR and Nycomed now has decision-making authority over clinical trials for the E.U. and other countries licensed to it. As between Nycomed and the Company, the Company will have funding responsibility for all current and future clinical trials intended for U.S. registration of POSIDUR and, commencing April 1, 2010, Nycomed will have sole funding responsibility for all clinical trials intended for E.U. registration of POSIDUR. The final decision making authority and financial responsibility for the remainder of the development activities, such as the non-clinical and CMC activities, will be jointly managed and funded by the Company and Nycomed. In addition, the Company will manufacture and supply the product to Nycomed for commercial sale in the territory licensed to Nycomed. Nycomed will pay the Company blended royalties on sales in the defined territory of 15-40% depending on annual sales, as well as a manufacturing markup. The Company retains full commercial rights to POSIDUR in all countries not licensed to Nycomed and Hospira. The agreement shall continue in effect until terminated. The agreement provides each party with specified termination rights, including the right of each party to terminate the agreement upon material breach of the agreement by the other party. In addition, Nycomed shall have the right to terminate the agreement after expiration of patents covering POSIDUR in all major market countries in the E.U. and for adverse product events, and within specified periods after clinical trials of POSIDUR.

For joint control and funding development activities, the Company recognizes revenue from the net reimbursement of the research and development expenses from our partner and records the net payment of research and development expenses to our partner as additional research and development expense. The Company and Nycomed each bear 50% of the agreed upon expenses under the collaboration agreement for POSIDUR.

The following tables provide a summary of the amounts comprising our net share of the research and development costs for POSIDUR under the Company's agreement with Nycomed (in thousands):

	<b>Three months ended</b>		
	<b>March 31,</b>	<b>June 30,</b>	
	<b>2010</b>	<b>2010</b>	<b>Total</b>
Research and development expenses reimbursable by Nycomed	\$ 523	\$ 365	\$ 888
Research and development expenses reimbursable by the Company	(820)	(78)	(898)
<b>Net payable to Nycomed</b>	<b>\$ (297)</b>	<b>\$</b>	<b>\$ (297)</b>
Net receivable from Nycomed	\$	\$ 287	\$ 287

	<b>Three months ended</b>		
	<b>March 31,</b>	<b>June 30,</b>	
	<b>2009</b>	<b>2009</b>	<b>Total</b>
Research and development expenses reimbursable by Nycomed	\$ 1,112	\$ 855	\$ 1,967
Research and development expenses reimbursable by the Company	(945)	(1,146)	(2,091)
<b>Net payable to Nycomed</b>	<b>\$</b>	<b>\$ (291)</b>	<b>\$ (291)</b>

Edgar Filing: DURECT CORP - Form 10-Q

Net receivable from Nycomed

\$ 167

\$

\$ 167

**Table of Contents****DURECT CORPORATION****NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**

The following table provides a summary of collaborative research and development revenue recognized under the agreement with Nycomed with regard to POSIDUR (in thousands). The cumulative aggregate payments received by the Company from Nycomed as of June 30, 2010 were \$35.5 million under this agreement. In addition, the cumulative aggregate payments paid by the Company to Nycomed were \$8.8 million as of June 30, 2010.

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Ratable recognition of upfront payment (1)	\$ 308	\$ 381	\$ 617	\$ 763
Research and development expenses reimbursable by Nycomed	287		287	167
<b>Total collaborative research and development revenue</b>	<b>\$ 595</b>	<b>\$ 381</b>	<b>\$ 904</b>	<b>\$ 930</b>

- (1) The Company's estimates of the remaining term of its continuing involvement were modified in the first and fourth quarters of 2009 as a result of an updated development plan for POSIDUR in Europe.

***Agreement with Endo Pharmaceuticals***

On March 10, 2005, the Company entered into a license agreement with Endo under which the Company granted to Endo the exclusive right to develop, market and commercialize TRANSDUR-Sufentanil in the U.S. and Canada. The Company received an initial payment of \$10.0 million in connection with the execution of the agreement. The license agreement was terminated by Endo effective August 26, 2009.

The Company recognized zero as collaborative research and development revenue from the ratable recognition of the \$10.0 million upfront fee for the three and six months ended June 30, 2010, compared to zero and \$875,000 for the corresponding periods in 2009, respectively. Total collaborative research and development revenue recognized under this arrangement was zero for the three and six months ended June 30, 2010, compared to zero and \$985,000 for the corresponding periods in 2009, respectively. The cumulative aggregate payments received by the Company as of June 30, 2010 were \$21.5 million under this agreement.

**Table of Contents**

**DURECT CORPORATION**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**

***Agreement with Pain Therapeutics***

In December 2002, the Company entered into an exclusive agreement with Pain Therapeutics, Inc. ( Pain Therapeutics ) to develop and commercialize on a worldwide basis Remoxy and other oral sustained release, abuse deterrent opioid products incorporating four specified opioid drugs, using the ORADUR technology. Total collaborative research and development revenue recognized under the agreement with Pain Therapeutics was \$27,000 and \$728,000 for the three and six months ended June 30, 2010, respectively, compared to \$46,000 and \$322,000 for the corresponding periods in 2009. The cumulative aggregate payments received by the Company as of June 30, 2010 were \$31.9 million under this agreement.

In March 2009, King assumed the responsibility for further development of Remoxy from Pain Therapeutics. As a result of this change, the Company continues to perform Remoxy related activities in accordance with the terms and conditions set forth in the license agreement between the Company and Pain Therapeutics, but with King substituted in lieu of Pain Therapeutics with respect to interactions with the Company in the Company's performance of those activities including the obligation to pay the Company with respect to all Remoxy-related costs incurred by the Company.

Total collaborative research and development revenue recognized for Remoxy-related work performed by the Company for King was \$1.1 million and \$1.9 million for the three and six months ended June 30, 2010, respectively, compared to \$370,000 and \$370,000 for the corresponding periods in 2009. Prior to March 2009, the Company recognized collaborative research and development revenue for Remoxy related work under the agreements with Pain Therapeutics. The cumulative aggregate payments received by the Company from King as of June 30, 2010 were \$2.3 million under this agreement.

**Table of Contents**

**DURECT CORPORATION**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**

***Long Term Supply Agreement with King***

During 2008, the Company began to manufacture commercial lots of certain key excipients that are included in Remoxy to meet the anticipated requirements for these components. In addition, during the second, third and fourth quarters of 2008 and the first quarter of 2009, the Company made shipments of these materials to meet the production requirements of King, which has rights to commercialize Remoxy upon approval by the FDA. During these periods, all product revenue and associated cost of goods sold was deferred pending the establishment of definitive final terms and conditions even though cash receipts and expenditures occurred during these periods.

In August 2009, the Company signed an exclusive long term excipient supply agreement with respect to Remoxy with King. This agreement stipulates the terms and conditions under which the Company will supply to King, based on the Company's manufacturing cost plus a specified percentage mark-up, two key excipients used in the manufacture of Remoxy. In the third quarter of 2009, the Company recognized \$3.0 million of product revenue and \$2.0 million of cost of goods sold related to its past shipments to King upon execution of the long term supply agreement at which point all criteria of revenue recognition were met.

In the three and six months ended June 30, 2010, respectively, the Company recognized zero and \$551,000 of product revenue for shipments made in 2008 and 2009 related to a price settlement after all criteria of revenue recognition were met. The price settlement related to additional manufacturing cost incurred by the Company and certain mark up for the goods produced and shipped in 2008 and 2009 pursuant to the long term excipient supply agreement. In addition, the Company also recognized zero and \$410,000 of product revenue related to the shipment of another excipient that is included in Remoxy upon shipment to King in the three and six months ended June 30, 2010, respectively. Total revenue recognized related to these excipients was zero and \$961,000 in the three and six months ended June 30, 2010, respectively, and the associated costs of goods sold was zero and \$315,000 compared to zero for the corresponding period in 2009. Revenue attributable to shipments of these key components aggregating \$1.7 million and cost of goods sold aggregating \$1.5 million in the three and six months ended June 30, 2009 was recognized upon the execution of a final supply agreement with King in the third quarter of 2009 rather than the first quarter of 2009.

**Table of Contents****DURECT CORPORATION****NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)****Note 3. Fair Value Measurements**

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company's valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The Company follows a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value. These levels of inputs are the following:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table sets forth the fair value of the Company's financial assets that were measured at fair value on a recurring basis as of June 30, 2010 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 1,242	\$	\$	\$ 1,242
Certificates of deposit		432		432
Commercial paper		14,847		14,847
Corporate debt securities		2,573		2,573
U.S. Government agencies		37,643		37,643
Total	\$ 1,242	\$ 55,495		