DURECT CORP
Form 10-Q
August 05, 2011
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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, 2011

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)

Delaware	**94-3297098**
(State or other jurisdiction of incorporation or organization)	**(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 x 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 x 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 x
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 x

As of July 29, 2011, there were 87,450,052 shares of the registrant s Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

	June 30, 2011 (unaudited)	December 31, 2010 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,486	$ 10,437
Short-term investments	29,247	35,005
Short-term restricted investments	0	66
Accounts receivable (net of allowances of $103 and $107 at June 30, 2011 and December 31, 2010, respectively)	3,290	3,716
Inventories	3,265	2,836
Prepaid expenses and other current assets	1,251	2,785
Total current assets	42,539	54,845
Property and equipment (net of accumulated depreciation of $22,124 and $22,386 at June 30, 2011 and December 31, 2010, respectively)	2,204	1,776
Goodwill	6,399	6,399
Intangible assets, net	62	71
Long-term investments	1,924	3,197
Long-term restricted investments	867	867
Other long-term assets	349	405
Total assets	$ 54,344	$ 67,560
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,001	$ 981
Accrued liabilities	4,303	6,524
Contract research liabilities	2,157	2,109
Deferred revenue, current portion	8,079	8,079
Other short-term liabilities	229	216
Total current liabilities	15,769	17,909
Deferred revenue, non-current portion	30,809	34,849
Other long-term liabilities	357	315
Commitments		
Stockholders equity:		
Common stock	9	8
Additional paid-in capital	355,757	351,251
Accumulated other comprehensive income	23	6
Accumulated deficit	(348,380)	(336,778)
Stockholders equity	7,409	14,487

Total liabilities and stockholders equity	$ 54,344	$ 67,560

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

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DURECT CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Collaborative research and development and other revenue	$ 5,188	$ 4,657	$ 10,700	$ 8,473
Product revenue, net	2,645	2,656	5,737	6,506
Total revenues	7,833	7,313	16,437	14,979
Operating expenses:				
Cost of product revenues (1)	1,085	861	2,486	2,239
Research and development (1)	8,708	9,204	18,588	18,625
Selling, general and administrative (1)	3,327	3,584	7,043	7,086
Total operating expenses	13,120	13,649	28,117	27,950
Loss from operations	(5,287)	(6,336)	(11,680)	(12,971)
Other income (expense):				
Interest and other income	43	48	83	59
Interest and other expense	(1)	(21)	(5)	(23)
Net other income	42	27	78	36
Net loss	$ (5,245)	$ (6,309)	$ (11,602)	$ (12,935)
Net loss per share, basic and diluted	$ (0.06)	$ (0.07)	$ (0.13)	$ (0.15)
Shares used in computing basic and diluted net loss per share	87,404	86,845	87,338	86,801

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

Cost of product revenues	$ 82	$ 86	$ 167	$ 170
Research and development	1,072	1,290	2,199	2,567
Selling, general and administrative	580	663	1,151	1,332
Total stock-based compensation	$ 1,734	$ 2,039	$ 3,517	$ 4,069

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

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DURECT CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six months ended June 30,	
	2011	**2010**
Cash flows from operating activities		
Net loss	$ (11,602)	$ (12,935)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	519	1,339
Stock-based compensation	3,517	4,069
Changes in assets and liabilities:		
Accounts receivable	426	(1,640)
Inventories	(435)	(68)
Prepaid expenses and other assets	1,590	(248)
Accounts payable	20	(88)
Accrued and other liabilities	(2,182)	(102)
Contract research liability	48	380
Deferred revenue	(4,040)	24,862
Total adjustments	(537)	28,504
Net cash (used in) provided by operating activities	(12,139)	15,569
Cash flows from investing activities		
Purchases of property and equipment	(937)	(163)
Purchases of available-for-sale securities	(14,458)	(29,920)
Proceeds from maturities of available-for-sale securities	21,572	25,070
Proceeds from sales of available-for-sale securities	0	2,207
Net cash provided by (used in) investing activities	6,177	(2,806)
Cash flows from financing activities		
Payments on equipment financing obligations	17	(23)
Net proceeds from issuances of common stock	994	246
Net cash provided by financing activities	1,011	223
Net (decrease) increase in cash and cash equivalents	(4,951)	12,986
Cash and cash equivalents, beginning of the period	10,437	8,287
Cash and cash equivalents, end of the period	$ 5,486	$ 21,273

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

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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, 2011, the operating results for the three and six months ended June 30, 2011 and 2010, and cash flows for the six months ended June 30, 2011 and 2010. The balance sheet as of December 31, 2010 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, 2010 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.

Inventories

Inventories are stated at the lower of cost or market, with cost determined on a first-in, first-out basis. The Company s inventories consisted of the following (in thousands):

	June 30, 2011 (unaudited)	December 31, 2010
Raw materials	$ 885	$ 519
Work in process	757	840
Finished goods	1,623	1,477
Total inventories	$ 3,265	$ 2,836

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 accounting standards contain a presumption that separate contracts entered into at or near the same time with the same entity or related parties were negotiated as a package and

should be evaluated as a single agreement.

In the first quarter of 2011, we adopted Accounting Standards Update (ASU) No. 2009-13, Revenue Recognition *Multiple Deliverable Revenue Arrangements* (ASU 2009-13) for multiple deliverable revenue arrangements, on a prospective basis, for applicable transactions originating or materially modified on or subsequent to January 1, 2011. ASU 2009-13 provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update changes the requirements for establishing separate units of accounting in a multiple element arrangement and establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable is based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or

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estimated selling price if neither vendor-specific nor third-party evidence is available. Implementation of ASU 2009-13 has had no impact on reported revenue as compared to revenue under previous guidance. Under ASU 2009-13, the Company may be required to exercise considerable judgment in determining the estimated selling price of delivered items under new agreements and the Company s revenue under new agreements may be more accelerated as compared to the prior accounting standard.

For multiple element arrangements entered into prior to January 1, 2011, the Company determined whether the elements had value on a stand-alone basis and whether there was objective and reliable evidence of fair value. When the delivered element did not have stand-alone value or there was insufficient evidence of fair value for the undelivered element(s), the Company recognized the consideration for the combined unit of accounting in the same manner as the revenue was recognized for the final deliverable, which was generally ratably over the longest period of involvement. For example, 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. Returns or credits related to the sale of products have not had a material impact on the Company s revenues or net loss.

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 at risk 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.

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

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Collaborator				
Hospira, Inc. (Hospira) (1)	$ 2,838	$ 747	$ 5,852	$ 747
Pfizer Inc. (Pfizer) (2)	1,098	2,695	2,715	5,270
Nycomed Danmark, APS (Nycomed) (3)	308	595	617	904
Pain Therapeutics, Inc. (Pain Therapeutics)	21	27	43	728
Others	923	593	1,473	824
Total collaborative research and development and other revenue	$ 5,188	$ 4,657	$ 10,700	$ 8,473

(1) Amounts related to the ratable recognition of upfront fees were $906,000 and $1.8 million for the three and six months ended June 30, 2011, respectively, compared to $302,000 for both of the corresponding periods in 2010.

(2)

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, 2011 and 2010, respectively. In February 2011, Pfizer acquired King Pharmaceuticals (King) and thereby assumed the rights and obligations of King under the agreements we formerly had in place with King; accordingly amounts attributed to King are now shown as Pfizer figures.

(3) Amounts related to the ratable recognition of upfront fees were $308,000 and $617,000 for the three and six months ended June 30, 2011 and 2010, respectively.

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Comprehensive Loss

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

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Net loss	$ (5,245)	$ (6,309)	$ (11,602)	$ (12,935)
Net change in unrealized gain on available-for-sale investments, net of tax	3	(5)	17	(10)
Comprehensive loss	$ (5,242)	$ (6,314)	$ (11,585)	$ (12,945)

Accumulated other comprehensive income as of June 30, 2011 and December 31, 2010 is entirely comprised of net unrealized gains on available-for-sale securities.

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.

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Outstanding dilutive securities not included in diluted net loss per share				
Options to purchase common stock	21,152	19,228	21,466	19,652
Warrants	1	1	1	1
Total	21,153	19,229	21,467	19,653

Recent Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05 *Comprehensive Income - Presentation of Comprehensive Income*. This Update is intended to increase the prominence of items reported in other comprehensive income (OCI) by eliminating the option to present components of OCI as part of the statement of changes in stockholders equity. The amendments in this standard require that all non-owner changes in stockholders equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. Under either method, adjustments must be displayed for items that are reclassified from OCI to net income in the financial statements where the components of net income and the components of OCI are presented. This guidance does not affect the underlying accounting for components of OCI, but will change the presentation of our financial statements. The Company will adopt this authoritative guidance retrospectively in the first quarter of our fiscal year 2012.

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.

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

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Research and development expenses reimbursable by Hospira	$ 1,932	$ 445	$ 4,039	$ 445
Research and development expenses reimbursable by the Company				
Net payable to Hospira	$	$	$	$
Net receivable from Hospira	$ 1,932	$ 445	$ 4,039	$ 445

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, 2011 were $33.7 million under this agreement.

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Ratable recognition of upfront payment	$ 906	$ 302	$ 1,813	$ 302
Research and development expenses reimbursable by Hospira	1,932	445	4,039	445
Total collaborative research and development revenue	$ 2,838	$ 747	$ 5,852	$ 747

Agreement with Alpharma Ireland Limited, an affiliate of Alpharma Inc. (Alpharma) (acquired by King which subsequently was acquired by Pfizer)

Effective October 2008, the Company and Alpharma entered into a development and license agreement granting Alpharma the exclusive worldwide rights to develop and commercialize ELADUR®, DURECT s investigational transdermal bupivacaine patch. As a result of the acquisition of Alpharma by King in December 2008, King assumed the rights and obligations of Alpharma under the agreement. In February 2011, Pfizer acquired King and thereby assumed the rights and obligations of King under the agreements we formerly had in place with King; accordingly amounts attributed to King are now shown as Pfizer figures.

The following table provides a summary of collaborative research and development revenue recognized under this agreement with regard to ELADUR (in thousands). The cumulative aggregate payments received by the Company as of June 30, 2011 were $28.8 million under this agreement.

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Ratable recognition of upfront payment	$ 804	$ 804	$ 1,609	$ 1,609
Research and development expenses reimbursable by Pfizer	290	765	1,045	1,725
Total collaborative research and development revenue	$ 1,094	$ 1,569	$ 2,654	$ 3,334

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 and February 2011. 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.

Prior to the amendment in February 2011, the agreement provided for the two parties to jointly direct and equally fund the non-clinical and Chemistry, Manufacturing, and Controls (CMC) activities for POSIDUR for the U.S. and E.U. territories. The 2011 amendment now provides that during the period commencing from January 1, 2011 until a specified period after the results are delivered from DURECT to Nycomed from DURECT s U.S. Phase III clinical trial for POSIDUR referred to as BESST (Bupivacaine Effectiveness and Safety in SABER Trial) (such period the Interim Period), DURECT shall assume full funding responsibility and final decision making authority for these activities. Furthermore, during this Interim Period, Nycomed s development and commercialization responsibility relating to POSIDUR for the territory licensed to Nycomed shall be confined to bringing its E.U. Phase IIb Clinical Trial in shoulder surgery to a full completion. Unless the Agreement is otherwise terminated, at the conclusion of the Interim Period, under the 2011 amendment, Nycomed would resume joint control and shared funding responsibility with

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DURECT for the non-clinical and Chemistry, Manufacturing, and Controls (CMC) activities for POSIDUR for the U.S. and E.U. territories. Prior to the Amendment, Nycomed had the right to terminate the Agreement after specified periods after data was received from certain clinical trials of POSIDUR in the E.U. and the U.S., including BESST. The foregoing right was modified by the 2011 amendment to provide that Nycomed may exercise its right to terminate the agreement at its sole election if BESST data is not available by December 31, 2011.

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

There were no research and development expenses reimbursable by Nycomed or by the Company in the three and six months ended June 30, 2011.

The following table provides 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) in the three months and six months ended June 30, 2010:

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

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, 2011 were $36.3 million under this agreement. In addition, the cumulative aggregate payments paid by the Company to Nycomed were $9.0 million as of June 30, 2011.

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Ratable recognition of upfront payment	$ 308	$ 308	$ 617	$ 617
Research and development expenses reimbursable by Nycomed		287		287
Total collaborative research and development revenue	$ 308	$ 595	$ 617	$ 904

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 $21,000 and $43,000 for the three and six months ended June 30, 2011, respectively, compared to $27,000 and $728,000 for the corresponding periods in 2010. The cumulative aggregate payments received by the Company from Pain Therapeutics as of June 30, 2011 were $32.7 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. Accordingly, King was substituted in lieu of Pain Therapeutics with respect to interactions with the Company in its performance of those activities including the obligation to pay the Company with respect to all REMOXY-related costs

incurred by the Company. In February 2011, Pfizer acquired King and thereby assumed the rights and obligations of King with respect to REMOXY; accordingly amounts attributed to King are now shown as Pfizer figures.

Total collaborative research and development revenue recognized for REMOXY-related work performed by the Company for Pfizer was $4,000 and $61,000 for the three and six months ended June 30, 2011, respectively, compared to $1.1 million and $1.9 million for the corresponding periods in 2010. 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 (now Pfizer) as of June 30, 2011 were $5.2 million under this agreement.

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Long Term Supply Agreement with King (now Pfizer)

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 February 2011, Pfizer acquired King and thereby assumed the rights and obligations of King under the agreements we formerly had in place with King; accordingly amounts attributed to King are now shown as Pfizer figures.

In the three months ended June 30, 2011 and 2010, the Company recognized no product revenue related to these excipients for REMOXY. In the six months ended June 30, 2011 and 2010, the Company recognized zero and $551,000 of product revenue related to a key excipient for REMOXY. The product revenue in the six months ended June 30, 2010 was 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 Pfizer in the six months ended June 30, 2011 and 2010, respectively. Total revenues recognized related to these excipients were zero in the three and six months ended June 30, 2011, compared to zero and $961,000 for the corresponding periods in 2010. The associated costs of goods sold were zero in the three and six months ended June 30, 2011, compared to zero and $315,000 for the corresponding periods in 2010.

Note 3. Financial Instruments

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 Company s financial instruments are valued using quoted prices in active markets or based upon other observable inputs. Money market funds are classified as Level 1 financial assets. Certificates of deposit, commercial paper, corporate debt securities, and U.S. Government agency securities are classified as Level 2 financial assets. The fair value of the Level 2 assets is estimated using pricing models using current observable market information for similar securities.

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The following is a summary of available-for-sale securities as of June 30, 2011 and December 31, 2010 (in thousands):

	June 30, 2011			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 103	$	$	$ 103
Certificates of deposit	1,917	1		1,918
Commercial paper	7,301	1		7,302
Corporate debt	1,652	6		1,658
U.S. Government agencies	22,295	16	(1)	22,310
	$ 33,268	$ 24	$ (1)	$ 33,291
Reported as:				
Cash and cash equivalents	$ 1,253	$	$	$ 1,253
Short-term investments	29,226	22	(1)	29,247
Long-term investments	1,922	2		1,924
Long-term restricted investments	867			867
	$ 33,268	$ 24	$ (1)	$ 33,291

	December 31, 2010			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 502	$	$	$ 502
Certificates of deposit	1,282			1,282
Commercial paper	11,404	1		11,405
Corporate debt	2,611	3		2,614
U.S. Government agencies	29,447	10	(8)	29,449
	$ 45,246	$ 14	$ (8)	$ 45,252
Reported as:				
Cash and cash equivalents	$ 6,117	$	$	$ 6,117
Short-term investments	34,999	12	(6)	35,005
Short-term restricted investments	66			66
Long-term investments	3,197	2	(2)	3,197
Long-term restricted investments	867			867
	$ 45,246	$ 14	$ (8)	$ 45,252

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The following is a summary of the cost and estimated fair value of available-for-sale securities at June 30, 2011, by contractual maturity (in thousands):

	June 30, 2011	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 31,346	$ 31,367
Mature after one year through five years	1,922	1,924
	$ 33,268	$ 33,291

There were no securities that have had an unrealized loss for more than 12 months as of June 30, 2011 and December 31, 2010.

As of June 30, 2011, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered to be temporary. The Company believes that it is more-likely-than-not that investments in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value.

Note 4. Stock-Based Compensation

As of June 30, 2011, the Company has four stock-based employee compensation plans. The employee stock-based compensation cost that has been included in the statements of operations was $1.7 million and $3.5 million for the three and six months ended June 30, 2011, respectively, compared to $2.0 million and $4.1 million for the corresponding periods in 2010.

As of June 30, 2011 and December 31, 2010, $49,000 and $44,000, respectively, of stock-based compensation cost was capitalized in inventory on the Company s balance sheets.

The Company uses the Black-Scholes option pricing model to value its stock options. The expected life computation is based on historical exercise patterns and post-vesting termination behavior. The Company considered its historical volatility in developing its estimate of expected volatility.

The Company used the following assumptions to estimate the fair value of options granted and shares purchased under its employee stock purchase plan for the three and six months ended June 30, 2011 and 2010:

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Stock options				
Risk-free rate	2.1-2.4%	2.1-2.4%	2.1-2.7%	2.1-2.92%
Expected dividend yield				
Expected life of option (in years)	6.25	6	6.25	6
Volatility	73-75%	82-83%	73-75%	82-83%
Forfeiture rate	6.1%	7.0%	6.1%	7.0%

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Employee Stock Purchase Plan				
Risk-free rate	0.1-1.0%	0.2-1.0%	0.1-1.0%	0.2-1.5%
Expected dividend yield				

Expected life of option (in years)	1.25	1.25	1.25	1.25
Volatility	50-163%	59-101%	50-163%	59-150%

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Note 5. Subsequent Events

On July 11, 2011, the Company and Zogenix, Inc., (Zogenix), entered into a Development and License Agreement (the License Agreement). Under the License Agreement, Zogenix will be responsible for the clinical development and commercialization of a proprietary, long-acting injectable formulation of risperidone using the Company s SABER controlled-release formulation technology in combination with Zogenix s DosePro® needle-free, subcutaneous drug delivery system. DURECT will be responsible for non-clinical, formulation and CMC development activities. The Company will be reimbursed by Zogenix for its research and development efforts on the product.

Zogenix paid a non-refundable upfront fee to the Company of $2.25 million in July 2011. The $2.25 million upfront fee will be recognized as collaborative research and development revenue ratably over the term of the Company s continuing involvement with Zogenix with respect to this product candidate. Zogenix is obligated to pay the Company up to $103 million in total future milestone payments with respect to the product subject to and upon the achievement of various development, regulatory and sales milestones. Zogenix is also required to pay a mid single-digit to low double-digit percentage patent royalty on annual net sales of the product determined on a jurisdiction-by-jurisdiction basis. The patent royalty term is equal to the later of the expiration of all DURECT technology patents or joint patent rights in a particular jurisdiction, the expiration of marketing exclusivity rights in such jurisdiction, or 15 years from first commercial sale in such jurisdiction. After the patent royalty term, Zogenix will continue to pay royalties on annual net sales of the product at a reduced rate for so long as Zogenix continues to sell the product in the jurisdiction. Zogenix is also required to pay to the Company a tiered percentage of fees received in connection with any sublicense of the licensed rights.

The Company granted to Zogenix an exclusive worldwide license, with sub-license rights, to the Company intellectual property rights related to the Company s proprietary polymeric and non-polymeric controlled-release formulation technology to make and have made, use, offer for sale, sell and import risperidone products, where risperidone is the sole active agent, for administration by injection in the treatment of schizophrenia, bipolar disorder or other psychiatric related disorders in humans. The Company retains the right to supply Zogenix s Phase 3 clinical trial and commercial product requirements on the terms set forth in the License Agreement.

The Company retains the right to terminate the License Agreement with respect to specific countries if Zogenix fails to advance the development of the product in such country, either directly or through a sublicensee. In addition, either party may terminate the License Agreement upon insolvency or bankruptcy of the other party, upon written notice of a material uncured breach or if the other party takes any act impairing such other party s relevant intellectual property rights. Zogenix may terminate the License Agreement upon written notice if during the development or commercialization of the product, the product becomes subject to one or more serious adverse drug experiences or if either party receives notice from a regulatory authority, independent review committee, data safety monitory board or other similar body alleging significant concern regarding a patient safety issue. Zogenix may also terminate the License Agreement with or without cause, at any time upon prior written notice.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

This Management s Discussion and Analysis of Financial Condition and Results of Operations for the three and six months ended June 30, 2011 and 2010 should be read in conjunction with our annual report on Form 10-K for the year ended December 31, 2010 filed with the Securities and Exchange Commission and Risk Factors section included elsewhere in this Form 10-Q. This Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. When used in this report, the words believe, anticipate, intend, plan, estimate, expect, may, will, could, would, ca similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations and beliefs. Any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors.

Forward-looking statements made in this report include, for example, statements about:

potential regulatory approval of REMOXY or any of our other product candidates;

the progress of our third-party collaborations, including estimated milestones;

our intention to seek, and ability to enter into strategic alliances and collaborations;

the potential benefits and uses of our products;

responsibilities of our collaborators, including the responsibility to make cost reimbursement, milestone, royalty and other payments to us, and our expectations regarding our collaborators plans with respect to our products;

our responsibilities to our collaborators, including our responsibilities to conduct research and development, clinical trials, protect intellectual property and manufacture products;

market opportunities for products in our product pipeline;

the number of patients enrolled and the timing of patient enrollment in clinical trials;

the progress and results of our research and development programs;

requirements for us to purchase supplies and raw materials from third parties, and the ability of third parties to provide us with required supplies and raw materials;

the results and timing of clinical trials and the commencement of future clinical trials;

conditions for obtaining regulatory approval of our product candidates;

submission and timing of applications for regulatory approval;

the impact of FDA, DEA, EMEA and other government regulation on our business;

the impact of potential Risk Evaluation and Mitigation Strategies on our business;

uncertainties associated with obtaining and protecting patents and other intellectual property rights, as well as avoiding the intellectual property rights of others;

products and companies that will compete with the products we license to third-party collaborators;

the possibility we may commercialize our own products and build up our commercial, sales and marketing capabilities and other required infrastructure;

our intention to develop additional manufacturing capabilities and our expectations regarding the number of employees involved in manufacturing;

our employees, including the number of employees and the continued services of key management, technical and scientific personnel;

our future performance, including our anticipation that we will not derive meaningful revenues from our pharmaceutical systems for at least twelve months and our expectations regarding our ability to achieve profitability;

sufficiency of our cash resources, anticipated capital requirements and capital expenditures and our need for additional financing;

our ability to utilize our equity line of credit facility with Azimuth Opportunity Ltd.;

our expectations regarding marketing expenses, research and development expenses, and selling, general and administrative expenses;

the composition of future revenues; and

accounting policies and estimates, including revenue recognition policies.

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Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of such forward looking statements and the potential risks and uncertainties that may impact upon their accuracy, see the Risk Factors section of this Quarterly Report on Form 10-Q and the Overview section of this Management s Discussion and Analysis of Financial Condition and Results of Operations. These forward-looking statements reflect our view only as of the date of this report. We undertake no obligations to update any forward-looking statements. You should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission.

Overview

We are a specialty pharmaceutical company focused on the development of pharmaceutical products based on our proprietary drug delivery technology platforms. Our product pipeline currently consists of seven investigational drug candidates in clinical development, with one program the subject of a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA), one program in Phase III, two programs in Phase II and three programs in Phase I. The more advanced programs are all in the field of pain management and we believe that each of these targets large market opportunities with product features that are differentiated from existing therapeutics. We have other programs underway in fields outside of pain management, including several efforts underway which seek to improve the administration of biotechnology agents such as proteins and peptides.

A central aspect of our business strategy involves advancing multiple product candidates at one time, which is enabled by leveraging our resources with those of corporate collaborators. Thus, certain of our programs are currently licensed to corporate collaborators on terms which typically call for our collaborator to fund all or a substantial portion of future development costs and then pay us milestone payments based on specific development or commercial achievements plus a royalty on product sales. At the same time, we have retained the rights to other programs, which are the basis of future collaborations and which over time may provide a pathway for us to develop our own commercial, sales and marketing organization.

Additional details of these programs and related strategic agreements are contained in our annual report on Form 10-K for the year ended December 31, 2010 and in Note 2 of our condensed financial statements included in Part 1 Item 1 above.

REMOXY® and other ORADUR-based opioid products licensed to Pain Therapeutics

In December 2002, we entered into an agreement with Pain Therapeutics, amended in December 2005, under which we granted Pain Therapeutics the exclusive, worldwide right to develop and commercialize selected long-acting oral opioid products using our ORADUR technology incorporating four specified opioid drugs. The first product being developed under the collaboration is REMOXY, a novel long-acting oral formulation of the opioid oxycodone targeted to decrease the potential for oxycodone abuse. REMOXY is intended for patients with chronic pain. In November 2005, Pain Therapeutics and King entered into collaboration and license agreements for the development and commercialization of REMOXY by King. In February 2011, Pfizer acquired King and thereby assumed the rights and obligations of King with respect to REMOXY and to the other ORADUR-based opioids.

An NDA was submitted in June 2008 by Pain Therapeutics, in response to which the FDA provided a Complete Response Letter in December 2008. King took over the NDA from Pain Therapeutics and resubmitted the NDA in December of 2010. On June 23, 2011, a Complete Response Letter from the FDA was received by Pfizer on the resubmission to the NDA for REMOXY. The FDA s June 2011 Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. It is our understanding that certain drug lots showed inconsistent release performance during in vitro testing and it is not known at this time whether this is an artifact of the testing method or a manufacturing deficiency. We understand that Pfizer is working to evaluate the issues described in the Complete Response Letter, has efforts underway to resolve these issues and plans to have further discussions with the FDA about them. Sufficient information does not yet exist to accurately assess the time required to resolve the concerns raised in the FDA s Complete Response Letter. Resolution of these issues and potential regulatory approval of REMOXY in the U.S. is unlikely to occur in less than one year, and could be delayed significantly longer than a year.

Phase I clinical trials have been conducted for two of the other ORADUR-based products (hydrocodone and hydromorphone), and an Investigational New Drug (IND) application has been accepted by the FDA for the fourth ORADUR-based opioid (oxymorphone).

NOTE: POSIDUR , SABER , TRANSDERM®, ORADUR®, ELADUR®, DURIN®, CHRONOGESIC®, MICRODUR , ALZET® and LACTEL® are trademarks of DURECT Corporation. Other trademarks referred to belong to their respective owners.

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POSIDUR (SABER -Bupivacaine)

Our post-operative pain relief depot, POSIDUR, is a sustained release injectable using our SABER delivery system to deliver bupivacaine, an off-patent anesthetic agent. SABER is a patented controlled drug delivery technology that can be formulated for systemic or local administration of drugs via the parenteral (i.e., injectable) route. POSIDUR is designed to be administered to a surgical site at the time of surgery for post-operative pain relief and is intended to provide local analgesia for up to 3 days, which we believe coincides with the time period of the greatest need for post surgical pain control in most patients.

We have entered into two strategic collaborations with respect to POSIDUR. In November 2006, we entered into a development and license agreement with Nycomed (amended in February 2010 and February 2011) under which we licensed to Nycomed the exclusive commercialization rights to POSIDUR for the European Union (E.U.) and certain other countries. In June 2010, we entered into a development and license agreement with Hospira to develop POSIDUR for the U.S. and Canada and under which we licensed to Hospira exclusive commercialization rights in the U.S. and Canada.

In January 2010, we announced that we had commenced BESST (Bupivacaine Effectiveness and Safety in SABER Trial), which is intended to be the pivotal Phase III clinical trial in the U.S. BESST is an international, multi-center, randomized, double-blind, controlled trial evaluating the safety, efficacy, and pharmacokinetics of POSIDUR in approximately 300 patients undergoing a variety of general abdominal surgical procedures. Eligible patients will be randomly assigned to one of three cohorts:

Cohort 1: An active comparator cohort in which patients are randomized to receive either POSIDUR 5.0 mL or commercially available Bupivacaine HCl solution after laparotomy.

Cohort 2: An active comparator cohort in which patients are randomized to receive either POSIDUR 5.0 mL or commercially available Bupivacaine HCl solution after laparoscopic cholecystectomy.

Cohort 3: A double blind, placebo controlled cohort in which patients are randomized to receive either POSIDUR 5.0 mL or SABER-Placebo after laparoscopically-assisted colectomy.

Efficacy evaluation in the BESST trial will encompass a number of parameters. The two co-primary efficacy endpoints for Cohort 3 will be mean pain intensity on movement (normalized) Area Under the Curve (AUC) during the period 0-72 hours post-dose and mean total morphine equivalent opioid dose for supplemental analgesia during a period 0-72 hours post-dose. An adaptive feature of BESST allows for increasing the patient sample size in Cohort 3 based on pooled and blinded analysis of the variability of data within BESST; that analysis has taken place and we do not intend to increase the size of the study. The purpose of Cohorts 1 and 2 is to give us additional experience with the use of POSIDUR in a broader group of surgeries and patients. As of August 3, 2011, we had dosed 293 patients out of our target of 304. At our current enrollment rate, we expect to complete enrollment in approximately a month. We continue to anticipate reporting top-line data in the fourth quarter of 2011.

In April 2010, we had a FDA interaction which increased our confidence that the BESST design and overall NDA strategy, subject to data review from the entire POSIDUR development program, addresses the FDA s comments provided during past interactions regarding safety and evaluation of a diverse patient population that is likely to be exposed to the marketed product.

ELADUR ® (TRANSDUR -Bupivacaine)

Our transdermal bupivacaine patch (ELADUR) uses our proprietary TRANSDUR transdermal technology and is intended to provide continuous delivery of bupivacaine for up to three days from a single application, as compared to a wearing time limited to 12 hours with currently available lidocaine patches. In December 2007, we announced positive results from a 60 patient Phase IIa study for post-herpetic neuralgia (PHN or post-shingles pain).

Effective in October 2008, we entered into a development and license agreement with Alpharma granting Alpharma the exclusive worldwide rights to develop and commercialize ELADUR. Alpharma paid us an upfront license fee of $20 million in October 2008. Alpharma was acquired by King in December 2008 and, as a result, the rights and obligations of the agreement were assumed by King. In February 2011, Pfizer acquired King and thereby assumed the rights and obligations of King with respect to ELADUR.

We reported top line data from a Phase II clinical trial conducted by King for ELADUR in April 2011. In this study of 263 patients suffering from chronic low back pain, the primary efficacy endpoint of demonstrating a positive treatment difference for the mean change in pain intensity scores from baseline to the mean of weeks 11 and 12 between ELADUR as compared to placebo was not met. Complete data analysis is on-going. We and Pfizer are continuing to analyze these data and will work together to determine next steps for ELADUR.

TRANSDUR -Sufentanil

Our transdermal sufentanil patch (TRANSDUR-Sufentanil) uses our proprietary TRANSDUR delivery system to deliver sufentanil, an opioid medication. TRANSDUR-Sufentanil is designed to provide extended chronic pain relief for up to seven days, as

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compared to the two to three days of relief provided with currently available opiate patches. We anticipate that the small size of our sufentanil patch (potentially as small as 1/5th the size of currently marketed transdermal fentanyl patches for a therapeutically equivalent dose) may offer improved convenience and compliance for patients. An end-of-Phase II meeting was conducted with the FDA in February 2009 and we have recently had discussions with the FDA and regulatory agencies in several major European countries to better understand development requirements for U.S. and European approval. We continue to have discussions with potential partners regarding licensing development and commercialization rights to this program to which we hold worldwide rights.

ORADUR-ADHD Program

We are developing a drug candidate (ORADUR-ADHD) based on DURECT s ORADUR Technology for the treatment of ADHD. This drug candidate is intended to provide once-a-day dosing with added tamper-resistant characteristics to address common methods of abuse and misuse of these types of drugs.

In August 2009, we entered into a development and license agreement with Orient Pharma Co., Ltd., a diversified multinational pharmaceutical, healthcare and consumer products company with headquarters in Taiwan, under which we granted to Orient Pharma development and commercialization rights in certain defined Asian and South Pacific countries to ORADUR-ADHD. DURECT retains rights to North America, Europe, Japan and all other countries not specifically licensed to Orient Pharma. In the second quarter of 2011, we and Orient Pharma completed a Phase I pharmacokinetic study with multiple formulations. We are continuing to optimize the formulation and are planning next steps in our ORADUR-ADHD program.

Other Programs

Relday (risperidone) Program

On July 11, 2011, we and Zogenix, Inc. (Zogenix) entered into a development and license agreement for the purpose of developing and commercializing Relday, a proprietary, long-acting injectable formulation of risperidone using our SABER-controlled release formulation technology in combination with Zogenix s DosePro® needle-free, subcutaneous drug delivery system. Risperidone is one of the most widely prescribed medications used to treat the symptoms of schizophrenia and bipolar I disorder in adults and teenagers 13 year of age and older. Under the agreement, we granted Zogenix worldwide development and commercialization rights to Relday. Zogenix expects to initiate clinical development of Relday in early 2012.

Biologics Programs

The proteins and genes identified by the biotechnology industry are large, complex, intricate molecules, and many are unsuitable as drugs. If these molecules are given orally, they are often digested before they can have an effect; if given by injection, they may be destroyed by the body s natural processes before they can reach their intended sites of action. The body s natural elimination processes require frequent, high dose injections that may result in unwanted side effects. As a result, the development of biotechnology molecules for the treatment of human diseases has been limited, and advanced drug delivery systems such as we possess are required to realize the full potential of many of these protein and peptide drugs. We have active programs underway to apply our drug delivery systems to various biotechnology drugs and drug candidates, and have entered into a number of feasibility studies with biotechnology and pharmaceutical companies to test their products in our systems.

Research and Development Programs in Other Therapeutic Categories

We have underway a number of research programs covering diseases and medical conditions other than pain. Such programs include various diseases and disorders of the central nervous system, cardiovascular disease and cancer. In conducting our research programs and determining which particular efforts to prioritize for formal development, we employ a rigorous opportunity assessment process that takes into account the unmet medical need, commercial opportunity, technical feasibility, clinical viability, intellectual property considerations, and the development path including costs to achieve various critical milestones.

Product Revenues

We also currently generate product revenue from the sale of three product lines:

ALZET® osmotic pumps for animal research use;

LACTEL® biodegradable polymers which are used by our customers as raw materials in their pharmaceutical and medical products; and

certain key excipients that are included in REMOXY.

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Operating Results

Since our inception in 1998, we have had a history of operating losses. At June 30, 2011, we had an accumulated deficit of $348.4 million and our net losses were $5.2 million and $11.6 million for the three and six months ended June 30, 2011, respectively. Our net losses were $22.9 million, $30.3 million and $43.9 million for the years ended December 31, 2010, 2009 and 2008, respectively. These losses have resulted primarily from costs incurred to research and develop our product candidates and to a lesser extent, from selling, general and administrative costs associated with our operations and product sales. We currently expect research and development expenses to be lower in the second half of 2011 than the first half of 2011 due to the timing of clinical trial activities. We expect selling, general and administrative expenses to remain comparable to recent quarters in the near future. We do not anticipate meaningful revenues from our pharmaceutical systems, should they be approved, for at least the next twelve months. Therefore, we expect to incur continuing losses and negative cash flow from operations for the foreseeable future.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. The most significant estimates and assumptions relate to revenue recognition, the recoverability of our long-lived assets, including goodwill and other intangible assets, accrued liabilities, contract research liabilities, inventories and stock-based compensation. Actual amounts could differ significantly from these estimates. There have been no material changes to our critical accounting policies and estimates as compared to the disclosures in our annual report on Form 10-K for the year ended December 31, 2010 except with respect to revenue recognition.

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 our part exists, the price is fixed or determinable and the collectability of the amounts owed is reasonably assured. We enter into license and collaboration agreements under which we may receive upfront license fees, research funding and contingent milestone payments and royalties. The accounting standards contain a presumption that separate contracts entered into at or near the same time with the same entity or related parties were negotiated as a package and should be evaluated as a single agreement.

In the first quarter of 2011, we adopted ASU No. 2009-13, Revenue Recognition *Multiple Deliverable Revenue Arrangements* (ASU 2009-13) for multiple deliverable revenue arrangements, on a prospective basis, for applicable transactions originating or materially modified on or subsequent to January 1, 2011. ASU 2009-13 provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update changes the requirements for establishing separate units of accounting in a multiple element arrangement and establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable is based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. Implementation of ASU 2009-13 has had no impact on reported revenue as compared to revenue under previous guidance. Under ASU 2009-13, we may be required to exercise considerable judgment in determining the estimated selling price of delivered items under new agreements and our revenue under new agreements may be more accelerated as compared to the prior accounting standard. For multiple element arrangements entered into prior to January 1, 2011, we determined whether the elements had value on a stand-alone basis and whether there was objective and reliable evidence of fair value. When the delivered element did not have stand-alone value or there was insufficient evidence of fair value for the undelivered element(s), we recognized the consideration for the combined unit of accounting in the same manner as the revenue was recognized for the final deliverable, which was generally ratably over the longest period of involvement. For example, 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 our 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 us and our third-party collaborators. Returns or credits related to the sale of products have not had a material impact on our revenues or net loss.

Research and development revenue related to services performed under the collaborative arrangements with our corporate collaborators is recognized as the related research and development services are performed and the collectability of the amounts owed is reasonably assured. 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

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of the respective agreements. Deferred revenue may result when we do not expend the required level of effort during a specific period in comparison to funds received under the respective agreement. Pursuant to ASC 808-10, *Collaborative Arrangements*, for joint control and funding development activities, we recognize revenue from the net reimbursement of the research and development expenses from our partners and record the net payment of research and development expenses to our partners as additional research and development expense.

Milestone payments under collaborative arrangements are recognized as revenue upon achievement of the at risk milestone events, which represent the culmination of the earnings process related to that milestone. 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 the amounts of the payments assigned thereto are commensurate with the milestone achieved. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone payment.

Inventories

Inventories include certain excipients that are sold to a customer and included in products awaiting regulatory approval. These inventories are capitalized based on management s judgment of probable sale prior to their expiration date which in turn is based on non-binding forecasts from our customer. The valuation of inventory requires us to estimate the value of inventory that may become expired prior to use. We may be required to expense previously capitalized inventory costs upon a change in our judgment, due to, among other potential factors, a denial or delay of approval of our customer s product by the necessary regulatory bodies, or new information that suggests that the inventory will not be saleable. In addition, these circumstances may cause us to record a liability related to minimum purchase agreements that we have in place for raw materials. As of June 30, 2011, we had $1.1 million in inventory related to excipients that are included in REMOXY and other programs. In addition, we have future purchase commitments totaling $500,000 per year through 2018. In the event that we determine that we will not utilize all of these materials, there could be a potential write-off related to this inventory and for future purchase commitments.

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Results of Operations

Three and six months ended June 30, 2011 and 2010

Collaborative research and development and other revenue

We recognize revenues from collaborative research and development activities and service contracts. Collaborative research and development revenue primarily represents net reimbursement of qualified expenses related to the collaborative agreements with various third parties to research, develop and commercialize potential products using our drug delivery technologies, revenue recognized from ratable recognition of upfront fees and milestone payments in connection with our collaborative agreements.

We expect our collaborative research and development revenue to fluctuate in future periods pending our efforts to enter into potential new collaborations and our existing third party collaborators commitment to and progress in the research and development programs. The collaborative research and development and other revenues associated with our major collaborators are as follows (in thousands):