ASURE SOFTWARE INC
Form 10-Q
May 12, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

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: 0-20008

ASURE SOFTWARE, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	74-2415696
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
110 Wild Basin Road, Suite 100 Austin, Texas	78746
(Address of Principal Executive Offices)	(Zip Code)

(512) 437-2700
(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 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 check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company (as defined in Rule 12b-2 of the Exchange Act).

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 May 9, 2016, the registrant had outstanding 6,291,596 shares of its Common Stock, $0.01 par value.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ASURE SOFTWARE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands)

	March 31, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 553	$ 1,158
Accounts and note receivable, net of allowance for doubtful accounts of $141 and $145 at March 31, 2016 and December 31, 2015, respectively	4,472	4,671
Inventory	634	784
Prepaid expenses and other current assets	928	1,072
Total current assets before funds held for clients	6,587	7,685
Funds held for clients	28,608	-
Total current assets	35,195	7,685
Property and equipment, net	2,242	2,212
Goodwill	26,556	17,436
Intangible assets, net	14,242	6,026
Other assets	474	458
Total assets	$ 78,709	$ 33,817
Liabilities and stockholders' equity		
Current liabilities:		
Current portion of notes payable, net of debt issuance cost	$ 4,696	$ 909
Accounts payable	1,936	2,670
Accrued compensation and benefits	854	715
Other accrued liabilities	1,816	1,181
Deferred revenue	10,523	10,803
Total current liabilities before client fund obligations	19,825	16,278
Client fund obligations	28,608	-
Total current liabilities	48,433	16,278
Long-term liabilities:		
Deferred revenue	939	947
Notes payable, net of debt issuance cost	26,691	12,384
Other liabilities	407	490
Total long-term liabilities	28,037	13,821
Total liabilities	76,470	30,099
Stockholders' equity:		
Preferred stock, $.01 par value; 1,500 shares authorized; none issued or outstanding	-	-
Common stock, $.01 par value; 11,000 shares authorized; 6,676 and 6,674 shares issued, 6,292 and 6,290 shares outstanding at March 31, 2016 and December 31, 2015, respectively	67	67
Treasury stock at cost, 384 shares at March 31, 2016 and December 31, 2015	(5,017)	(5,017)
Additional paid-in capital	279,689	279,649
Accumulated deficit	(272,457)	(270,903)

Accumulated other comprehensive loss	(43)	(78)
Total stockholders' equity	2,239	3,718
Total liabilities and stockholders' equity	$78,709	$33,817

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

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ASURE SOFTWARE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Amounts in thousands, except share and per share data)
(Unaudited)

	FOR THE THREE MONTHS ENDED MARCH 31,	
	2016	2015
Revenues:		
Cloud revenue	$3,862	$3,371
Hardware revenue	693	585
Maintenance and support revenue	1,239	1,566
On premise software license revenue	140	166
Professional services revenue	788	644
Total revenues	6,722	6,332
Cost of Sales	1,730	1,652
Gross margin	4,992	4,680
Operating expenses		
Selling, general and administrative	4,327	3,449
Research and development	811	738
Amortization of intangible assets	377	505
Total operating expenses	5,515	4,692
Loss from operations	(523)	(12)
Other income (loss)		
Interest income	10	-
Loss on debt refinancing	-	(110)
Foreign currency gain (loss)	1	(11)
Interest expense and other	(292)	(282)
Interest expense - amortization of original issue discount (OID)	-	(8)
Acquisition costs	(706)	-
Total other loss	(987)	(411)
Loss from operations before income taxes	(1,510)	(423)
Income tax provision	(44)	(60)
Net loss	$(1,554)	$(483)
Other comprehensive income (loss):		
Foreign currency translation gain	35	6
Other comprehensive loss	$(1,519)	$(477)
Basic and diluted net loss per share		
Basic	$(0.25)	$(0.08)
Diluted	$(0.25)	$(0.08)
Weighted average basic and diluted shares		
Basic	6,290,000	6,055,000

Diluted	6,290,000	6,055,000

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

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ASURE SOFTWARE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)
(Unaudited)

	FOR THE THREE MONTHS ENDED MARCH 31,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(1,554)	$(483)
Adjustments to reconcile net loss to net cash provided by operations:		
Depreciation and amortization	716	785
Provision for doubtful accounts	10	15
Share-based compensation	39	37
Other	-	8
Changes in operating assets and liabilities:		
Accounts and note receivable	723	401
Inventory	150	(93)
Prepaid expenses and other assets	187	(195)
Accounts payable	(798)	648
Accrued expenses and other long-term obligations	(748)	(65)
Deferred revenue	637	(512)
Net cash provided by operating activities	(638)	546
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisitions net of cash acquired	(12,000)	-
Purchases of property and equipment	(5)	(658)
Disposals of property and equipment	-	26
Collection of note receivable	(11)	-
Net change in funds held for clients	(12,189)	-
Net cash used in investing activities	(24,205)	(632)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from notes payable	12,500	1,000
Payments on notes payable	-	(887)
Payments on amendment of senior notes payable	-	(75)
Debt financing fees	(438)	-
Payments on capital leases	(53)	(51)
Net proceeds from exercise of stock options	3	42
Net change in client fund obligations	12,189	-
Net cash provided by financing activities	24,201	29
Effect of foreign exchange rates	37	11
Net decrease in cash and cash equivalents	(605)	(46)
Cash and cash equivalents at beginning of period	1,158	320

Cash and cash equivalents at end of period	$553	$274
SUPPLEMENTAL INFORMATION:		
Cash paid for:		
Interest	$22	$197
Non-cash Investing and Financing Activities:		
Subordinated Notes Payable- Mangrove acquisition	$6,000	-

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

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ASURE SOFTWARE, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(Amounts in thousands, except share and per share data unless otherwise noted)

NOTE 1 – THE COMPANY AND BASIS OF PRESENTATION

Asure Software, Inc., a Delaware corporation, is a provider of cloud-based software-as-a-service ("SaaS") time and labor management and Agile Workplace management solutions that enable organizations to manage their office environments as well as their human resource and payroll processes effectively and efficiently. Asure develops, markets, sells and supports its offerings worldwide through its principal office in Austin, Texas and through additional offices in Dedham, Massachusetts; Traverse City, Michigan and London, United Kingdom.

We have prepared the accompanying unaudited condensed consolidated financial statements in accordance with the rules and regulations of the Securities and Exchange Commission and accordingly, they do not include all information and footnotes required under U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, these interim financial statements contain all adjustments, consisting of normal, recurring adjustments, necessary for a fair presentation of our financial position as of March 31, 2016 and December 31, 2015, the results of operations for the three months ended March 31, 2016 and 2015, and the cash flows for the three months ended March 31, 2016 and 2015.

You should read these condensed consolidated financial statements in conjunction with our audited consolidated financial statements and notes thereto filed with the Securities and Exchange Commission in our annual report on Form 10-K for the fiscal year ended December 31, 2015. The results for the interim periods are not necessarily indicative of results for a full fiscal year.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

CASH AND CASH EQUIVALENTS

Cash and cash equivalents include cash deposits and highly liquid investments with an original maturity of three months or less when purchased.

LIQUIDITY

As of March 31, 2016, Asure's principal sources of liquidity consisted of approximately $553 of cash and cash equivalents, future cash generated from operations and $3,000 available for borrowing under our Wells Fargo revolver discussed in Note 6 – Notes Payable. We believe that we have and/or will generate sufficient cash for our short- and long-term needs, including meeting the requirements of our term loan, and the related debt covenant requirements. We continue to seek reductions in our expenses as a percentage of revenue on an annual basis and thus may utilize our cash balances in the short-term to reduce long-term costs. Based on current internal projections, we believe that we have and/or will generate sufficient cash for our operational needs, including any required debt payments, for at least the next twelve months.

Management is focused on growing our existing product offering, as well as our customer base, to increase our recurring revenues. We are also exploring additional strategic acquisitions in the near future, although we have no agreements to make any acquisition at this time. We expect to fund any future acquisitions with equity, available cash, future cash from operations, or debt from outside sources.

We cannot assure that we can grow our cash balances or limit our cash consumption and thus maintain sufficient cash balances for our planned operations or future acquisitions. Future business demands may lead to cash utilization at levels greater than recently experienced. We may need to raise additional capital in the future. However, we cannot assure that we will be able to raise additional capital on acceptable terms, or at all. Subject to the foregoing, management believes that we have sufficient capital and liquidity to fund and cultivate the growth of our current and future operations for at least the next 12 months and to maintain compliance with the terms of our debt agreements and related covenants or to obtain compliance through debt repayments made with the available cash on hand or anticipated for receipt in the ordinary course of operations.

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ASURE SOFTWARE, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(Amounts in thousands, except share and per share data unless otherwise noted)

RECENT ACCOUNTING PRONOUNCEMENTS

In May 2014, the FASB issued FASB ASU No. 2014-09, “Revenue from Contracts with Customers (Topic 606),” which supersedes the revenue recognition requirements in ASC 605, “Revenue Recognition”. The core principle of ASU 2014-09 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance provides a five-step process to achieve that core principle. ASU 2014-09 requires disclosures enabling users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about contracts with customers, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. In August 2015, the FASB issued FASB ASU No. 2015-14, “Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date”, which deferred the effective date of ASU 2014-09 by one year. ASU 2014-09 is now effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, using one of two retrospective application methods. Early application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. In March 2016, the FASB issued FASB ASU No. 2016-08, “Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)”. ASU 2016-08 clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, “Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing.” ASU 2016-10 clarifies the implementation guidance in Topic 606 for identifying performance obligations and determining when to recognize revenue on licensing agreements for intellectual property. In May 2016, the FASB issued ASU No. 2016-11, “Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting.” ASU 2016-11 rescinds certain SEC staff comments previously made in regard to these ASU’s. We are currently evaluating the effect that the adoption of ASU 2014-09, ASU 2015-14, ASU 2016-08, ASU 2016- 10 and ASU 2016-11 will have on our consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, “Disclosure of Uncertainties About an Entity’s Ability to Continue as a Going Concern,” which requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern (meet its obligations as they become due) within one year after the date that the financial statements are issued. If conditions or events raise substantial doubt about the entity’s ability to continue as a going concern, certain disclosures are required. This ASU is effective for annual reporting periods ending after December 15, 2016, and interim reporting periods thereafter. We adopted the provisions of ASU 2014-15 on January 1, 2016. This adoption did not have any impact on our consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03,” Interest — Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs”. This ASU requires reporting entities to record costs paid to third parties that are directly related to issuing debt, and that otherwise would not be incurred, as a deduction to the corresponding debt for presentation purposes. In addition, in August 2015, FASB issued ASU 2015-15, “Interest — Imputation of Interest (Subtopic 835-30): Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements-Amendments to SEC Paragraphs Pursuant to Staff Announcement at the June 18, 2015 Emerging Issues Task Force ("EITF") Meeting”. Given the absence of authoritative guidance within ASU 2015-03 for debt issuance costs related to line-of-credit arrangements, ASU 2015-15 states the SEC staff would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs

ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. The provisions of each ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. A reporting entity should apply each amendment retrospectively. We adopted ASU 2015-03 on January 1, 2016 for debt issuance costs on our term loan, on a retrospective basis. The impact of adopting ASU 2015-03 on our current period condensed consolidated financial statements was the classification of all deferred financing costs as a deduction to the corresponding debt in addition to the reclassification of deferred financing costs in other current and long term assets to short and long term notes payable as of December 31, 2015, within the condensed consolidated balance sheets to conform to the current period presentation. Other than these reclassifications and additional disclosures, the adoption of ASU 2015-03 did not have an impact on our consolidated financial position, results of operations or cash flows.

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ASURE SOFTWARE, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(Amounts in thousands, except share and per share data unless otherwise noted)

In July 2015, the FASB issued ASU 2015-11, “Simplifying the Measurement of Inventory”. Inventory within the scope of this update is required to be measured at the lower of its cost or net realizable value, with net realizable value being the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. This ASU is effective prospectively for fiscal years and interim periods beginning after December 15, 2016, with early adoption permitted. We are currently assessing the impact of adopting this standards update on our consolidated financial statements.

In September 2015, the FASB issued ASU 2015-16, “Business Combinations: Simplifying the Accounting for Measurement-Period Adjustments,” which requires acquirers to recognize adjustments to provisional amounts identified during the reporting period in which the adjustment amounts are determined. Acquirers should record, in the same period’s financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. Application of the standard, which should be applied prospectively, is required for the annual and interim periods beginning after December 15, 2015. We adopted the provisions of ASU 2015-16 on January 1, 2016. The adoption o achieve profitability;

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sufficiency of our cash resources, anticipated capital requirements and capital expenditures, our ability to comply with covenants of our term loan, and our need for additional financing, including potential sales under our shelf registration statement;

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.

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 and 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 biopharmaceutical company focused on the development of pharmaceuticals based on our proprietary drug delivery technology platforms, new chemical entities derived from our Epigenomic Regulator Program, and our expertise in drug development. 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) for which a Complete Response Letter was received in June 2011, another program the subject of a NDA with the FDA for which a Complete Response Letter was received in February 2014, one program in Phase 3 in Taiwan, one program in Phase 2 and three programs in Phase 1. The most advanced programs are 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 central nervous system disorders, metabolic disorders, cardiovascular disease, acute organ injury, ophthalmic conditions and other chronic diseases.

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, 2014 and in Note 2 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.

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

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Pain Therapeutics submitted an NDA for REMOXY to the FDA in June 2008, and in August 2008 the FDA accepted the NDA and granted priority review. In December 2008, Pain Therapeutics received a Complete Response Letter for its NDA for REMOXY in which the FDA determined that the NDA was not approved. According to Pain Therapeutics, the FDA indicated that additional non-clinical data would be required to support the approval of REMOXY, but the FDA had not requested or recommended additional clinical efficacy studies prior to approval. King assumed responsibility for further development of REMOXY from Pain Therapeutics in March 2009. In July 2009, King met with the FDA to discuss the Complete Response Letter. King took over the NDA from Pain Therapeutics and resubmitted the NDA in December of 2010. In February 2011, King was acquired by Pfizer. 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. Pfizer undertook efforts to resolve these issues. In October 2013, Pfizer stated that, having achieved technical milestones related to manufacturing, they would continue the development program for REMOXY. Following guidance received from the FDA earlier in 2013, Pfizer announced that they were proceeding with the additional clinical studies and other actions required to address the Complete Response Letter. Pfizer stated that these new clinical studies will include, in part, a pivotal bioequivalence study with the modified REMOXY formulation to bridge to the clinical data related to the original REMOXY formulation, and an abuse-potential study with the modified formulation. We understand these studies have been completed, although we have not seen the results. It is possible that the results of such studies will not be satisfactory to the FDA or that they could suggest a lower commercial potential for REMOXY than previously had been expected. In October 2014, Pfizer notified Pain Therapeutics that Pfizer had decided to discontinue development of REMOXY, and that Pfizer would return all rights, including responsibility for regulatory activities, to Pain Therapeutics and that Pfizer would continue ongoing activities under the agreement until the scheduled termination date in April 2015. On April 21, 2015, Pain Therapeutics stated that it had resumed responsibility for REMOXY under the terms of a letter agreement with Pfizer. Pain Therapeutics further stated that Pfizer had started to transfer to Pain Therapeutics documents, data and regulatory responsibilities related to REMOXY, and that they expected the transfer to be substantially completed in the second quarter of 2015. In July 2015, Pain Therapeutics stated that it had substantially completed the transition of REMOXY from Pfizer, and that Pain Therapeutics expected to resubmit the NDA in the first quarter of 2016.

Phase I clinical trials have been conducted for two of the other ORADUR-based opioid product candidates (hydrocodone and hydromorphone), and an Investigational New Drug (IND) application has been accepted by the FDA for the fourth ORADUR-based opioid (oxymorphone). In October 2013, Pain Therapeutics stated that it had regained all rights from Pfizer with respect to the three other ORADUR-based opioid drug candidates (hydrocodone, hydromorphone and oxymorphone). In May 2015, Pain Therapeutics sent a letter to us that provided us with formal written notice that Pain Therapeutics is deleting, effective as of January 12, 2015, the opioid drug hydrocodone (and only hydrocodone) as a licensed product under our agreement. The letter does not alter the terms of our agreement regarding the remaining three licensed products (REMOXY, hydromorphone or oxymorphone) or otherwise amend the agreement.

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 pharmaceutical agent. SABER is a patented controlled drug delivery technology that is administered via the parenteral (i.e., injectable) route to deliver drugs that act systemically or locally. POSIDUR is designed to be administered to a surgical site at the end 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 are in discussions with potential partners regarding licensing development and commercialization rights to POSIDUR, for which we hold worldwide rights.

In April 2013, we submitted an NDA as a 505(b)(2) application, which relies in part on the FDA s findings of safety and effectiveness of a reference drug. In June 2013, we announced that our NDA submission had been accepted by the FDA indicating that the application is sufficiently complete to permit a substantive review. In February 2014, we received a Complete Response Letter from the FDA. Based on its review, the FDA determined that they cannot approve the NDA in its present form, stating the NDA does not contain sufficient information to demonstrate that POSIDUR is safe when used in the manner described in the proposed label, and the FDA indicated that additional clinical safety studies need to be conducted. We had a face-to-face meeting with the FDA in September 2014 to discuss what needs to be done to address the issues cited in the Complete Response Letter. As a result of this meeting and based on subsequent communications with the FDA, we announced in June 2015 that we plan to conduct a new POSIDUR Phase 3 clinical trial consisting of approximately 300 patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery. We anticipate beginning the trial in the fall of 2015 and expect that it will take approximately one year to complete enrollment. This clinical trial is designed to generate data necessary to support an NDA resubmission.

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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.

In February 2012, Pfizer gave notice that its rights with respect to ELADUR were being returned to us. In January 2014, we and Impax Laboratories, Inc. (Impax) entered into a definitive agreement (the Impax Agreement) pursuant to which we have granted Impax an exclusive worldwide license to our proprietary TRANSDUR transdermal delivery technology and other intellectual property to develop and commercialize ELADUR, in addition to selling certain assets and rights in and related to the product. Impax will control and fund the development and commercialization programs, and the parties have established a joint management committee to oversee, review and coordinate the development and commercialization activities of the parties under the Impax Agreement.

ORADUR-ADHD Program

We are developing drug candidates (ORADUR-ADHD) based on DURECT s ORADUR Technology for the treatment of ADHD. These drug candidates are intended to provide once-a-day dosing, or immediate release dosing, in each case 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-Methylphenidate. DURECT retains rights to North America, Europe, Japan and all other countries not specifically licensed to Orient Pharma. Since 2010, we and Orient Pharma have conducted several Phase I clinical trials in this program with multiple formulations. In 2013, we and Orient Pharma selected a lead formulation based on its potential for rapid onset of action, long duration for once-a-day dosing and target pharmacokinetic profile as demonstrated in a Phase 1 trial. In addition, this product candidate is expected to utilize a small capsule size relative to the leading existing long-acting products on the market. Orient Pharma has initiated a Phase 3 study in Taiwan and anticipates completing it in 2016. We retain rights to all other territories in the world and are engaged in licensing discussions with other companies.

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 years of age and older. Under the agreement, we granted Zogenix worldwide development and commercialization rights to Relday.

On January 3, 2013, Zogenix reported positive single-dose pharmacokinetic (PK) results from the Phase 1 clinical trial of Relday. According to Zogenix, adverse events in the Phase 1 trial in patients diagnosed with schizophrenia were generally mild to moderate and consistent with other risperidone products. The Phase 1 clinical trial for Relday was conducted as a single-center, open-label, safety and PK trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. Per Zogenix, based on the favorable safety and PK profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, Zogenix extended the study to include a 100 mg dose of the same formulation. In May 2013, Zogenix announced positive results with the 100 mg arm, demonstrating dose proportionality across the full dose range that would be anticipated to be used in clinical practice. According to Zogenix, the positive results from this study extension positions Zogenix to begin a multi-dose clinical trial, which would provide the required steady-state pharmacokinetic and safety data prior to initiating Phase 3 development studies. In

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March 2015, Zogenix commenced this multi-dose clinical trial and stated that they anticipated results from this study would be available in the third quarter of 2015 and that they are targeting an end-of-Phase 2 meeting with the FDA by early 2016.

Epigenomic Regulator Program and New Chemical Entities

DURECT s Epigenomic Regulator Program involves a multi-year collaborative effort between DURECT and the Department of Internal Medicine at Virginia Commonwealth University (VCU), the VCU Medical Center and the McGuire VA Medical Center. The discoveries in this program are a result of more than 20 years of lipid research by Shunlin Ren, M.D., Ph.D., Professor of Internal Medicine at the VCU Medical Center and a recipient of multiple grants from the National Institutes of Health (NIH) for metabolic disease research. Epigenetics is the study of how reversible modifications of a cell s DNA or histones (proteins associated with DNA) affect gene expression without altering the DNA sequence. Epigenomics is the study of large scale effects on cellular function and interrelated collections of epigenetic modifications. Epigenetic and epigenomics modifications play an important role in regulation of key cellular processes. DUR-928 is the program s lead product candidate. DURECT holds the exclusive worldwide right to develop and commercialize DUR-928 and related molecules discovered in the program.

During the course of this program, a number of compounds have been identified that may have therapeutic utility for various diseases and syndromes for orphan indications as well as for broader patient populations. The lead compound from this program DUR-928 is an endogenous, orally bioavailable small molecule that modulates the activity of various nuclear receptors that play an important regulatory role in lipid homeostasis, inflammation and cell survival. A systems biology study involving over 23,000 genes showed that DUR-928 modulates the activity of more than 240 genes, including ACC, FAS, HMGR, Cyp7A1, LXR, PPARg, NFkB/IkB, TNFa, IL-1a, IL-6, COX-2, PCSK9, and others.

The biological activity of DUR-928 has been demonstrated in 7 different animal disease models involving three animal species. Four of these models represent acute organ injury (endotoxin shock, kidney, liver and brain) and three represent chronic disorders of hepatic lipid accumulation and dysfunction (e.g., nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH)).

In pharmacokinetic and toxicity studies conducted in mice, hamsters, rats, dogs and monkeys, DUR-928 has been found to be orally bioavailable and safe at all doses tested to date. These non-clinical results supported the initiation of DUR-928 into human safety trials with an oral formulation. An oral formulation, envisioned for use in chronic conditions, has undergone initial testing in humans. An injectable formulation, envisioned for use in acute conditions, is undergoing animal testing.

The initial Phase 1 trial of DUR-928 was a single-site, randomized, double-blinded, placebo-controlled, single-ascending-dose study that evaluated the safety, tolerability and pharmacokinetics of DUR-928 when orally administered. The 30-subject study evaluated DUR-928 in five cohorts of healthy volunteers receiving DUR-928 at escalating doses that resulted in peak plasma concentrations at least 100-fold higher than endogenous levels. DUR-928 was well-tolerated at all dose levels, with no treatment-related adverse events reported and no subjects withdrawing from the study. We subsequently conducted a Phase 1 multiple-ascending-dose, oral administration trial in 20 healthy subjects, evaluating DUR-928 in two consecutive 10-subject cohorts, the first receiving DUR-928 at a lower dose and the second at a higher dose. Following multiple dosing, DUR-928 was well-tolerated at both dose levels, with no clinically significant changes in vital signs, laboratory values or ECG parameters, no severe or serious drug-related adverse events reported and no subjects withdrawing from the study. Peak plasma concentrations achieved were at least 100-fold higher than endogenous levels, no accumulation in plasma concentrations were observed with repeat dosing, and dose related increases in plasma concentrations were observed with peak plasma

concentration at approximately 2 6 hours after dosing.

Future Development Plans

In addition to the oral administration studies described above, DURECT anticipates commencing a Phase 1 single-dose, injectable administration trial in healthy subjects in the second half of 2015 as precursor to a multiple-ascending-dose Phase 1 trial. Assuming no undue safety results from these trials, DURECT would then be positioned to commence one or more Phase 2 patient trials in 2016.

DURECT is currently evaluating potential indications for DUR-928 in order to prioritize the development program. Long term opportunities fall into four broad categories: (a) orphan acute indications, (b) broader acute indications, (c) orphan chronic indications, and (d) broader chronic indications. DURECT s initial Phase 2 studies will be designed to show an efficacy signal in patients suffering from one orphan acute condition such as acute kidney injury and one broad chronic indication such as NAFLD/NASH. DURECT plans to provide more detail on the Phase 2 studies later this year.

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Other Programs

Depot Injectable Programs

In addition to biologic drugs, many traditional small molecule drugs have to be given by frequent injections, which is costly, inconvenient and may result in either unwanted side effects or suboptimal efficacy. We have active programs underway to improve our depot injectable systems and to apply those systems to various 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. The Relday program with Zogenix and the ophthalmic program with Santen are two projects which started as depot injectable feasibility projects and then matured into development and license agreements.

Research and Development Programs in Other Therapeutic Categories

We have underway a number of research programs covering medical diseases and conditions other than pain. Such programs include various diseases and disorders of the central nervous system, cardiovascular disease, ophthalmic conditions and metabolic disorders. 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 and one excipient that is included in a currently marketed animal health product.

Because we consider our core business to be developing and commercializing pharmaceuticals, we do not intend to significantly increase our investments in or efforts to sell or market any of our existing product lines. However, we expect that we will continue to make efforts to increase our revenue related to collaborative research and development by entering into additional research and development agreements with third-party collaborators to develop product candidates based on our drug delivery technologies.

Operating Results

Since our inception in 1998, we have had a history of operating losses. At June 30, 2015, we had an accumulated deficit of $393.2 million. Our net loss was $10.3 million for the six months ended June 30, 2015. Our net losses were $22.1 million and $21.5 million for the years ended December 31, 2014 and 2013, 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 expect our research and

development expenses to increase in the near future compared to recent quarters. We expect selling, general and administrative expenses to increase modestly in the near future compared to the second quarter of 2015. We do not anticipate meaningful revenues from our pharmaceutical product candidates, 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, 2014.

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Results of Operations

Three and Six months ended June 30, 2015 and 2014

Collaborative research and development and other revenue

We recognize revenues from collaborative research and development activities, service contracts and the royalty on a currently marketed animal health product. Collaborative research and development revenue primarily represents net reimbursement of qualified expenses related to collaborative agreements with various third parties to research, develop and commercialize potential products using our drug delivery technologies, and 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 in the next few quarters to remain comparable with the second quarter of 2015, pending establishment of new collaborations or an increase in activities undertaken by us under existing collaborations. In general, 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 as well as our role in the workplans for those programs at any point in time. The collaborative research and development and other revenues associated with our major collaborators are as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Collaborator				
Zogenix, Inc. (Zogenix) (1)	$ 1,121	$ 1,383	$ 2,278	$ 2,164
Santen Pharmaceutical Co. Ltd. (Santen) (2)	241		548	
Pain Therapeutics, Inc. (Pain Therapeutics)	163	246	163	697
Pfizer Inc. (Pfizer)		73		87
Impax Laboratories, Inc. (Impax) (3)				2,090
Others	253	33	527	209
Total collaborative research and development and other revenue	$ 1,778	$ 1,735	$ 3,516	$ 5,247

(1) Amounts related to ratable recognition of upfront fees were $64,000 and $127,000 for the three and six months ended June 30, 2015 respectively, compared to $64,000 and $127,000 for the corresponding periods in 2014.

(2) Amounts related to ratable recognition of upfront fees were $71,000 and $142,000 for the three and six months ended June 30, 2015 respectively, compared to zero for the corresponding periods in 2014; the Company and Santen signed a license agreement effective December 11, 2014.

(3) Amounts related to recognition of upfront fees were zero for both the three and six months ended June 30, 2015, compared with zero and $2.0 million for the corresponding periods in 2014; the Company and Impax signed a license agreement effective January 3, 2014.

Product revenue

A portion of our revenues is derived from product sales, which include our ALZET mini pump product line, our LACTEL biodegradable polymer product line and certain excipients that are included in REMOXY and another product. Net product revenues were $2.7 million and $5.7 million in the three and six months ended June 30, 2015, respectively, compared to $2.8 million and $5.6 million for the corresponding periods in 2014. The decrease in the three months ended June 30, 2015 was primarily attributable to lower revenue from our ALZET mini pump product line and from our LACTEL polymer product line as a result of lower units sold, partially offset by higher product revenue from the sale of certain excipients included in REMOXY and another product compared to the corresponding period in 2014. The increase in the six months ended June 30, 2015 was primarily attributable to higher product revenue from the sale of certain excipients included in REMOXY and another product, partially offset by lower revenue from our ALZET mini pump product line and from our LACTEL polymer product line as a result of lower units sold compared to the corresponding period in 2014.

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Cost of product revenues. Cost of product revenues were $1.0 million and $2.0 million for the three and six months ended June 30, 2015, respectively, compared to $1.1 million and $2.2 million for the corresponding periods in 2014. The decreases in the cost of product revenue were primarily the result of lower cost of goods sold related to our ALZET mini pump product line and our LACTEL product line arising from lower units sold in the three and six months ended June 30, 2015, partially offset by higher cost of goods sold related to the sale of certain excipients included in REMOXY and another product compared to the corresponding periods in 2014. Cost of product revenues and gross profit margin will fluctuate from period to period depending upon the product mix in a particular period and unit volumes sold. Stock-based compensation expense recognized related to cost of product revenues was $27,000 and $56,000 for the three and six months ended June 30, 2015, respectively, compared to $38,000 and $75,000 for the corresponding periods in 2014, respectively.

As of June 30, 2015 and 2014, we had 22 manufacturing employees. We expect the number of employees involved in manufacturing will remain comparable in the near future.

Research and development. Research and development expenses are primarily comprised of salaries, benefits, stock-based compensation and other compensation cost associated with research and development personnel, overhead and facility costs, preclinical and non-clinical development costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs. Research and development expenses were $5.6 million and $11.0 million for the three and six months ended June 30, 2015, respectively, compared to $6.1 million and $11.6 million for the corresponding periods in 2014. The decrease in the three months ended June 30, 2015 was primarily attributable to lower research and development costs associated with POSIDUR, depot injectable programs, Relday, REMOXY and other ORADUR-based opioid products licensed to Pain Therapeutics, ELADUR, and ORADUR-ADHD, partially offset by higher research and development costs associated with DUR-928, the Santen ophthalmic program and other research programs compared to the corresponding period in 2014 as more fully discussed below. The decrease in the six months ended June 30, 2015 was primarily attributable to lower research and development costs associated with POSIDUR, depot injectable programs, REMOXY and other ORADUR-based opioid products licensed to Pain Therapeutics, ELADUR, and ORADUR-ADHD, partially offset by higher research and development costs associated with DUR-928, Relday, the Santen ophthalmic program and other research programs compared to the corresponding period in 2014 as more fully discussed below. Stock-based compensation expense recognized related to research and development personnel was $332,000 and $683,000 for the three and six months ended June 30, 2015, respectively, compared to $424,000 and $839,000 for the corresponding periods in 2014. As of June 30, 2015, we had 55 research and development employees compared with 54 as of June 30, 2014. We expect research and development expenses to increase in the near future compared to recent quarters as we increase development activities for POSIDUR and DUR-928.

Research and development expenses associated with our major development programs approximate the following (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
DUR-928	$ 2,022	$ 1,243	$ 4,195	$ 2,325
POSIDUR (1)	1,468	2,007	2,414	3,901
Relday (1)	1,030	1,288	2,040	2,012
Depot Injectable Programs	508	559	1,002	1,306
Santen ophthalmic program (1)	207	22	456	45

REMOXY (1)	87	117	152	235
ORADUR-ADHD	77	148	156	247
Other ORADUR-based opioid products licensed to Pain Therapeutics (1)	31	347	115	677
ELADUR (1)	1	155	60	437
Others	207	202	415	372
Total research and development expenses	$ 5,638	$ 6,088	$ 11,005	$ 11,557

(1) See Note 2 Strategic Agreements in the condensed financial statements for more details about our agreements with Impax, Pfizer, Pain Therapeutics, Zogenix and Santen.

DUR-928

Our research and development expenses for DUR-928 were $2.0 million and $4.2 million in the three and six months ended June 30, 2015, respectively, compared to $1.2 million and $2.3 million for the corresponding periods in 2014. The increases in the

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three and six months ended June 30, 2015 were primarily due to higher employee-related costs, clinical trial expenses and non-clinical related expenses incurred for this drug candidate compared with the corresponding periods in 2014.

POSIDUR

Our research and development expenses for POSIDUR were $1.5 million and $2.4 million in the three and six months ended June 30, 2015, respectively, compared to $2.0 million and $3.9 million for the corresponding periods in 2014. The decreases in the three and six months ended June 30, 2015 were primarily due to lower employee-related costs and outside consulting expenses for POSIDUR compared with the corresponding period in 2014.

Relday

Our research and development expenses for Relday were $1.0 million and $2.0 million in the three and six months ended June 30, 2015, respectively, compared to $1.3 million and $2.0 million for the corresponding periods in 2014. The decrease in the three months ended June 30, 2015 was primarily due to decreased development activities and lower employee-related costs incurred for this drug candidate compared with the corresponding period in 2014. The increase in the six months ended June 30, 2015 was primarily due to increased development activities and higher employee-related costs incurred for this drug candidate compared with the corresponding period in 2014.

Depot Injectable Programs

Our research and development expenses for depot injectable programs were $508,000 and $1.0 million in the three and six months ended June 30, 2015, respectively, compared to $559,000 and $1.3 million for the corresponding periods in 2014. The decreases in the three and six months ended June 30, 2015 were primarily due to lower employee-related costs and lower costs related to research supplies for these programs compared with the corresponding periods in 2014.

Santen ophthalmic program

Our research and development expenses for the Santen ophthalmic program were $207,000 and $456,000 in the three and six months ended June 30, 2015, respectively, compared to $22,000 and $45,000 for the corresponding periods in 2014. The increases in the three and six months ended June 30, 2015 were primarily due to higher employee-related costs as a result of increased formulation development activities associated with this drug candidate compared with the corresponding periods in 2014.

REMOXY

Our research and development expenses for REMOXY were $87,000 and $152,000 in the three and six months ended June 30, 2015, respectively, compared to $117,000 and $235,000 for the corresponding periods in 2014. The decreases in the three and six months ended June 30, 2015 were primarily due to lower employee-related costs for REMOXY compared with the corresponding period in 2014.

ORADUR-ADHD

Our research and development expenses for ORADUR-ADHD were $77,000 and $156,000 in the three and six months ended June 30, 2015, respectively, compared to $148,000 and $247,000 for the corresponding periods in 2014. The decreases in the three and six months ended June 30, 2015 were primarily due to lower employee-related costs for these drug candidates compared with the corresponding periods in 2014.

Other ORADUR-based opioid products licensed to Pain Therapeutics

Our research and development expenses for other ORADUR-based opioid products licensed to Pain Therapeutics were $31,000 and $115,000 in the three and six months ended June 30, 2015, respectively, compared to $347,000 and $677,000 for the corresponding periods in 2014. The decreases in the three and six months ended June 30, 2015 were primarily due to lower employee-related costs as well as lower outside expenses associated with these product candidates compared with the corresponding periods in 2014.

ELADUR

Our research and development expenses for ELADUR were $1,000 and $60,000 in the three and six months ended June 30, 2015, respectively, compared to $155,000 and $437,000 for the corresponding periods in 2014. The decreases in the three and six months ended June 30, 2015 were primarily due to lower employee-related costs associated with this product candidate compared with the corresponding period in 2014.

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Other DURECT research programs

Our research and development expenses for all other programs were $207,000 and $415,000 in the three and six months ended June 30, 2015, respectively, compared to $202,000 and $372,000 for the corresponding periods in 2014, respectively. The increases in the three and six months ended June 30, 2015 were primarily due to higher employee-related costs incurred for these programs compared with the corresponding periods in 2014.

We cannot reasonably estimate the timing and costs of our research and development programs due to the risks and uncertainties associated with developing pharmaceuticals, as outlined in the Risk Factors section of this report. The duration of development of our research and development programs may span as many as ten years or more, and estimation of completion dates or costs to complete would be highly speculative and subjective due to the numerous risks and uncertainties associated with developing pharmaceutical products, including significant and changing government regulation, the uncertainties of future preclinical and clinical study results, the uncertainties with our collaborators commitment and progress to the programs and the uncertainties associated with process development and manufacturing as well as sales and marketing. In addition, with respect to our development programs subject to third-party collaborations, the timing and expenditures to complete the programs are subject to the control of our collaborators. Therefore, we cannot reasonably estimate the timing and estimated costs of the efforts necessary to complete the research and development programs. For additional information regarding these risks and uncertainties, see Risk Factors below.

Selling, general and administrative. Selling, general and administrative expenses are primarily comprised of salaries, benefits, stock-based compensation and other compensation cost associated with finance, legal, business development, sales and marketing and other administrative personnel, overhead and facility costs, and other general and administrative costs. Selling, general and administrative expenses were $2.7 million and $5.5 million for the three and six months ended June 30, 2015, respectively, compared to $2.9 million and $6.2 million for the corresponding periods in 2014. The decreases in selling, general and administrative expenses in the three and six months ended June 30, 2015 were primarily due to lower patent related expenses, lower outside expenses in connection with the signing of the Impax agreement in the first quarter of 2014, and lower consulting related expenses compared to the corresponding periods in 2014. Stock-based compensation expense recognized related to selling, general and administrative personnel was $265,000 and $535,000 for the three and six months ended June 30, 2015, respectively, compared to $313,000 and $587,000 for the corresponding periods in 2014.

As of June 30, 2015, we had 26 selling, general and administrative employees compared with 25 as of June 30, 2014. We expect selling, general and administrative expenses to increase modestly in the near future compared to the second quarter of 2015.

Other income (expense). Interest and other income was $23,000 and $151,000 for the three and six months ended June 30, 2015, respectively, compared to $3,000 and $6,000 for the corresponding periods in 2014. The increase in interest and other income in the three months ended June 30, 2015 was primarily the result of higher cash and investments balance in the second quarter of 2015 compared with the same period in 2014. The increase in interest and other income in the six months ended June 30, 2015 was primarily the result of a realized gain from the sale of a marketable equity security in the first quarter of 2015.

Interest expense was $558,000 and $1.1 million for the three and six months ended June 30, 2015, respectively, compared to $33,000 and $34,000 for the corresponding periods in 2014. The increases in interest expense in the three and six months ended June 30, 2015 were primarily due to interest expense and amortization of debt discount related to a long-term debt arrangement entered into in June 2014.

Liquidity and Capital Resources

We had cash, cash equivalents and investments totaling $37.8 million at June 30, 2015 compared to $34.9 million at December 31, 2014. These balances include $250,000 and $350,000 of interest-bearing marketable securities classified as restricted investments on our balance sheets as of June 30, 2015 and December 31, 2014, respectively. The increase in cash, cash equivalents and investments during the six months ended June 30, 2015 was primarily the result of $11.6 million of cash received from the sale of approximately 5.9 million shares of its common stock in the open market through the agreement with Cantor Fitzgerald, $886,000 of cash received from exercises of stock options and purchases under our employee stock purchase plan, and payments received from collaboration partners and customers, partially offset by the ongoing operating expenses and interest payments.

We used $9.5 million of cash in operating activities for the six months ended June 30, 2015 compared to $6.9 million for the corresponding period in 2014. The cash used for operations was primarily to fund operations. In the six months ended June 30, 2014, we received a $2.0 million upfront payment from Impax. The increase in cash used for operations during the six months ended June 30, 2015 was also attributable to increases in inventory and prepaid expenses as well as decreases in accounts payable and accrued liabilities compared to the corresponding period in 2014.

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Investing activities provided $289,000 of cash for the six months ended June 30, 2015 compared to investing activities using $2.2 million of cash for the corresponding period in 2014. The increase in cash provided by investing activities was primarily due to an increase in net proceeds from maturities of available-for-sale securities for the six months ended June 30, 2015 compared to the corresponding period in 2014, partially offset by a smaller increase in purchases of available-for-sale securities. We anticipate incurring capital expenditures of approximately $100,000 in 2015 to purchase research and development and other capital equipment. The amount and timing of these capital expenditures will depend on, among other things, the timing of clinical trials for our products and our collaborative research and development activities.

We received $12.5 million of cash from financing activities for the six months ended June 30, 2015 compared to $20.0 million for the corresponding period in 2014. The decrease in cash provided by financing activities in the six months ended June 30, 2015 was primarily a result of $19.8 million received from a term loan in the six months ended June 30, 2014, which compared to an increase of $12.3 million in proceeds from sales of our common stock in the open market and from exercises of stock options compared to the corresponding period in 2014.

We anticipate that cash used in operating activities will increase in the near future compared to recent quarters.

During the six months ended June 30, 2015, there have been no significant changes in our commercial commitments and contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

We believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations, contractual commitments, planned capital expenditures and service our debt through at least the next 12 months. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. Additionally, we do not expect to generate meaningful revenues from our pharmaceutical product candidates currently under development for at least the next twelve months, if at all. Depending on whether we enter into additional collaborative agreements in the near term, we may be required to raise additional capital through a variety of sources, including:

- the public equity markets;
- private equity financings;
- collaborative arrangements; and/or
- public or private debt.

There can be no assurance that we will enter into additional collaborative agreements in the near term or additional capital will be available on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, either of which could have a material adverse effect on our business, financial condition and results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders.

Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. We select investments that maximize interest income to the extent possible given these two constraints. We satisfy liquidity requirements by investing excess cash in securities with different maturities to match projected cash needs and limit concentration of credit risk by diversifying our investments among a variety of high credit-quality issuers.

Off-Balance Sheet Arrangements

As of June 30, 2015, we did not have any off-balance sheet arrangements, as defined under SEC Regulation S-K Item 303(a)(4)(ii).

Item 3. Quantitative and Qualitative Disclosures about Market Risk

During the six months ended June 30, 2015, there have been no significant changes in market risks as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures: The Company s principal executive and financial officers reviewed and evaluated the Company s disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period

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covered by this Form 10-Q. Based on that evaluation, the Company s principal executive and financial officers concluded that the Company s disclosure controls and procedures are effective at ensuring that information required to be disclosed by the Company in reports that the Company files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to management, including the Company s principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting: There were no significant changes in the Company s internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) during the Company s most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

We are not a party to any material legal proceedings.

Item 1A. Risk Factors

In addition to the other information in this Form 10-Q, a number of factors may affect our business and prospects. These factors include but are not limited to the following, which you should consider carefully in evaluating our business and prospects.

Risks Related To Our Business

Regulatory approval of POSIDUR has been delayed and may be denied, and regulatory approval of our other product candidates is subject to delay or may be denied, which could harm our business

In February 2014, we received a Complete Response Letter to our NDA for POSIDUR from the FDA. Based on its review, the FDA determined that they cannot approve the NDA in its present form, stating the NDA does not contain sufficient information to demonstrate that POSIDUR is safe when used in the manner described in the proposed label, and the FDA has indicated that additional clinical safety studies need to be conducted. We had a face-to-face meeting with the FDA on September 23, 2014 to address the issues cited in the Complete Response Letter. As a result of this meeting and based on subsequent communications with the FDA, we announced in June 2015 that we plan to conduct a new POSIDUR Phase 3 clinical trial consisting of approximately 300 patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery. We anticipate beginning the trial in the fall of 2015 and expect that it will take approximately one year to complete enrollment. There can be no assurance that this clinical trial will be enrolled as quickly as expected or generate data necessary to support a successful NDA resubmission, or that it will be completed in a timely manner. The failure to adequately demonstrate the safety and effectiveness of a pharmaceutical product candidate under development to the satisfaction of FDA and other regulatory agencies has, with respect to POSIDUR and could, with respect to other product candidates, delay or prevent regulatory clearance of the potential product candidate, resulting in delays to the commercialization of our product candidate, and could materially harm our business. Clinical trials may not demonstrate the sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our product candidates, or may require such significant numbers of patients or additional costs to make it impractical to satisfy the FDA s requirements, and thus our product candidates may not be approved for marketing. During the review process, the FDA may request more information regarding the safety of our product candidates, as they have in their Complete Response Letter for POSIDUR, and answering such questions could require significant additional work and expense, and take a significant amount of time, resulting in a material delay of approval or the failure to obtain approval. During the review process, the FDA may also request more information regarding the chemistry, manufacturing or controls related to our product candidates, as they have in their Complete Response Letter for REMOXY, and answering such questions could require significant additional work and expense, and take a significant amount of time, resulting in a material delay of approval or the failure to obtain approval.

Development of REMOXY may be significantly delayed and adversely affected by Pfizer s discontinuation of its development

We have relied on Pfizer and its subsidiaries to devote time and resources to the development, manufacturing and commercialization of REMOXY. In October 2014, Pfizer notified Pain Therapeutics that Pfizer had decided to discontinue development of REMOXY and that Pfizer would return all rights, including responsibility for regulatory activities, to Pain Therapeutics. There can be no assurance that the transition of all required information and assets necessary for the timely and successful resubmission of the NDA has been completed successfully. There can also be no assurance that Pain Therapeutics will continue development of REMOXY, or if Pain Therapeutics continues development of REMOXY, there can be no assurance that their resubmission of the NDA will be timely, or that it will satisfy the FDA s requirements. Pain Therapeutics and its subsidiaries and affiliates may commercialize, develop or acquire drugs or drug candidates that may compete indirectly or compete for resources with REMOXY. Any further delay or discontinuation in the development of REMOXY will significantly harm our prospects and would be likely to have a negative effect on the price of our common stock.

Development of our pharmaceutical product candidates is not complete, and we cannot be certain that our product candidates will be able to be commercialized

To be profitable, we or our third-party collaborators must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our pharmaceutical product candidates under development. For each product candidate that we or our third-party collaborators intend to commercialize, we must successfully meet a number of critical developmental milestones for each disease or medical condition targeted, including:

with respect to our Drug Delivery Program product candidates, selecting and developing a drug delivery technology to deliver the proper dose of drug over the desired period of time;

with respect to each new chemical entity, determining appropriate indications;

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determining the appropriate drug dosage for use in the pharmaceutical product candidate;

developing drug compound formulations that will be tolerated, safe and effective and that will be compatible with the active pharmaceutical agent;

demonstrating the drug formulation will be stable for commercially reasonable time periods;

demonstrating through clinical trials that the drug formulation is safe and effective in patients for the intended indication; and

completing the manufacturing development and scale-up to permit manufacture of the pharmaceutical product candidate in commercial quantities and at acceptable cost.

The time frame necessary to achieve these developmental milestones for any individual product is long and uncertain, and we may not successfully complete these milestones for any of our products in development. We have not yet completed development of any of our product candidates, including POSIDUR, REMOXY, ELADUR, ORADUR-ADHD and other ORADUR-based opioid products, Relday or DUR-928, and we have limited experience in developing such products. We may not be able to finalize the design or formulation of any of these product candidates. In addition, we may select components, solvents, excipients or other ingredients to include in our product candidates that have not been previously approved for use in pharmaceutical products, which may require us or our collaborators to perform additional studies and may delay clinical testing and regulatory approval of our product candidates. Even after we complete the design of a product candidate, the product candidate must still complete required clinical trials and additional safety testing in animals before approval for commercialization. We are continuing testing and development of our product candidates and may explore possible design or formulation changes to address issues of safety, manufacturing efficiency and performance. We or our collaborators may not be able to complete development of any product candidates that will be safe and effective and that will have a commercially reasonable treatment and storage period. If we or our third-party collaborators are unable to complete development of POSIDUR, REMOXY, ELADUR, ORADUR-ADHD and other ORADUR-based opioid products, Relday or DUR-928, or other product candidates, we will not be able to earn revenue from them, which would materially harm our business.

We or our third-party collaborators must show the safety and efficacy of our drug candidates in animal studies and human clinical trials to the satisfaction of regulatory authorities before they can be sold; failure to obtain approvals for POSIDUR, REMOXY or our other product candidates would significantly harm our business, prospects and financial condition

Before we or our third-party collaborators can obtain government approval to sell any of our pharmaceutical product candidates, we or they, as applicable, must demonstrate through laboratory performance studies and safety testing, nonclinical (animal) studies and clinical (human) trials that each system is safe and effective for human use for each targeted indication. The clinical development status of our major development programs is as follows:

REMOXY In December 2010, King (now Pfizer) resubmitted the NDA in response to a Complete Response Letter received in December 2008 by Pain Therapeutics. On June 23, 2011, a Complete Response Letter

from the FDA was received by Pfizer on the resubmission to the NDA for REMOXY. The issues raised in the Complete Response Letter relate primarily to manufacturing. In October 2013, Pfizer stated that, having achieved technical milestones related to manufacturing, it would continue developing REMOXY. Pfizer had also announced that it was proceeding with additional clinical studies in support of resubmission of the NDA. We understand these studies have been completed, although we have not seen the results. It is possible that the results of such studies will not be satisfactory to the FDA or that they could suggest a lower commercial potential for REMOXY than previously had been expected. In October 2014, Pfizer notified Pain Therapeutics that Pfizer had decided to discontinue development of REMOXY, and that Pfizer would return all rights, including responsibility for regulatory activities, to Pain Therapeutics and that Pfizer would continue ongoing activities under the agreement until the scheduled termination date in April 2015. In April 2015, Pain Therapeutics stated that it had resumed responsibility for REMOXY under the terms of a letter agreement with Pfizer. In July 2015, Pain Therapeutics stated that it had substantially completed the transition of REMOXY from Pfizer, and that Pain Therapeutics expected to resubmit the NDA in the first quarter of 2016. There can be no assurance that Pain Therapeutics will successfully resubmit the NDA or that Pain Therapeutics will obtain a new commercialization partner.

POSIDUR In April 2013, we submitted a new drug application as a 505(b)(2) application, which relies in part on the FDA s findings of safety and effectiveness of a reference drug. In February 2014, we received a Complete Response Letter from the FDA. Based on its review, the FDA determined that they cannot approve the NDA in its present form, stating the NDA does not contain sufficient information to demonstrate that POSIDUR is safe when used in the manner described in the proposed label, and the FDA indicated that additional clinical safety studies need to be conducted. We had a face-to-face meeting with the FDA in September 2014 to discuss what needs to be done to address the issues cited in the Complete Response Letter. As a result of this meeting and based on subsequent communications with the FDA, we announced in June 2015 that we plan to conduct a new POSIDUR Phase 3 clinical trial consisting of approximately 300 patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery. DURECT anticipates beginning the trial in the fall of 2015 and expects that it will take approximately one year to complete enrollment. There can be no assurance that we will be able to

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adequately address all of FDA s concerns regarding the POSIDUR NDA or there could be a delay in addressing such concerns, the FDA may not grant regulatory approval of POSIDUR, adverse effects may arise from additional testing or use of POSIDUR, and the data that we have generated or may generate may not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of POSIDUR.

ELADUR A Phase 2a clinical trial in post-herpetic neuralgia (PHN or post-shingles pain) was completed and positive efficacy trends were reported in the fourth quarter of 2007. King, which assumed worldwide development and commercialization rights for ELADUR through its acquisition of Alpharma, conducted a Phase 2 clinical trial to evaluate ELADUR for the treatment of chronic low back pain and reported in April 2011 that the primary efficacy endpoint for the trial was not met. In February 2012, Pfizer, which assumed worldwide development and commercialization rights to ELADUR through its acquisition of King, notified us that they were returning their worldwide development and commercialization rights to ELADUR. In January 2014, we and Impax entered into an agreement, pursuant to which we have granted Impax an exclusive worldwide license to our proprietary TRANSDUR transdermal delivery technology and other intellectual property to develop and commercialize ELADUR. There can be no assurance that Impax will continue to develop ELADUR or will be able to successfully develop ELADUR to obtain marketing approval by the FDA or other regulatory agencies.

Relday In January 2013, Zogenix announced positive single-dose pharmacokinetic (PK) results from the Phase 1 clinical trial of Relday. Per Zogenix, based on the favorable safety and PK profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, Zogenix extended the study to include a 100 mg dose of the same formulation. In May 2013, Zogenix announced positive results with the 100 mg arm, demonstrating dose proportionality across the full dose range that would be anticipated to be used in clinical practice. According to Zogenix, the positive results from this study extension positions Zogenix to begin a multi-dose clinical trial, which would provide the required steady-state pharmacokinetic and safety data prior to initiating Phase 3 development studies. In March 2015, Zogenix commenced this multi-dose clinical trial and stated that they anticipated results from this study would be available in the third quarter of 2015 and that they are targeting an end-of-Phase 2 meeting with the FDA by early 2016. There can be no assurance that Zogenix will obtain results from the multi-dose clinical trial in the third quarter of 2015 or that the results of such a trial will warrant continued development of Relday.

ORADUR-ADHD Since 2010, we and Orient Pharma have conducted several Phase 1 studies to evaluate multiple formulations of ORADUR-Methylphenidate. We and Orient Pharma have selected a lead formulation containing the active pharmaceutical ingredient methylphenidate. This formulation was chosen based on its potential for rapid onset of action, long duration for once-a-day dosing and target pharmacokinetic profile as demonstrated in the latest Phase 1 trial. In addition, this product candidate will utilize a small capsule size relative to the leading existing long-acting products on the market. Orient Pharma, our licensee in defined Asian and South Pacific countries, has initiated a Phase 3 study in Taiwan and anticipates completing it in 2016. DURECT retains rights to all other territories in the world and is engaged in licensing discussions with other companies. There can be no assurance that we will be able to successfully develop ORADUR-methylphenidate to obtain marketing approval by the TFDA or the U.S. FDA or other regulatory agencies, nor is there any assurance that we will be able to find a collaborator with respect to the development and commercialization of this drug candidate for the territories not currently licensed to Orient Pharma.

ORADUR-based opioids Phase 1 clinical trials have been conducted for two of these ORADUR-based product candidates (hydrocodone and hydromorphone), and an IND has been accepted by the FDA for the third ORADUR-based opioid (oxymorphone). In October 2013, Pain Therapeutics stated that it had regained all rights from Pfizer with respect to the three ORADUR-based opioid drug candidates (hydrocodone, hydromorphone and oxymorphone). During 2014, we conducted research and development activities on these programs under approved workplans with Pain Therapeutics. In May 2015, Pain Therapeutics sent a letter to us that provided us with formal written notice that Pain Therapeutics is deleting, effective as of January 12, 2015, the opioid drug hydrocodone (and only hydrocodone) as a licensed product under our agreement. The letter does not alter the terms of our agreement regarding the remaining three licensed products (REMOXY, hydromorphone or oxymorphone) or otherwise amend the agreement. There can be no assurance that we or our collaborator will be able to successfully develop ORADUR-based formulations of hydrocodone, hydromorphone or oxymorphone to obtain marketing approval by the FDA or other regulatory agencies.

DUR-928 In February 2015, we announced the successful completion of the initial Phase 1 human safety trial of DUR-928, which was a single-site, randomized, double-blinded, placebo-controlled, single-ascending-dose study that evaluated the safety, tolerability and pharmacokinetics of DUR-928 when orally administered. The 30-subject study evaluated DUR-928 in five cohorts of healthy volunteers receiving DUR-928 at escalating doses that resulted in peak concentrations at least 100-fold higher than endogenous levels. In May 2015, we announced the successful completion of a Phase 1 multi-dose, oral administration trial in 20 healthy subjects. We also anticipate commencing a Phase 1 single-dose, injectable administration trial in healthy subjects in the second half of 2015 as precursor to a multi-dose Phase 1 trial. There can be no assurance that biological activity demonstrated in previous animal disease models will also be seen in human trials, that further human trials will not identify safety issues, or that we will be able to successfully develop DUR-928 to obtain marketing approval by the FDA or other regulatory agencies.

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We are currently in the clinical, preclinical or research stages with respect to all of our product candidates under development. We plan to continue extensive and costly tests, clinical trials and safety studies in animals to assess the safety and effectiveness of our product candidates. These studies include laboratory performance studies and safety testing, clinical trials and animal toxicological studies necessary to support regulatory approval of development products in the United States and other countries of the world. These studies are costly, complex and last for long durations, and may not yield data supportive of the safety or efficacy of our drug candidates or required for regulatory approval.

New chemical entities derived from our Epigenomic Regulator Program, which is in the early stages of development, may require more time and resources for development, testing and regulatory approval than our Drug Delivery Program product candidates, and may not result in viable commercial products

Our Epigenomic Regulator Program is in the early stages of development, involves unproven technology, requires significant further research and development and regulatory approvals and is subject to the risks of failure inherent in the development of products based on innovative technologies. New chemical entities derived from our Epigenomic Regulator Program are molecules that have not previously been approved and marketed as therapeutics, unlike product candidates in our Drug Delivery Programs, in which we apply our formulation expertise and technologies largely to active pharmaceutical ingredients whose safety and efficacy have previously been established but which we aim to improve in some manner through a new formulation. As a result, the product candidates from our Epigenomic Regulator Program may face greater risk of unanticipated safety issues or other side-effects, or may not demonstrate efficacy. Further, the regulatory pathway for our new chemical entities will be more demanding than that for product candidates under our Drug Delivery Programs, for which we may be able to leverage existing data under Section 505(b)(2) of the Act to reduce development risk, time and cost.

Also, because our Epigenomic Regulator Program is in early stages, we have not defined with precision those indications we wish to pursue initially, each of which may have unique challenges. If the first indications pursued do not show positive results, the credibility of any product candidate from this program may be tarnished, even if the molecule might be effective for other indications. Our decisions regarding which indications to pursue may cause us to fail to capitalize on indications that could have given rise to viable commercial products and profitable market opportunities.

Early clinical trial results may not predict the results of later trials, and our clinical trials or those of our collaborators for POSIDUR or REMOXY may not satisfy regulatory agencies

While some clinical trials of our product candidates have shown indications of safety and efficacy of our product candidates, there can be no assurance that these results will be confirmed in subsequent clinical trials or provide a sufficient basis for regulatory approval. In addition, side effects observed in clinical trials, or other side effects that appear in later clinical trials, may adversely affect our or our collaborators ability to obtain regulatory approval or market our product candidates. For example, the finding that DUR-928 appears safe in the first Phase 1 trials may not be confirmed in subsequent Phase 1 or other clinical trials. In the Phase 2b hysterectomy trial and the BESST Phase 3 abdominal surgery trial of POSIDUR, transient local hematoma-like discolorations were observed near the surgical site. Side effects such as these, toxicity or other safety issues associated with the use of our drug candidates could require us to perform additional studies or halt development of our drug candidates. We or our collaborators may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our pharmaceutical product candidates which we have not planned or anticipated. For example, the FDA s Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. There can be no assurance that Pain Therapeutics will resolve these issues to the satisfaction of the FDA in a timely manner or ever, which could harm our business, prospects and financial condition.

Further, the FDA s Complete Response Letter for POSIDUR raised concerns that insufficient safety data had been provided and FDA has indicated that an additional clinical trial for POSIDUR needs to be conducted, which would be expensive and could delay or preclude product approval, harming our business, prospects and financial condition.

Regulatory action or failure to obtain product approvals could delay or limit development and commercialization of our product candidates and result in failure to achieve anticipated revenues

The manufacture and marketing of our pharmaceutical product candidates and our research and development activities are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. We or our third-party collaborators must obtain clearance or approval from applicable regulatory authorities before we or they, as applicable, can perform clinical trials, market or sell our products in development in the United States or abroad. Clinical trials, manufacturing and marketing of products are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. In particular, recalls of and reported adverse side effects of marketed drugs have made regulatory agencies,

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including the FDA, increasingly focus on the safety of drug products. Regulatory agencies are requiring more extensive and ever increasing showings of safety at every stage of drug development and commercialization from initial clinical trials to regulatory approval and beyond. These rigorous and evolving standards may delay and increase the expenses of our development efforts. The FDA or other foreign regulatory agency may, at any time, halt our and our collaborators development and commercialization activities due to safety concerns, in which case our business will be harmed. In addition, the FDA or other foreign regulatory agency may refuse or delay approval of our or our collaborators drug candidates for failure to collect sufficient clinical or animal safety data, and require us or our collaborators to conduct additional clinical or animal safety studies which may cause lengthy delays and increased costs to our programs.

The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. These laws and regulations are complex and subject to change. Furthermore, these laws and regulations may be subject to varying interpretations, and we may not be able to predict how an applicable regulatory body or agency may choose to interpret or apply any law or regulation to our pharmaceutical product candidates. As a result, clinical trials and regulatory approval can take a number of years to accomplish and require the expenditure of substantial resources. We or our third-party collaborators, as applicable, may encounter delays or rejections based upon administrative action or interpretations of current rules and regulations. We or our third-party collaborators, as applicable, may not be able to timely reach agreement with the FDA on our clinical trials or on the required clinical or animal data we or they must collect to continue with our clinical trials or eventually commercialize our product candidates.

We or our third-party collaborators, as applicable, may also encounter delays or rejections based upon additional government regulation from future legislation, administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. We or our third-party collaborators, as applicable, may encounter similar delays in foreign countries. Sales of our pharmaceutical product candidates outside the United States are subject to foreign regulatory standards that vary from country to country.

The time required to obtain approvals from foreign countries may be shorter or longer than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements. We or our third-party collaborators, as applicable, may be unable to obtain requisite approvals from the FDA and foreign regulatory authorities, and even if obtained, such approvals may not be on a timely basis, or they may not cover the clinical uses that we specify. If we or our third-party collaborators, as applicable, fail to obtain timely clearance or approval for our development products, we or they will not be able to market and sell our pharmaceutical product candidates, which will limit our ability to generate revenue.

Many of our drug candidates under development, including REMOXY and our other ORADUR-based opioids are subject to mandatory Risk Evaluation and Mitigation Strategy (REMS) programs, which could delay the approval of these drug candidates, reduce demand for them, and increase the cost, burden and liability associated with their commercialization

On February 6, 2009, the FDA sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drugs continue to outweigh the risks. The affected opioid drugs include brand name and generic products and are formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone.

On April 19, 2011, the Office of National Drug Control Policy (ONDCP) released the Obama Administration s *Epidemic: Responding to America s Prescription Drug Abuse Crisis* a comprehensive action plan to address the national prescription drug abuse epidemic. This plan includes action in four major areas to reduce prescription drug

abuse: education, monitoring, proper disposal, and enforcement. In support of the action plan, the FDA announced the elements of a Risk Evaluation and Mitigation Strategy (REMS) that will require all manufacturers of long-acting and extended-release opioids to ensure that training is provided to prescribers of these medications and to develop information that prescribers can use when counseling patients about the risks and benefits of opioid use. The FDA wants drug makers to work together to develop a single system for implementing the REMS strategies.

On July 9, 2012 the FDA approved a REMS for extended-release (ER) and long-acting (LA) opioids. The REMS is part of a federal initiative to address the prescription drug abuse, misuse, and overdose epidemic. The REMS introduces new safety measures designed to reduce risks and improve the safe use of ER/LA opioids, while ensuring access to needed medications for patients in pain. The new ER/LA opioid REMS will affect more than 20 companies that manufacture these opioid analgesics. Under the new REMS, companies will be required to make education programs available to prescribers based on an FDA Blueprint. It is expected that companies will meet this obligation by providing educational grants to continuing education (CE) providers, who will develop and deliver the training. The REMS also will require companies to make available FDA-approved patient education materials on the safe use of these drugs. The companies will be required to perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program.

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On September 10, 2013, the FDA announced safety labeling changes and post-market study requirements for extended-release and long-acting opioid analgesics (ER/LA opioids). The updated class-wide labeling changes state that ER/LA opioids are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The updated indication further clarifies that, because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, these drugs should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain; ER/LA opioid analgesics are not indicated for as-needed pain relief. Recognizing that more information is needed to assess the serious risks associated with long-term use of ER/LA opioids, the FDA is requiring the drug companies that make these products to conduct further post-market studies and clinical trials. These changes may result in a decrease in prescriptions for this class of drugs and will increase the costs borne by manufacturers of ER/LA opioids.

Many of our drug candidates including REMOXY and other ORADUR-based opioid drug candidates are subject to the REMS requirement. The FDA s REMS requirements have been evolving, and until the contours of required REMS programs are established by the FDA and understood by drug developers and marketers such as ourselves and our collaborators, there may be delays in marketing approvals for these drug candidates. In addition, there may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of drug candidates subject to the REMS requirement, as well as decreased demand resulting from new labeling requirements, which could negatively impact the commercial benefits to us and our collaborators from the sale of these drug candidates.

We depend to a large extent on third-party collaborators, and we have limited or no control over the development, sales, distribution and disclosure for our pharmaceutical product candidates which are the subject of third-party collaborative or license agreements

Our performance depends to a large extent on the ability of our third-party collaborators to successfully develop and obtain approvals for our pharmaceutical product candidates. We have entered into agreements with Pain Therapeutics, Zogenix, Impax, Santen, Orient Pharma and others under which we granted such third parties the right to develop, apply for regulatory approval for, market, promote or distribute REMOXY and certain other ORADUR-based products, Relday, ELADUR and other product candidates, subject to payments to us in the form of product royalties and other payments. We have limited or no control over the expertise or resources that any collaborator may devote to the development, clinical trial strategy, regulatory approval, marketing or sale of these product candidates, or the timing of their activities. Any of our present or future collaborators may not perform their obligations as expected. These collaborators may breach or terminate their agreement with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Enforcing any of these agreements in the event of a breach by the other party could require the expenditure of significant resources and consume a significant amount of management time and attention. Our collaborators may also conduct their activities in a manner that is different from the manner we would have chosen, had we been developing such product candidates ourselves. Further, our collaborators may elect not to develop or commercialize product candidates arising out of our collaborative arrangements or not devote sufficient resources to the development, clinical trials, regulatory approval, manufacture, marketing or sale of these product candidates. If any of these events occur, we may not recognize revenue from the commercialization of our product candidates based on such collaborations. In addition, these third parties may have similar or competitive products to the ones which are the subject of their collaborations with us, or relationships with our competitors, which may reduce their interest in developing or selling our product candidates. We may not be able to control public disclosures made by some of our third-party collaborators, which could negatively impact our stock price.

Cancellation of collaborations regarding our product candidates may impact our near-term revenues and adversely affect potential economic benefits

Third-party collaboration agreements typically allow the third party to terminate the agreement (or a specific program within an agreement) by providing notice. For example, in January 2012, we were notified that Nycomed was terminating the Development and License Agreement between Nycomed and us relating to the development and commercialization of POSIDUR in Europe and their other licensed territories. In February 2012, we were notified that Pfizer was terminating the worldwide Development and License Agreement between Alpharma (acquired by King which subsequently was acquired by Pfizer) and us relating to the development and commercialization of ELADUR. In March 2012, we were notified that Hospira was terminating the Development and License Agreement between Hospira and us relating to the development and commercialization of POSIDUR in the United States and Canada. In October 2014, we were notified that Pfizer had decided to discontinue development of REMOXY, and that Pfizer would return all rights, including responsibility for regulatory activities, to Pain Therapeutics. If there have been payments under such agreements that are being recognized over time, termination of such agreements (or programs) can lead to a near-term increase in our reported revenues resulting from the immediate recognition of the balance of such payments. Termination deprives us of potential future economic benefits under such agreements, and may make it more difficult to enter into agreements with other third parties for use of the assets that were subject to the terminated agreement. Termination of our agreements with Pain Therapeutics, Zogenix, Impax, Santen or Orient Pharma could have similar effects.

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Our revenues depend on collaboration agreements with other companies. These agreements subject us to obligations which must be fulfilled and also make our revenues dependent on the performance of such third parties. If we are unable to meet our obligations or manage our relationships with our collaborators under these agreements or enter into additional collaboration agreements or if our existing collaborations are terminated, our revenues may decrease. Acquisitions of our collaborators can be disruptive

Our revenues are based to a significant extent on collaborative arrangements with third parties, pursuant to which we receive payments based on our performance of research and development activities set forth in these agreements. We may not be able to fulfill our obligations or attain milestones set forth in any specific agreement, which could cause our revenues to fluctuate or be less than anticipated and may expose us to liability for contractual breach. In addition, these agreements may require us to devote significant time and resources to communicating with and managing our relationships with such collaborators and resolving possible issues of contractual interpretation which may detract from time our management would otherwise devote to managing our operations. Such agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property under collaborations. Such disputes can delay or prevent the development of potential new product candidates, or can lead to lengthy, expensive litigation or arbitration. In general, our collaboration agreements, including our agreements with Pain Therapeutics with respect to REMOXY and certain other ORADUR-based opioids, Orient Pharma with respect to ORADUR-Methylphenidate, Zogenix with respect to Relday, Impax with respect to ELADUR, and Santen with respect to an ophthalmic product may be terminated by the other party at will or upon specified conditions including, for example, if we fail to satisfy specified performance milestones or if we breach the terms of the agreement. From time to time, our licensees may be the subject of an acquisition by another company. For example, Alpharma was acquired by King in December 2008, King was acquired by Pfizer in February 2011 and, Nycomed was acquired by Takeda in October 2011. Such transactions can lead to turnover of program staff, a review of development programs and strategies by the acquirer, and other events that can disrupt a program, resulting in program delays or discontinuations.

If any of our collaborative agreements are terminated or delayed, our anticipated revenues may be reduced or not materialize, and our products in development related to those agreements may not be commercialized.

Our cash flows are likely to differ from our reported revenues

Our revenues will likely differ from our cash flows from revenue-generating activities. Upfront payments received upon execution of collaborative agreements are recorded as deferred revenue and generally recognized on a straight-line basis over the period of our continuing involvement with the third-party collaborator pursuant to the applicable agreement. The period of continuing involvement may also be revised on a prospective basis. As of June 30, 2015, we had $3.2 million of deferred revenue which will be recognized in future periods and may cause our reported revenues to be greater than cash flows from our ongoing revenue-generating activities.

Our revenues also depend on milestone payments based on achievements by our third-party collaborators. Failure of such collaborators to attain such milestones would result in our not receiving additional revenues

In addition to payments based on our performance of research and development activities, our revenues also depend on the attainment of milestones set forth in our collaboration agreements. Such milestones are typically related to development activities or sales accomplishments. While our involvement is necessary to the achievement of development-based milestones, the performance of our third-party collaborators is also required to achieve those milestones. Under our third-party collaborative agreements, our third party collaborators will take the lead in commercialization activities and we are typically not involved in the achievement of sales-based milestones. Therefore, we are even more dependent upon the performance of our third-party collaborators in achieving sales-based

milestones. To the extent we and our third-party collaborators do not achieve such development-based milestones or our third-party collaborators do not achieve sales-based milestones, we will not receive the associated revenues, which could harm our financial condition and may cause us to defer or cut-back development activities or forego the exploitation of opportunities in certain geographic territories, any of which could have a material adverse effect on our business.

Our business strategy includes the entry into additional collaborative agreements. We may not be able to enter into additional collaborative agreements or may not be able to negotiate commercially acceptable terms for these agreements

Our current business strategy includes the entry into additional collaborative agreements for the development and commercialization of our pharmaceutical product candidates. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators and require significant time and resources from our officers, business development, legal, and research and development staff. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well the collaborators own internal product opportunities. We may not be able to consummate additional collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements. If we do not consummate additional collaborative agreements, we may have to consume money more rapidly on our product development efforts, defer development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business.

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We will require and may have difficulty raising needed capital in the future

Our business currently does not generate sufficient revenues to meet our capital requirements and we do not expect that it will do so in the near future. We have expended and will continue to expend substantial funds to complete the research, development and clinical testing of our pharmaceutical product candidates. We will require additional funds for these purposes, to establish additional clinical- and commercial-scale manufacturing arrangements and facilities, and to provide for the marketing and distribution of our product candidates. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable from operations or additional sources of financing, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs which would materially harm our business, financial condition and results of operations.

We believe that our cash, cash equivalents and investments, will be adequate to satisfy our capital needs for at least the next 12 months. However, our actual capital requirements will depend on many factors, including:

- regulatory actions with respect to our product candidates;
- continued progress and cost of our research and development programs;
- the continuation of our collaborative agreements that provide financial funding for our activities;
- success in entering into collaboration agreements and meeting milestones under such agreements;
- progress with preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability and that of our collaborators to sell our pharmaceutical product candidates;
- costs involved in establishing manufacturing capabilities for clinical and commercial quantities of our product candidates;
- competing technological and market developments;

market acceptance of our product candidates;

costs for recruiting and retaining employees and consultants; and

unexpected legal, accounting and other costs and liabilities related to our business.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through equity or debt financings, convertible debt financings, collaborative arrangements with corporate collaborators or other sources, which may be dilutive to existing stockholders and may cause the price of our common stock to decline. In addition, in the event that additional funds are obtained through arrangements with collaborators or other sources, we may have to relinquish rights to some of our technologies or pharmaceutical product candidates that we would otherwise seek to develop or commercialize ourselves. If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in delays in generating future product revenue.

We and our third-party collaborators may not be able to manufacture sufficient quantities of our pharmaceutical product candidates and components to support the clinical and commercial requirements of our collaborators and ourselves at an acceptable cost or in compliance with applicable government regulations, and we have limited manufacturing experience

We or our third-party collaborators to whom we have assigned such responsibility must manufacture our pharmaceutical product candidates and components in clinical and commercial quantities, either directly or through third parties, in compliance with regulatory requirements and at an acceptable cost. The manufacturing processes associated with our product candidates are complex. We and our third-party collaborators, where relevant, have not yet completed development of the manufacturing process for any product candidates or components, including POSIDUR, REMOXY and our other ORADUR-based drug candidates, ELADUR, Relday and DUR-928. If we and our third-party collaborators, where relevant, fail to timely complete the development of the manufacturing process for our product candidates, we and our third-party collaborators, where relevant, will not be able to timely produce product for clinical trials and commercialization of our product candidates. We have also committed to manufacture and supply product candidates or components under a number of our collaborative agreements with third-party companies. We have limited experience manufacturing pharmaceutical products, and we may not be able to timely accomplish these tasks. If we and our third-party collaborators, where relevant, fail to develop manufacturing processes to permit us to manufacture a product candidate or component at an acceptable cost, then we and our third-party collaborators may not be able to commercialize that product candidate or we may be in breach of our supply obligations to our third-party collaborators.

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Our manufacturing facility in Cupertino is a multi-disciplinary site that we have used to manufacture only research and clinical supplies of several of our pharmaceutical product candidates, including POSIDUR, REMOXY and our other ORADUR-based drug candidates, ELADUR, Relday and DUR-928. If we experience delays or technical difficulties in scaling up the manufacturing of our product candidates, it could result in delays or added cost in our development programs. We have not manufactured commercial quantities of any of our product candidates. In the future, we intend to develop additional manufacturing capabilities for our product candidates and components to meet our demands and those of our third-party collaborators by contracting with third-party manufacturers and by potentially constructing additional manufacturing space at our facilities in California and Alabama. We have limited experience building and validating manufacturing facilities, and we may not be able to accomplish these tasks in a timely or cost effective manner.

If we and our third-party collaborators, where relevant, are unable to manufacture our pharmaceutical product candidates or components in a timely manner or at an acceptable cost, quality or performance level, and are unable to attain and maintain compliance with applicable regulations, the clinical trials and the commercial sale of our product candidates and those of our third-party collaborators could be delayed. Additionally, we may need to alter our facility design or manufacturing processes, install additional equipment or do additional construction or testing in order to meet regulatory requirements, optimize the production process, increase efficiencies or production capacity or for other reasons, which may result in additional cost to us or delay production of product needed for the clinical trials and commercial launch of our product candidates and those of our third-party collaborators.

We have entered into a supply agreement with Hospira Worldwide, Inc. for clinical and commercial supplies of POSIDUR. This third party is currently our sole source for drug product required for development and commercialization of this drug candidate. Our agreement with Hospira terminates at the end of 2015 and we are planning to contract with a different party for future supply of POSIDUR. There may be technical risks associated with establishing an alternative commercial manufacturer that could entail delays in supply, quality issues or delays in the possible regulatory approval of POSIDUR. Furthermore, we and our contract manufacturer may also need or choose to subcontract with additional third-party contractors to perform manufacturing steps of POSIDUR or supply required components for POSIDUR. Where third party contractors perform manufacturing services for us, we will be subject to the schedule, expertise and performance of third parties as well as incur significant additional costs. Failure of third parties to perform their obligations could adversely affect our operations, development timeline and financial results. We expect to put in place in the future second source supply arrangements, which may be costly and time consuming.

If we or our third-party collaborators cannot manufacture our pharmaceutical product candidates or components in time to meet the clinical or commercial requirements of our collaborators or ourselves or at an acceptable cost, our operating results will be harmed.

Failure to comply with ongoing governmental regulations for our pharmaceutical product candidates could materially harm our business in the future

Marketing or promoting a drug is subject to very strict controls. Furthermore, clearance or approval may entail ongoing requirements for post-marketing studies. The manufacture and marketing of drugs are subject to continuing FDA and foreign regulatory review and requirements that we update our regulatory filings. Later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. Any of the following or other similar events, if they were to occur, could delay or preclude us from further developing, marketing or realizing full commercial use of our product candidates, which in turn would materially harm our business, financial condition and results of operations:

failure to obtain or maintain requisite governmental approvals;

failure to obtain approvals for clinically intended uses of our pharmaceutical product candidates under development; or

FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects in our product candidates.

Manufacturers of drugs must comply with the applicable FDA good manufacturing practice regulations, which include production design controls, testing, quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. Compliance with current good manufacturing practices regulations is difficult and costly. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed before they can be used for the commercial manufacture of our development products. We and/or our present or future suppliers and distributors may be unable to comply with the applicable good manufacturing practice regulations and other FDA regulatory requirements. We have not been subject to a good manufacturing regulation inspection by the FDA relating to our product candidates. If we, our third-party collaborators or our respective suppliers do not achieve compliance for our product candidates we or

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they manufacture, the FDA may refuse or withdraw marketing clearance or require product recall, which may cause interruptions or delays in the manufacture and sale of our product candidates.

We have a history of operating losses, expect to continue to have losses in the future and may never achieve or maintain profitability

We have incurred significant operating losses since our inception in 1998 and, as of June 30, 2015, had an accumulated deficit of approximately $393.2 million. We expect to continue to incur significant operating losses over the next several years as we continue to incur significant costs for research and development, clinical trials, manufacturing, sales, and general and administrative functions. Our ability to achieve profitability depends upon our ability, alone or with others, to successfully complete the development of our proposed product candidates, obtain the required regulatory clearances, and manufacture and market our proposed product candidates. Development of pharmaceutical product candidates is costly and requires significant investment. In addition, we may choose to license from third parties either additional drug delivery platform technology or rights to particular drugs or other appropriate technology for use in our product candidates. The license fees for these technologies or rights would increase the costs of our product candidates.

To date, we have not generated significant revenue from the commercial sale of our pharmaceutical product candidates and do not expect to do so in the near future. Our current revenues are from the sale of the ALZET product line, the sale of LACTEL biodegradable polymers and certain excipient sales, and from payments under collaborative research and development agreements with third parties. We do not expect our product revenues to increase significantly in the near future, and we do not expect that collaborative research and development revenues will exceed our actual operating expenses. We do not anticipate meaningful revenues to derive from the commercialization and marketing of our product candidates in development in the near future, and therefore do not expect to generate sufficient revenues to cover expenses or achieve profitability in the near future.

We may develop our own sales force and commercial group to market future products but we have limited sales and marketing experience with respect to pharmaceuticals and may not be able to do so effectively

We have a small sales and marketing group focused on our ALZET and LACTEL product lines. We may choose to develop our own sales force and commercial group to market products that we may develop in the future, or to market POSIDUR if we do not enter into an agreement with a third party to commercialize POSIDUR. Developing a sales force and commercial group will require substantial expenditures and the hiring of qualified personnel. We have limited sales and marketing experience, and may not be able to effectively recruit, train or retain sales personnel. If we are not able to put in place an appropriate sales force and commercial group for POSIDUR, we may not be able to effectively launch the product. We may not be able to effectively sell our product candidates, if approved, and our failure to do so could limit or materially harm our business.

We and our third-party collaborators may not sell our product candidates effectively

We and our third-party collaborators compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts and those of our third-party collaborations may be unable to compete successfully against these other companies. We and our third-party collaborators, if relevant, may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all. We and our third-party collaborators, if relevant, may be unable to engage qualified distributors. Even if engaged, these distributors may:

fail to satisfy financial or contractual obligations to us;

fail to adequately market our product candidates;

cease operations with little or no notice to us;

offer, design, manufacture or promote competing product lines;

fail to maintain adequate inventory and thereby restrict use of our product candidates; or

build up inventory in excess of demand thereby limiting future purchases of our product candidates resulting in significant quarter-to-quarter variability in our sales.

The failure of us or our third-party collaborators to effectively develop, gain regulatory approval for, sell, manufacture and market our product candidates will hurt our business, prospects and financial results.

We rely heavily on third parties to support development, clinical testing and manufacturing of our product candidates

We rely on third-party contract research organizations, service providers and suppliers to provide critical services to support development, clinical testing, and manufacturing of our product candidates. For example, we currently depend on third-party vendors to manage and monitor our clinical trials and to perform critical manufacturing steps for our product candidates. These third parties may not execute their responsibilities and tasks competently in compliance with applicable laws and regulations or in a timely fashion. We rely on third-parties to manufacture or perform manufacturing steps relating to our product candidates or components. We anticipate that we will continue to rely on these and other third-party contractors to support development, clinical testing, and manufacturing of our product candidates. Failure of these contractors to provide the required services in a competent or timely manner

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or on reasonable commercial terms could materially delay the development and approval of our development products, increase our expenses and materially harm our business, financial condition and results of operations.

Key components of our product candidates are provided by limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs

Certain components and drug substances used in our product candidates (including POSIDUR, REMOXY, our other ORADUR-based drug candidates, ELADUR and Relday are currently purchased from a single or a limited number of outside sources. In particular, Eastman Chemical is the sole supplier, pursuant to a supply agreement entered into in December 2005, of our requirements of sucrose acetate isobutyrate, a necessary component of POSIDUR, REMOXY, our other ORADUR-based drug candidates, ELADUR, Relday and certain other pharmaceutical product candidates we have under development, and Hospira is currently our sole supplier for clinical and commercial supplies of POSIDUR. The reliance on a sole or limited number of suppliers could result in:

- delays associated with redesigning a pharmaceutical product candidate due to a failure to obtain a single source component;
- an inability to obtain an adequate supply of required components; and
- reduced control over pricing, quality and delivery time.

We have supply agreements in place for certain components of our pharmaceutical product candidates, but do not have in place long term supply agreements with respect to all of the components of any of our product candidates. Therefore the supply of a particular component could be terminated at any time without penalty to the supplier. In addition, we may not be able to procure required components or drugs from third-party suppliers at a quantity, quality and cost acceptable to us. Any interruption in the supply of single source components could cause us to seek alternative sources of supply or manufacture these components internally. Furthermore, in some cases, we are relying on our third-party collaborators to procure supply of necessary components. If the supply of any components for our product candidates is interrupted, components from alternative suppliers may not be available in sufficient volumes or at acceptable quality levels within required timeframes, if at all, to meet our needs or those of our third-party collaborators. This could delay our ability to complete clinical trials and obtain approval for commercialization and marketing of our product candidates, causing us to lose sales, incur additional costs, delay new product introductions and could harm our reputation.

If we are unable to adequately protect, maintain or enforce our intellectual property rights or secure rights to third-party patents, we may lose valuable assets, experience reduced market share or incur costly litigation to protect our rights or our third-party collaborators may choose to terminate their agreements with us

Our ability to commercially exploit our products will depend significantly on our ability to obtain and maintain patents, maintain trade secret protection and operate without infringing the proprietary rights of others.

As of July 24, 2015, we held over 55 unexpired issued U.S. patents and over 360 unexpired issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have over 30 pending U.S. patent applications and over 75 foreign applications pending in Europe, Australia, Japan, Canada and other countries.

The patent status of our lead drug candidates, REMOXY and POSIDUR, are as follows:

In the U.S., REMOXY is covered by five patent families. Three patent families include granted patents expiring in at least 2015, 2025, and 2031, respectively. The patent family providing protection until at least 2025 includes eight granted patents. The other two patent families include pending patent applications, which if granted, could result in patents expiring in 2034, plus any eligible patent term adjustments and extensions. We currently have pending U.S. applications for four of these five patent families. There can be no assurance that the pending patent applications will be granted. In Europe, REMOXY is covered by two granted patents expiring in 2016 and 2023, respectively, plus any eligible patent term extensions.

In the U.S., POSIDUR is covered by two patent families, which include granted patents expiring in at least 2015 and 2025, respectively. In Europe, POSIDUR is covered by two granted patents expiring in 2016 and 2025, respectively, plus any eligible patent term extensions.

Our Epigenomic Regulator Program includes six in-licensed patent families. One of these patent families includes a granted patent expiring in at least 2026. The other patent families include pending patent applications, which if granted, could result in patents expiring in 2032, 2033, 2034, 2035, and 2035, respectively, plus any eligible patent term adjustments and extensions. There can be no assurance that the pending patent applications will be granted. Further, there can be no assurance that VCU will not attempt to terminate their license to us, which termination would result in the loss of our rights to these patent families.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications or those that are licensed to us may not issue into patents, and any issued patents may not provide protection against competitive technologies or may be held invalid if challenged. Our competitors may also independently

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develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

The patent laws of the U.S. have recently undergone changes through court decisions which may have significant impact on us and our industry. Decisions of the U.S. Supreme Court and other courts with respect to the standards of patentability, enforceability, availability of injunctive relief and damages may make it more difficult for us to procure, maintain and enforce patents. In addition, the America Invents Act was signed into law in September 2011, which among other changes to the U.S. patent laws, changes patent priority from first to invent to first to file, implements a post-grant opposition system for patents and provides a prior user defense to infringement. These judicial and legislative changes have introduced significant uncertainty in the patent law landscape and may potentially negatively impact our ability to procure, maintain and enforce patents to provide exclusivity for our products.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual s relationship with us will be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology.

We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology. We may have to resort to litigation to protect our intellectual property rights, or to determine their scope, validity or enforceability. In addition, interference, derivation, post-grant oppositions, and similar proceedings may be necessary to determine rights to inventions in our patents and patent applications. Enforcing or defending our proprietary rights is expensive, could cause diversion of our resources and may be unsuccessful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

Our collaboration agreements may depend on our intellectual property

We are party to collaborative agreements with Pain Therapeutics, Zogenix, Orient Pharma, Impax and Santen among others. Our third-party collaborators have entered into these agreements based on the exclusivity that our intellectual property rights confer on the products being developed. The loss or diminution of our intellectual property rights could result in a decision by our third-party collaborators to terminate their agreements with us. In addition, these agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property and data under collaborations. Such disputes can lead to lengthy, expensive litigation or arbitration requiring us to devote management time and resources to such dispute which we would otherwise spend on our business. To the extent that our agreements call for future royalties to be paid conditional on our having patents covering the royalty-bearing subject matter, the decision by the Supreme Court in the case of *MedImmune v. Genentech* could encourage our licensees to challenge the validity of our patents and thereby seek to avoid future royalty obligations without losing the benefit of their license. Should they be successful in such a challenge, our ability to collect future royalties could be substantially diminished.

We may be sued by third parties claiming that our product candidates infringe on their intellectual property rights, particularly because there is substantial uncertainty about the validity and breadth of medical patents

We or our collaborators may be exposed to future litigation by third parties based on claims that our product candidates or activities infringe the intellectual property rights of others or that we or our collaborators have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents and the breadth and scope of trade secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us or our collaborators, whether or not valid, could result in substantial costs, could place a significant strain on our financial resources and could harm our reputation. We also may not have sufficient funds to litigate against parties with substantially greater resources. In addition, pursuant to our collaborative agreements, we have provided our collaborators with the right, under specified circumstances, to defend against any claims of infringement of the third party intellectual property rights, and such collaborators may not defend against such claims adequately or in the manner that we would do ourselves. Intellectual property litigation or claims could force us or our collaborators to do one or more of the following, any of which could harm our business or financial results:

cease selling, incorporating or using any of our pharmaceutical product candidates that incorporate the challenged intellectual property, which would adversely affect our revenue;

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obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or

redesign our product candidates, which would be costly and time-consuming.

Technologies and businesses which we acquire or license may be difficult to integrate, disrupt our business, dilute stockholder value or divert management attention

We may acquire technologies, products or businesses to broaden the scope of our existing and planned product lines and technologies. Future acquisitions expose us to:

increased costs associated with the acquisition and operation of the new businesses or technologies and the management of geographically dispersed operations;

the risks associated with the assimilation of new technologies, operations, sites and personnel;

the diversion of resources from our existing business and technologies;

the inability to generate revenues to offset associated acquisition costs;

the requirement to maintain uniform standards, controls, and procedures; and

the impairment of relationships with employees and customers or third party collaborators as a result of any integration of new management personnel.

Acquisitions may also result in the issuance of dilutive equity securities, the incurrence or assumption of debt or additional expenses associated with the amortization of acquired intangible assets or potential businesses. Acquisitions may not generate any additional revenue or provide any benefit to our business.

Some of our pharmaceutical product candidates contain controlled substances, the making, use, sale, importation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies

Some of our product candidates currently under development contain, and our products in the future may contain, controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation and distribution. REMOXY and our other ORADUR-based drug candidates, and certain other product candidates we have under development contain active ingredients which are classified as controlled substances under the regulations of the U.S. Drug Enforcement Agency. For our product candidates containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation and distribution of controlled substances. These regulations are extensive and include regulations governing

manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, record keeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of drug candidates including controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. In addition, because of their restrictive nature, these regulations could limit our commercialization of our product candidates containing controlled substances. In particular, among other things, there is a risk that these regulations may interfere with the supply of the drugs used in our clinical trials, and in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand.

Write-offs related to the impairment of long-lived assets, inventories and other non-cash charges, as well as stock-based compensation expenses may adversely impact or delay our profitability

We may incur significant non-cash charges related to impairment write-downs of our long-lived assets, including goodwill and other intangible assets. We will continue to incur non-cash charges related to amortization of other intangible assets. We are required to perform periodic impairment reviews of our goodwill at least annually. The carrying value of goodwill on our balance sheet was $6.4 million at June 30, 2015. To the extent these reviews conclude that the expected future cash flows generated from our business activities are not sufficient to recover the cost of our long-lived assets, we will be required to measure and record an impairment charge to write-down these assets to their realizable values. We completed our last review during the fourth quarter of 2014 and determined that goodwill was not impaired as of December 31, 2014. However, there can be no assurance that upon completion of subsequent reviews a material impairment charge will not be recorded. If future periodic reviews determine that our assets are impaired and a write-down is required, it will adversely impact or delay our profitability.

Inventories, in part, include certain excipients that are sold to customers and included in products in development. These inventories are capitalized based on management s judgment of probable sale prior to their expiration date which in turn is primarily based on management s internal estimates. 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,

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among other potential factors, a denial or delay of approval of a product by the necessary regulatory bodies, changes in product development timelines, or other 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. For example, we recorded charges to cost of goods sold of approximately $1.6 million, of which approximately $1.1 million related to the write-down of the cost basis of inventory and approximately $500,000 related to the accrual of a liability for the minimum purchase commitment for excipients in the year ended December 31, 2014 as a result of a change in the forecasted demand for the excipients after Pfizer announced that it had decided to discontinue the development and commercialization of REMOXY and return its rights to Pain Therapeutics.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents, short-term investments or long-term investments and our ability to meet our financing objectives

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term investments consist primarily of readily marketable debt securities with original maturities of greater than 90 days from the date of purchase but remaining maturities of less than one year from the balance sheet date. Our long-term investments consist primarily of readily marketable debt securities with maturities in one year or beyond from the balance sheet date. While, as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments or long-term investments since June 30, 2015, no assurance can be given that deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents, short-term investments or long-term investments or our ability to meet our financing objectives.

We depend upon key personnel who may terminate their employment with us at any time, and we may need to hire additional qualified personnel

Our success will depend to a significant degree upon the continued services of key management, technical and scientific personnel, including Felix Theeuwes, our Chairman and Chief Scientific Officer, and James E. Brown, our President and Chief Executive Officer. In addition, our success will depend on our ability to attract and retain other highly skilled personnel, particularly as we develop and expand our Epigenomic Regulator Program. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to product development or approval, loss of sales and diversion of management resources.

We may not successfully manage our company through varying business cycles

Our success will depend on properly sizing our company through growth and contraction cycles caused in part by changing business conditions, which places a significant strain on our management and on our administrative, operational and financial resources. To manage through such cycles, we must expand or contract our facilities, our operational, financial and management systems and our personnel. If we were unable to manage growth and contractions effectively our business would be harmed.

Our business involves environmental risks and risks related to handling regulated substances

In connection with our research and development activities and our manufacture of materials and pharmaceutical product candidates, we are subject to federal, state and local laws, rules, regulations and policies governing the use,

generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the use, generation and disposal of hazardous materials, including but not limited to certain hazardous chemicals, solvents, agents and biohazardous materials. The extent of our use, generation and disposal of such substances has increased substantially since we started manufacturing and selling biodegradable polymers. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances generated by us, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

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Our corporate headquarters, manufacturing facilities and personnel are located in a geographical area that is seismically active

Our corporate headquarters, primary manufacturing facilities and personnel are located in a geographical area that is known to be seismically active and prone to earthquakes. Should such a natural disaster occur, our ability to conduct our business could be severely restricted, and our business and assets, including the results of our research, development and manufacturing efforts, could be destroyed.

We currently have significant debt. Compliance with repayment obligations and other covenants may be difficult, and failure by us to fulfill our obligations under the applicable loan agreements may cause the repayment obligations to accelerate.

In June 2014, we entered into a Loan and Security Agreement (the Loan Agreement) with Oxford Finance LLC, pursuant to which Oxford provided a $20 million secured single-draw term loan to us with a maturity date of July 1, 2018. The term loan was fully drawn at close and the proceeds are to be used for working capital and general business requirements. The term loan was amended in July 2015. As amended, the term loan repayment schedule provides for interest only payments until February 1, 2017, followed by consecutive equal monthly payments of principal and interest in arrears starting on February 1, 2017 and continuing through the amended maturity date (July 1, 2019), with interest accruing at 7.95% plus an additional payment equal to 10% of the principal amount of the term loan, which is due when the term loan becomes due or upon the prepayment of the facility. In addition, if we elect to prepay the loan, there is also a prepayment fee between 1% and 3% of the principal amount of the term loan depending on the timing and circumstances of prepayment. Our debt repayment obligations under the Loan Agreement may prove a burden to the Company as they become due, particularly following the expiration of the interest-only period.

In addition, the term loan is secured by substantially all of our assets, except that the collateral does not include any equity interests in the Company, any intellectual property (including all licensing, collaboration and similar agreements relating thereto), and certain other excluded assets. The Loan Agreement contains customary representations, warranties and covenants by us, which covenants limit our ability to convey, sell, lease, transfer, assign or otherwise dispose of certain of our assets; engage in any business other than the businesses currently engaged in by us or reasonably related thereto; liquidate or dissolve; make certain management changes; undergo certain change of control events; create, incur, assume, or be liable with respect to certain indebtedness; grant certain liens; pay dividends and make certain other restricted payments; make certain investments; make payments on any subordinated debt; and enter into transactions with any of our affiliates outside of the ordinary course of business or permit our subsidiaries to do the same. Complying with these covenants may make it more difficult for us to successfully execute our business strategy.

The Loan Agreement also contains customary events of default, including, among other things, our failure to fulfill certain of our obligations under the Loan Agreement and the occurrence of a material adverse change in our business, operations or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of lender s lien in the collateral or in the value of such collateral. In the event of default by us under the Loan Agreement, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Loan Agreement, which could harm our business, operations and financial condition.

Risks Related To Our Industry

The market for our pharmaceutical product candidates is rapidly changing and competitive, and new products or technologies developed by others could impair our ability to grow our business and remain competitive

The pharmaceutical industry is subject to rapid and substantial technological change. Developments by others may render our product candidates under development or technologies noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

We may face competition from other companies in numerous industries including pharmaceuticals, medical devices and drug delivery. POSIDUR, ELADUR, Relday, DUR-928, REMOXY and other ORADUR-based drug candidates, if approved, will compete with currently marketed oral opioids, transdermal opioids, non-opioid pain medications, local anesthetic patches, anti-psychotics, stimulants, cardiovascular and metabolic disease pharmaceuticals, anti-inflammatory agents, implantable and external infusion pumps which can be used for infusion of opioids and local anesthetics. Our pain products, if approved, will compete with currently marketed products by Purdue Pharma, Knoll, Janssen, Medtronic, Endo, AstraZeneca, Arrow International, Tricumed, Halyard Health, Cumberland Pharmaceuticals, Pacira, Acorda Therapeutics, Mallinckrodt, Shire, Johnson & Johnson, Eli Lilly, Pfizer, Novartis and others. POSIDUR, if approved, would compete with other non-opioid post-surgical pain products such as those currently marketed by Pacira and Halyard Health and may compete with other products in development by companies including Innocoll, Heron and others. Purdue Pharma, Pernix Therapeutics, Par Pharmaceutical, Sandoz, Actavis, Collegium Pharmaceutical, Pfizer, Impax Laboratories, Elite Pharmaceuticals, Egalet, Teva Pharmaceuticals and others have also announced regulatory approval or development plans for

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abuse deterrent opioid products, and REMOXY, if approved, will compete directly with these products. Our ORADUR-ADHD product candidates, if approved, will compete with currently marketed or approved products by Shire, Johnson & Johnson, UCB, Novartis, Noven, Celgene, Eli Lilly, Pfizer, Actavis and others. Relday, if approved, will compete with currently marketed products by Johnson & Johnson, Eli Lilly, Astra Zeneca, Pfizer, Bristol-Myers Squibb and others. Competition for DUR-928, if approved, will depend on the specific indications for which DUR-928 is approved. Intercept, Gilead, Raptor Pharmaceuticals, Shire, LaJolla Pharmaceuticals, Conatus Pharmaceuticals, Galectin Therapeutics, Genfit, Pfizer, Trophos, Galmed Pharmaceuticals, Tobira Therapeutics, Enanta Pharmaceuticals, Novo Nordisk, Takeda, Vital Therapies and others have development plans for products to treat NAFLD/NASH. Ischemix, Thrasos Therapeutics, AM-Pharma, Complexa, AbbVie, AlloCure, Quark Pharmaceuticals and others have development plans for products to treat acute kidney injury.

Numerous companies are applying significant resources and expertise to the problems of drug delivery and several of these are focusing or may focus on delivery of drugs to the intended site of action, including Alkermes, Pacira, Immune Pharmaceuticals, Innocoll, Nektar, Halyard Health, Acorda Therapeutics, Flamel, Alexza, Hospira, Cumberland Pharmaceuticals, Egalet, Acura, Elite Pharmaceuticals, Phosphagenics, Intellipharmaceutics, Collegium Pharmaceutical, Heron Therapeutics, Teva and others. Some of these competitors may be addressing the same therapeutic areas or indications as we are. Our current and potential competitors may succeed in obtaining patent protection or commercializing products before us. Many of these entities have significantly greater research and development capabilities than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors research and development, financial, marketing, manufacturing and other resources.

We are engaged in the development of novel therapeutic technologies. Our resources are limited and we may experience technical challenges inherent in such novel technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our product candidates. Our competitors may develop products that are safer, more effective or less costly than our product candidates and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our product candidates even if commercialized. Chronic and post-operative pain are currently being treated by oral medication, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices which will be competitive with our product candidates. These treatments are widely accepted in the medical community and have a long history of use. The established use of these competitive products may limit the potential for our product candidates to receive widespread acceptance if commercialized.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. As a pharmaceutical company, even though we do not and may not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our

business. These regulations include:

the Federal Healthcare Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid, and which will constrain our marketing practices and the marketing practices of our licensees, educational programs, pricing policies, and relationships with healthcare providers or other entities;

the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of designated health services with whom the physician or a member of the physician s immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;

federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent, and which may expose entities that provide coding and billing advice to customers to potential criminal and civil penalties, including through civil whistleblower or qui tam actions, and including as a result of claims presented in

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violation of the Federal Healthcare Anti-Kickback Statute, the Stark Law or other healthcare-related laws, including laws enforced by the FDA;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services, and which as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

federal physician sunshine requirements under the Affordable Care Act, which requires manufacturers of drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws requiring pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and which may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state and foreign laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws such as HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Healthcare reform measures could hinder or prevent our product candidates commercial success.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our collaborators or potential collaborators. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which is intended to contain or reduce the costs of medical products and services. For example, in March 2010, the President signed one of the most significant healthcare reform measures in decades, the Affordable Care Act. It contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things:

- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell branded prescription drugs ;
- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- requires collection of rebates for drugs paid by Medicaid managed care organizations;
- addresses new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extension products;
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D; and
- mandates a further shift in the burden of Medicaid payments to the states.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, automatic reductions to several government programs were enacted during sequestration . These reductions included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced

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Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates once approved or additional pricing pressures.

We could be exposed to significant product liability claims which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage

The testing, manufacture, marketing and sale of our product candidates involve an inherent risk that product liability claims will be asserted against us. Although we are insured against such risks up to an annual aggregate limit in connection with clinical trials and commercial sales of our product candidates, our present product liability insurance may be inadequate and may not fully cover the costs of any claim or any ultimate damages we might be required to pay. Product liability claims or other claims related to our product candidates, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant damages. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our product candidates.

Acceptance of our pharmaceutical product candidates in the marketplace is uncertain, and failure to achieve market acceptance will delay our ability to generate or grow revenues

Our future financial performance will depend upon the successful introduction and customer acceptance of our products in research and development, including POSIDUR, REMOXY and other ORADUR-based drug candidates, ELADUR, Relday and DUR-928. Even if approved for marketing, our product candidates may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products, including oral medication, transdermal drug delivery products such as drug patches, or external or implantable drug delivery products; and
- pricing and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations, hospital formularies and other health plan administrators.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our products. If we are unable to obtain regulatory approval, commercialize and market our future products when planned and achieve market acceptance, we will not achieve anticipated revenues.

If users of our products are unable to obtain adequate reimbursement from third-party payors, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and third-party collaborators and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care, and the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

The successful commercialization of our product candidates will depend in part on the extent to which appropriate reimbursement levels for the cost of our product candidates and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly limiting payments or reimbursement for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may limit reimbursement or payment for our

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products. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

If we or our third-party collaborators are unable to train physicians to use our pharmaceutical product candidates to treat patients diseases or medical conditions, we may incur delays in market acceptance of our products

Broad use of our product candidates will require extensive training of numerous physicians on the proper and safe use of our product candidates. The time required to begin and complete training of physicians could delay introduction of our products and adversely affect market acceptance of our products. We or third parties selling our product candidates may be unable to rapidly train physicians in numbers sufficient to generate adequate demand for our product candidates. Any delay in training would materially delay the demand for our product candidates and harm our business and financial results. In addition, we may expend significant funds towards such training before any orders are placed for our products, which would increase our expenses and harm our financial results.

Potential new accounting pronouncements and legislative actions are likely to impact our future financial position or results of operations

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations, PCAOB pronouncements and NASDAQ rules, are creating uncertainty for companies such as ours and insurance, accounting and auditing costs are high as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Risks Related To Our Common Stock

Our stock price has in the past and may in the future not meet the minimum bid price for continued listing on the Nasdaq Global Market. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from The Nasdaq Global Market or if we are unable to transfer our listing to another stock market

On each of January 16, 2013 and December 9, 2014, we received written notification from Nasdaq informing us that because the closing bid price of our common stock was below $1.00 for 30 consecutive trading days, our shares no longer complied with the minimum closing bid price requirement for continued listing on the Nasdaq Global Market under Nasdaq Marketplace Rule 5450(a)(1). Each time, we were given a period of 180 days from the date of the notification to regain compliance with Nasdaq s listing requirements by having the closing bid price of our common stock listed on Nasdaq be at least $1.00 for at least 10 consecutive trading days.

While we regained compliance within the applicable time periods as of February 1, 2013 and March 6, 2015, respectively, if our shares again no longer comply with the minimum closing bid price requirement for continued listing on the Nasdaq Global Market under Nasdaq Marketplace Rule 5450(a)(1) and we do not regain compliance within the applicable 180-day time period, we may transfer our common stock listing to The Nasdaq Capital Market,

provided that the Company (i) meets the applicable market value of publicly held shares requirement for continued listing and all other applicable requirements for initial listing on The Nasdaq Capital Market (except for the closing bid price requirement) based on the Company s most recent public filings and market information and (ii) notifies Nasdaq of its intent to cure this deficiency. Following a transfer to The Nasdaq Capital Market, the Company would be afforded the remainder of an additional 180 calendar day grace period in order to regain compliance with the minimum closing bid price requirement of $1.00 per share under The Nasdaq Capital Market, unless it does not appear to NASDAQ that it would be possible for the Company to cure the deficiency.

If compliance is not demonstrated within the applicable compliance period, Nasdaq will notify the Company that its securities will be subject to delisting. The Company may appeal Nasdaq s determination to delist its securities to a Hearings Panel. During any appeal process, shares of the Company s common stock would continue to trade on the Nasdaq Global Market or Nasdaq Capital Market, as applicable.

There can be no assurance that we will maintain or regain compliance with the requirements for listing our common stock on the Nasdaq Global Market or that our common stock would be eligible for transfer to the Nasdaq Capital Market and remain in compliance with the requirements for listing on that market. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative

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results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Our operating history makes evaluating our stock difficult

Our quarterly and annual results of operations have historically fluctuated and we expect will continue to fluctuate for the foreseeable future. We believe that period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties encountered by companies with no approved pharmaceutical products, particularly companies in new and rapidly evolving markets such as pharmaceuticals, drug delivery and biotechnology. To address these risks, we must, among other things, obtain regulatory approval for and commercialize our product candidates, which may not occur. We may not be successful in addressing these risks and difficulties. We may require additional funds to complete the development of our product candidates and to fund operating losses to be incurred in the next several years.

Investors may experience substantial dilution of their investment

Investors may experience dilution of their investment if we raise capital through the sale of additional equity securities or convertible debt securities or grant additional stock options to employees and consultants. In December 2013, we filed a new shelf registration statement on Form S-3 with the SEC, which upon being declared effective in January 2014, allowed us to offer up to $100.9 million of securities from time to time in one or more public offerings of our common stock. In addition, we entered into a Controlled Equity Offering℠ sales agreement with Cantor Fitzgerald, under which we may sell, subject to certain limitations, up to $25 million of common stock through Cantor Fitzgerald, acting as agent. During the third quarter of 2014, we raised net proceeds (net of commissions) of approximately $4.7 million from the sale of 2,907,664 shares of our common stock in the open market through the agreement with Cantor Fitzgerald at a weighted average price of $1.65 per share. During the second quarter of 2015, we raised net proceeds (net of commissions) of approximately $11.6 million from the sale of 5,856,299 shares of our common stock in the open market through the agreement with Cantor Fitzgerald at a weighted average price of $2.04 per share. As of July 24, 2015, the Company had up to $8.2 million of common stock available for sale under the Controlled Equity Offering ℠ program. Any additional sales in the public market of our common stock, under the agreement with Cantor Fitzgerald or otherwise under the shelf registration statement, could adversely affect prevailing market prices for our common stock.

The price of our common stock may be volatile

The stock markets in general, and the markets for pharmaceutical stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock.

Price declines in our common stock could result from general market and economic conditions and a variety of other factors, including:

- failure of third-party collaborators to continue development of the respective product candidates they are developing;

adverse results (including adverse events or failure to demonstrate safety or efficacy) or delays in our clinical and non-clinical trials of POSIDUR, REMOXY or our other ORADUR-based drug candidates, ELADUR, Relday, DUR-928 or other product candidates;

announcements of FDA non-approval of our product candidates, or delays in the FDA or other foreign regulatory agency review process;

adverse actions taken by regulatory agencies or law enforcement agencies with respect to our product candidates, clinical trials, manufacturing processes or sales and marketing activities, or those of our third party collaborators;

announcements of technological innovations, patents, product approvals or new products by our competitors;

regulatory, judicial and patent developments in the United States and foreign countries;

any lawsuit involving us or our product candidates including intellectual property infringement or product liability suits;

announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;

developments concerning our strategic alliances or acquisitions;

actual or anticipated variations in our operating results;

changes in recommendations by securities analysts or lack of analyst coverage;

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deviations in our operating results from the estimates of analysts;

sales of our common stock by our executive officers or directors or sales of substantial amounts of common stock by us or others;

potential failure to meet continuing listing standards from The NASDAQ Global Market;

loss or disruption of facilities due to natural disasters;

changes in accounting principles; or

loss of any of our key scientific or management personnel.

The market price of our common stock may fluctuate significantly in response to factors which are beyond our control. The stock market in general has recently experienced extreme price and volume fluctuations. In addition, the market prices of securities of technology and pharmaceutical companies have also been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of our common stock.

In the past, following periods of volatility in the market price of a particular company s securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive and divert management s attention and our company s resources.

We have broad discretion over the use of our cash and investments, and their investment may not always yield a favorable return

Our management has broad discretion over how our cash and investments are used and may from time to time invest in ways with which our stockholders may not agree and that do not yield favorable returns.

Executive officers, directors and principal stockholders have substantial control over us, which could delay or prevent a change in our corporate control favored by our other stockholders

Our directors, executive officers and principal stockholders, together with their affiliates, have substantial control over us. The interests of these stockholders may differ from the interests of other stockholders. As a result, these stockholders, if acting together, could have the ability to exercise control over all corporate actions requiring stockholder approval irrespective of how our other stockholders may vote, including:

the election of directors;

the amendment of charter documents;

the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets; or

the defeat of any non-negotiated takeover attempt that might otherwise benefit the public stockholders.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage another company from acquiring us

Provisions of Delaware law, our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

authorizing the issuance of blank check preferred stock without any need for action by stockholders;

providing for a classified board of directors with staggered terms;

requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;

eliminating the ability of stockholders to call special meetings of stockholders;

prohibiting stockholder action by written consent; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

None

Item 5. Other Information

None

Item 6. Exhibits

10.1*	DURECT Corporation 2000 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K ((File No. 000-31615) filed on June16, 2015).
31.1	Rule 13a-14(a) Section 302 Certification of James E. Brown.
31.2	Rule 13a-14(a) Section 302 Certification of Matthew J. Hogan.
32.1	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of James E. Brown.
32.2	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of Matthew J. Hogan.
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101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Management contract or compensatory plan or arrangement.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DURECT CORPORATION

By: /S/ JAMES E. BROWN
James E. Brown

Chief Executive Officer

Date: August 4, 2015

By: /S/ MATTHEW J. HOGAN
Matthew J. Hogan

Chief Financial Officer and Principal Accounting Officer

Date: August 4, 2015

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