

GERON CORP
Form 10-Q
May 07, 2015
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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, 2015

OR

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

For the transition period from to .

GERON CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation or organization)

75-2287752

(I.R.S. Employer
Identification No.)

149 COMMONWEALTH DRIVE, SUITE 2070, MENLO PARK, CA

(Address of principal executive offices)

94025

(Zip Code)

(650) 473-7700

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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 website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer
Non-accelerated filer
(Do not check if a smaller reporting company)

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

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Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class:
Common Stock, \$0.001 par value

Outstanding at April 30, 2015:
158,087,513 shares

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GERON CORPORATION

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2015

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	MARCH 31, 2015 (UNAUDITED)	DECEMBER 31, 2014 (NOTE 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,182	\$ 42,796
Restricted cash	266	266
Marketable securities	135,655	108,645
Interest and other receivables	1,190	963
Prepaid assets	604	736
Total current assets	147,897	153,406
Noncurrent marketable securities	17,739	18,932
Property and equipment, net	171	173
	\$ 165,807	\$ 172,511
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 1,180	\$ 1,033
Accrued compensation and benefits	2,135	4,213
Accrued collaboration charges	626	
Accrued restructuring charges	316	
Accrued liabilities	1,375	1,537
Deferred revenue	35,000	35,000
Fair value of derivatives		16
Total current liabilities	40,632	41,799
Commitments and contingencies		
Stockholders' equity:		
Common stock	158	157
Additional paid-in capital	1,062,782	1,059,072
Accumulated deficit	(937,748)	(928,433)
Accumulated other comprehensive loss	(17)	(84)
Total stockholders' equity	125,175	130,712
	\$ 165,807	\$ 172,511

See accompanying notes.

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GERON CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)
(UNAUDITED)

	THREE MONTHS ENDED	
	2015	2014
	MARCH 31,	
Revenues:		
License fees and royalties	\$ 537	\$ 474
Operating expenses:		
Research and development	4,987	5,211
Restructuring charges	406	
General and administrative	4,600	3,994
Total operating expenses	9,993	9,205
Loss from operations	(9,456)	(8,731)
Unrealized gain on derivatives	16	224
Interest and other income	149	83
Interest and other expense	(24)	(16)
Net loss	\$ (9,315)	\$ (8,440)
Basic and diluted net loss per share	\$ (0.06)	\$ (0.06)
Shares used in computing basic and diluted net loss per share	157,547,568	143,465,818

See accompanying notes.

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GERON CORPORATION
CONDENSED STATEMENTS OF COMPREHENSIVE LOSS
(IN THOUSANDS)
(UNAUDITED)

	THREE MONTHS ENDED			
	MARCH 31,			
	2015		2014	
Net loss	\$	(9,315)	\$	(8,440)
Net unrealized gain (loss) on marketable securities		67		(76)
Comprehensive loss	\$	(9,248)	\$	(8,516)

See accompanying notes.

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GERON CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
CHANGE IN CASH AND CASH EQUIVALENTS
(IN THOUSANDS)
(UNAUDITED)

	THREE MONTHS ENDED		MARCH 31,	
	2015	2014	2015	2014
Cash flows from operating activities:				
Net loss	\$	(9,315)	\$	(8,440)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		9		15
Accretion and amortization on investments, net		629		606
Stock-based compensation for services by non-employees		67		65
Stock-based compensation for employees and directors		2,013		1,641
Amortization related to 401(k) contributions		154		12
Unrealized gain on derivatives		(16)		(224)
Changes in assets and liabilities:				
Other current and noncurrent assets		(95)		(646)
Other current liabilities		(1,151)		(2,534)
Net cash used in operating activities		(7,705)		(9,505)
Cash flows from investing activities:				
Purchases of property and equipment		(7)		
Purchases of marketable securities		(78,869)		(107,144)
Proceeds from maturities of marketable securities		52,490		17,363
Net cash used in investing activities		(26,386)		(89,781)
Cash flows from financing activities:				
Proceeds from issuance of common stock, net of issuance costs		1,477		97,620
Net cash provided by financing activities		1,477		97,620
Net decrease in cash and cash equivalents		(32,614)		(1,666)
Cash and cash equivalents at the beginning of the period		42,796		12,990
Cash and cash equivalents at the end of the period	\$	10,182	\$	11,324

See accompanying notes.

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

MARCH 31, 2015

(UNAUDITED)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The terms Geron, the Company, we and us as used in this report refer to Geron Corporation. The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles, or GAAP, for complete financial statements. In the opinion of management of Geron, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three month period ending March 31, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015 or any other period. These financial statements and notes should be read in conjunction with the financial statements for each of the three years ended December 31, 2014, included in the Company's Annual Report on Form 10-K. The accompanying condensed balance sheet as of December 31, 2014 has been derived from audited financial statements at that date.

Net Loss Per Share

Basic earnings (loss) per share is calculated based on the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is calculated based on the weighted average number of shares of common stock and potential dilutive securities outstanding during the period. Potential dilutive securities primarily consist of outstanding stock options, restricted stock awards and warrants to purchase common stock and are determined using the treasury stock method at an average market price during the period.

Because we are in a net loss position, diluted loss per share excludes the effects of potential dilutive securities. Had we been in a net income position, diluted earnings per share would have included the shares used in the computation of basic net loss per share as well as an additional 4,122,123 and 5,596,655 shares for the three months ended March 31, 2015 and 2014, respectively, related to outstanding stock options, restricted stock awards and warrants (as determined using the treasury stock method at the estimated average market value).

Use of Estimates

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The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On a regular basis, management evaluates these estimates and assumptions. Actual results could differ from those estimates.

Fair Value of Financial Instruments

Cash Equivalents and Marketable Securities

We consider all highly liquid investments with an original maturity of three months or less to be cash equivalents. We are subject to credit risk related to our cash equivalents and marketable securities. We place our cash and cash equivalents in money market funds and cash operating accounts. Our marketable securities include U.S. government-sponsored enterprise securities, commercial paper and corporate notes with original maturities ranging from four to 20 months.

We classify our marketable securities as available-for-sale. We record available-for-sale securities at fair value with unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses are included in interest and other income and are derived using the specific identification method for determining the cost of securities sold and have been insignificant to date. Dividend and interest income are recognized when earned and included in interest and other income in our condensed statements of operations. We recognize a charge when the declines in the fair values below the amortized cost basis of our available-for-sale securities are judged to be other-than-temporary. We consider various factors in determining whether to recognize an other-than-temporary charge, including whether we intend to sell the security or whether it is more likely than not that we would be required to sell the security before recovery of the amortized cost basis. Declines in market value associated with credit losses judged as other-than-temporary result in a charge to interest and other income. Other-than-temporary charges not related to credit losses are included in accumulated other comprehensive income (loss) in stockholders' equity. We have not recorded any other-than-temporary impairment charges on our available-for-sale securities for the three months ended March 31, 2015 and 2014. See Note 2 on Fair Value Measurements.

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

MARCH 31, 2015

(UNAUDITED)

Fair Value of Derivatives

For non-employee options classified as liabilities, the fair value of these instruments is recorded on the condensed balance sheet at inception and adjusted to fair value at each financial reporting date. The change in fair value of the non-employee options is recorded in the condensed statements of operations as unrealized gain (loss) on derivatives. Fair value of non-employee options is estimated using the Black Scholes option-pricing model. The non-employee options continue to be reported as a liability until such time as the instruments are exercised or expire or are otherwise modified to remove the provisions which require this treatment, at which time these instruments are marked to fair value and reclassified from liabilities to stockholders' equity. As of March 31, 2015, all non-employee options classified as liabilities expired unexercised. For non-employee options classified as permanent equity, the fair value of the non-employee options is recorded in stockholders' equity as of their respective vesting dates and no further adjustments are made. See Note 2 on Fair Value Measurements.

Revenue Recognition

In general, we recognize revenue for each unit of accounting when all of the following criteria have been met: (a) persuasive evidence of an arrangement exists, (b) delivery has occurred or services have been rendered, (c) the seller's price to the buyer is fixed or determinable, and (d) collectability is reasonably assured. Amounts received prior to satisfying these revenue recognition criteria are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as noncurrent deferred revenue.

License and/or Collaboration Agreements

In addition to the exclusive collaboration and license agreement, or Collaboration Agreement, that we entered into with Janssen Biotech, Inc., or Janssen, in November 2014 (which is more fully described in Note 3 on Collaboration and License Agreement), we have entered into several license or collaboration agreements with various oncology, diagnostics, research tools and biologics production companies. Economic terms in these agreements may include non-refundable license payments in cash or equity securities, option payments in cash or equity securities, cost reimbursements, cost-sharing arrangements, milestone payments, royalties on future sales of products, or any combination of these items. In applying the appropriate revenue recognition guidance related to these agreements, we first assess whether the arrangement contains multiple elements. In this evaluation, we consider: (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires us to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered item(s) has value to the customer on a standalone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or

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performance of the undelivered item(s) is considered probable and substantially in our control. In assessing whether an item has standalone value, we consider factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, we consider whether the collaboration partner can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s) and whether there are other vendors that can provide the undelivered element(s).

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. We then apply the applicable revenue recognition criteria noted above to each of the separate units of accounting in determining the appropriate period and pattern of recognition. We determine how to allocate arrangement consideration to identified units of accounting based on the selling price hierarchy provided under relevant accounting guidance. The estimated fair value of deliverables under the arrangement may be derived using a best estimate of selling price if vendor-specific-objective evidence and third-party evidence are not available.

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Upfront non-refundable signing, license or non-exclusive option fees are recognized as revenue: (i) when rights to use the intellectual property, related to a license that has standalone value from the other deliverables to be provided under the agreement, have been delivered or (ii) over the term of the agreement if we have continuing performance obligations as the arrangement would be accounted for as a single unit of accounting. When payments are received in equity securities, we do not recognize any revenue unless such securities are determined to be realizable in cash.

At the inception of an arrangement that includes milestone payments, we assess whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (i) the consideration is commensurate with either the performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We consider various factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. Milestone payments for milestones that are considered substantive would be recognized as revenue in their entirety upon successful accomplishment of the milestone, assuming all other revenue recognition criteria are met. Milestone payments for milestones that are not considered substantive would be recognized as revenue over the remaining period of performance, assuming all other revenue recognition criteria are met.

Royalties are recognized as earned in accordance with contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received. Revenue from commercial milestone payments is accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

Cost-sharing expenses are recorded as earned or owed based on the performance requirements by both parties under the respective contracts. For arrangements in which we and our collaboration partner in the agreement are exposed to significant risks and rewards depending on the commercial success of the activity, we recognize payments between the parties on a net basis and record such amounts as a reduction or addition to research and development expense. For arrangements in which we have agreed to perform certain research and development services for our collaboration partner and are not exposed to significant risks and rewards depending on the commercial success of the activity, we recognize the respective cost reimbursements as revenue under the collaborative agreement as the related research and development services are rendered.

Restricted Cash

Restricted cash consists of funds maintained in a separate certificate of deposit account for credit card purchases.

Research and Development Expenses

Research and development expenses consist of expenses incurred in identifying, developing and testing product candidates resulting from our independent efforts as well as efforts associated with collaborations. These expenses include, but are not limited to, in-process research and development acquired in an asset acquisition and deemed to have no alternative future use, payroll and personnel expense, lab supplies, preclinical studies, clinical trials, including support for investigator-sponsored clinical trials, raw materials to manufacture clinical trial drugs, manufacturing costs for research and clinical trial materials, sponsored research at other labs, consulting, costs to maintain technology licenses, our proportionate share of research and development costs under cost-sharing arrangements with collaborators and research-related overhead. Research and development costs are expensed as incurred, including payments made under our license agreements.

Table of Contents**GERON CORPORATION****NOTES TO CONDENSED FINANCIAL STATEMENTS****MARCH 31, 2015****(UNAUDITED)*****Clinical Trial Costs***

A significant component of our research and development expenses has historically been clinical trial costs. Substantial portions of our preclinical studies and all of our clinical trials have been performed by third-party contract research organizations, or CROs, and other vendors. We accrue expenses for preclinical studies performed by our vendors based on certain estimates over the term of the service period and adjust our estimates as required. We accrue expenses for our clinical trial activities performed by CROs based upon the estimated amount of work completed on each study. For our clinical trial expenses, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites and the duration for which the patients have been enrolled in the study. Pass through costs from CROs include, but are not limited to, regulatory expenses, investigator fees, lab fees, travel costs and other miscellaneous costs, including shipping and printing fees. We accrue pass through costs based on estimates of the amount of work completed for the clinical trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. We base our estimates on the best information available at the time. However, additional information may become available to us which would allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain.

Depreciation and Amortization

We record property and equipment at cost and calculate depreciation using the straight-line method over the estimated useful lives of the assets, generally four years. Leasehold improvements are amortized over the shorter of the estimated useful life or remaining term of the lease.

Stock-Based Compensation

We recognize stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period. The following table summarizes the stock-based compensation expense included in operating expenses on our condensed statements of operations related to stock options, restricted stock awards and employee stock purchases for the three months ended March 31, 2015 and 2014 which was allocated as follows:

(In thousands)	Three Months Ended March 31,			
	2015		2014	
Research and development	\$	622	\$	589
Restructuring charges		90		

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General and administrative		1,301		1,052
Stock-based compensation expense included in operating expenses	\$	2,013	\$	1,641

In connection with a restructuring we announced in March 2015, the post-termination exercise period for certain stock options previously granted to employees affected by the restructuring was extended from 90 days to one year from their respective termination dates, subject to each employee's continuous service until his/her specified termination date. The incremental value associated with these stock option modifications is being recognized as non-cash stock-based compensation expense over each employee's remaining service period with the Company and recorded as restructuring charges on our condensed statements of operations as reflected in the table above. See Note 4 on Restructuring for a further discussion of the March 2015 restructuring.

As stock-based compensation expense recognized in our condensed statements of operations for the three months ended March 31, 2015 and 2014 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures, but at a minimum, reflects the grant-date fair value of those awards that actually vested in the period. Forfeitures have been estimated at the time of grant based on historical data and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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MARCH 31, 2015
(UNAUDITED)

Stock Options

We grant options with service-based vesting under our equity plans to employees, non-employee directors and consultants. The vesting period for employee options is generally four years. The fair value of options granted during the three months ended March 31, 2015 and 2014 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2015	2014
Dividend yield	0%	0%
Expected volatility	0.884	0.922
Risk-free interest rate range	1.70%	1.64% to 1.92%
Expected term	5.5 yrs	5.5 yrs

Employee Stock Purchase Plan

The fair value of employees' purchase rights during the three months ended March 31, 2015 and 2014 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2015	2014
Dividend yield	0%	0%
Expected volatility range	0.721 to 1.392	0.835 to 1.062
Risk-free interest rate range	0.11% to 0.25%	0.09% to 0.15%
Expected term range	6 12 mos	6 12 mos

Dividend yield is based on historical cash dividend payments. The expected volatility is based on historical volatilities of our stock since traded options on Geron stock do not correspond to option terms and the trading volume of options is limited. The risk-free interest rate is based on the U.S. Zero Coupon Treasury Strip Yields for the expected term in effect on the date of grant for an award. The expected term of options is derived from actual historical exercise and post-vesting cancellation data and represents the period of time that options granted are expected to be outstanding. The expected term of employees' purchase rights is equal to the purchase period.

Restricted Stock Awards

We have granted restricted stock awards to employees and non-employee directors with service-based vesting schedules that generally vest annually over four years. The fair value for service-based restricted stock awards is determined using the fair value of our common stock on the date of grant. The fair value is amortized as stock-based compensation expense over the requisite service period of the award, which is generally the vesting period, on a straight-line basis and is reduced for estimated forfeitures, as applicable.

Non-Employee Stock-Based Awards

For our non-employee stock-based awards, the measurement date on which the fair value of the stock-based award is calculated is equal to the earlier of: (i) the date at which a commitment for performance by the counterparty to earn the equity instrument is reached or (ii) the date at which the counterparty's performance is complete. We recognize stock-based compensation expense for the fair value of the vested portion of non-employee awards in our condensed statements of operations.

Recent Accounting Pronouncements

In January 2015, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update No. 2015-01, *Income Statement - Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items*, or ASU 2015-01. ASU 2015-01 eliminates the concept of an extraordinary item from GAAP. As a result, an entity will no longer be required to segregate extraordinary items from the results of ordinary operations to separately present an extraordinary item on its income statement, net of tax, after income from continuing operations or to disclose income taxes and earnings-per-share data applicable to an extraordinary item. However, ASU 2015-01 will still retain the presentation and disclosure guidance for items that are unusual in nature and occur infrequently. ASU 2015-01 becomes effective for annual periods, and interim periods within those annual periods, beginning on or after December 15, 2015. Early adoption is permitted. The adoption of ASU 2015-01 is not expected to have a material impact on our financial statements.

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

MARCH 31, 2015

(UNAUDITED)

2. FAIR VALUE MEASUREMENTS

We categorize financial instruments recorded at fair value on our condensed balance sheets based upon the level of judgment associated with inputs used to measure their fair value. The categories are as follows:

Level 1 Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.