

ACCURAY INC  
Form 10-Q  
November 08, 2010  
Table of Contents

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2010**

**or**

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

**For the transition period from                      to**

**Commission File Number: 001-33301**

**ACCURAY INCORPORATED**

(Exact Name of Registrant as Specified in Its Charter)

Edgar Filing: ACCURAY INC - Form 10-Q

**Delaware**

(State or Other Jurisdiction of Incorporation or Organization)

**20-8370041**

(IRS Employer Identification Number)

**1310 Chesapeake Terrace**

**Sunnyvale, California 94089**

(Address of Principal Executive Offices Including Zip Code)

**(408) 716-4600**

(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 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 (§ 229.405 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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a 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 October 15, 2010, there were 58,959,789 shares of the Registrant's Common Stock, par value \$0.001 per share, outstanding.

Table of Contents

**Accuray Incorporated**

**Form 10-Q for the Quarter Ended September 30, 2010**

**Table of Contents**

	<b>Page No.</b>
<b><u>PART I.</u></b>	
<b><u>Financial Information</u></b>	<b>3</b>
<b><u>Item 1.</u></b>	
<u>Condensed Consolidated Financial Statements (unaudited):</u>	3
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations</u>	4
<u>Condensed Consolidated Statements of Cash Flows</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<b><u>Item 2.</u></b>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<b><u>Item 3.</u></b>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	29
<b><u>Item 4.</u></b>	
<u>Controls and Procedures</u>	30
<b><u>PART II.</u></b>	
<b><u>Other Information</u></b>	<b>30</b>
<b><u>Item 1.</u></b>	
<u>Legal Proceedings</u>	30
<b><u>Item 1A.</u></b>	
<u>Risk Factors</u>	31
<b><u>Item 2.</u></b>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	53
<b><u>Item 3.</u></b>	
<u>Defaults Upon Senior Securities</u>	53
<b><u>Item 4.</u></b>	
<u>(Removed and Reserved)</u>	53
<b><u>Item 5.</u></b>	
<u>Other Information</u>	53
<b><u>Item 6.</u></b>	
<u>Exhibits</u>	53
<b><u>Signatures</u></b>	<b>54</b>

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements****Accuray Incorporated****Condensed Consolidated Balance Sheets**

(in thousands, except share and per share amounts)

	September 30, 2010 (Unaudited)	June 30, 2010
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 42,542	\$ 45,434
Restricted cash	22	22
Short-term available-for-sale securities	98,330	99,881
Accounts receivable, net of allowance for doubtful accounts of \$266 and \$115 at September 30, 2010 and June 30, 2010, respectively	36,779	37,955
Inventories	30,014	28,186
Prepaid expenses and other current assets	10,637	19,356
Deferred cost of revenue - current	8,494	7,889
Total current assets	226,818	238,723
Deferred cost of revenue - noncurrent	3,066	3,213
Property and equipment, net	17,065	14,684
Goodwill	4,495	4,495
Intangible assets, net	323	388
Other assets	1,815	1,681
Total assets	\$ 253,582	\$ 263,184
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 10,677	\$ 10,317
Accrued compensation	8,275	10,786
Other accrued liabilities	5,855	10,669
Customer advances	15,730	12,884
Deferred revenue - current	37,552	42,019
Total current liabilities	78,089	86,675
Long-term other liabilities	1,019	1,059
Deferred revenue - noncurrent	5,774	5,374
Total liabilities	84,882	93,108
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; authorized: 5,000,000 shares; no shares issued and outstanding		
Common stock, \$0.001 par value; authorized: 100,000,000 shares; issued: 60,999,300 and 60,666,974 shares at September 30, 2010 and June 30, 2010, respectively; outstanding: 58,859,282 and 58,526,956 shares at September 30, 2010 and June 30, 2010, respectively	60	59
Additional paid-in capital	290,937	287,764

Edgar Filing: ACCURAY INC - Form 10-Q

Accumulated other comprehensive income	46	(71)
Accumulated deficit	(122,343)	(117,676)
Total stockholders' equity	168,700	170,076
Total liabilities and stockholders' equity	\$ 253,582	\$ 263,184

Condensed consolidated balance sheet at June 30, 2010 has been derived from audited consolidated financial statements.

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

Table of Contents**Accuray Incorporated****Condensed Consolidated Statements of Operations**

(in thousands, except per share amounts)

(unaudited)

	<b>Three Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
Net revenue:		
Products	\$ 19,275	\$ 30,346
Shared ownership programs	641	481
Services	17,734	19,654
Other	418	94
Total net revenue	38,068	50,575
Cost of revenue:		
Cost of products	7,325	14,651
Cost of shared ownership programs	172	321
Cost of services	11,800	13,920
Cost of other	534	64
Total cost of revenue	19,831	28,956
Gross profit	18,237	21,619
Operating expenses:		
Selling and marketing	7,760	8,649
Research and development	8,047	7,662
General and administrative	8,559	8,930
Total operating expenses	24,366	25,241
Loss from operations	(6,129)	(3,622)
Other income, net	1,616	485
Loss before provision for income taxes	(4,513)	(3,137)
Provision for income taxes	127	139
Net loss	\$ (4,640)	\$ (3,276)
Net loss per share:		
Basic and diluted net loss per share	\$ (0.08)	\$ (0.06)
Weighted average common shares used in computing basic and diluted net loss per share	58,667	56,713

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

Table of Contents**Accuray Incorporated****Condensed Consolidated Statements of Cash Flows**

(in thousands)

(unaudited)

	<b>Three Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (4,640)	\$ (3,276)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,389	1,842
Stock-based compensation	2,496	3,105
Realized gain on investments	(3)	(2)
Unrealized loss on long-term trading securities, net of gain on put option		(136)
Provision for bad debts	151	(460)
Provision for write-down of inventories	421	2,090
Loss on disposal of property and equipment	9	14
Restricted cash		(1,012)
Changes in assets and liabilities:		
Accounts receivable	1,576	6,316
Inventories	(3,030)	1,340
Prepaid expenses and other current assets	(1,089)	(1,873)
Deferred cost of revenue	(458)	1,201
Other assets	(133)	(34)
Accounts payable	(1,359)	(6,442)
Accrued liabilities	(3,629)	(1,111)
Customer advances	2,453	1,995
Deferred revenue	(4,401)	(11,513)
Net cash used in operating activities	(10,247)	(7,956)
<b>Cash Flows From Investing Activities</b>		
Purchases of property and equipment	(1,332)	(585)
Purchase of investments	(46,903)	(22,139)
Sale and maturity of investments	54,336	26,400
Net cash provided by investing activities	6,101	3,676
<b>Cash Flows From Financing Activities</b>		
Proceeds from issuance of common stock	803	834
Net cash provided by financing activities	803	834
Effect of exchange rate changes on cash	451	(49)
Net decrease in cash and cash equivalents	(2,892)	(3,495)
Cash and cash equivalents at beginning of period	45,434	36,835
Cash and cash equivalents at end of period	\$ 42,542	\$ 33,340
<b>Supplemental Disclosure of Cash Flow Information</b>		
Non-cash operating activity related to deconsolidation of Morphormics (Note 6)	\$ 27	\$

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





Table of Contents

**Accuray Incorporated**

**Notes to Condensed Consolidated Financial Statements**

**(unaudited)**

**1. Description of Business**

**Organization**

Accuray Incorporated (the Company) designs, develops and sells the CyberKnife system ( CyberKnife ), which is an image-guided robotic radiosurgery system used for the treatment of solid tumors anywhere in the body.

The Company is incorporated in Delaware, USA and has thirteen wholly-owned subsidiaries: Accuray International SARL, located in Geneva, Switzerland, Accuray Europe SAS, located in Paris, France, Accuray UK Ltd, located in London, United Kingdom, Accuray Asia Limited, located in Hong Kong, SAR, Accuray Japan KK, located in Tokyo, Japan, Accuray Spain, S.L.U., located in Madrid, Spain, Accuray Medical Equipment (India) Private Ltd., located in New Delhi, India, Accuray Medical Equipment (SEA) Private Limited, located in Singapore, Accuray Medical Equipment (Rus) LLC, located in Moscow, Russia, Accuray Medical Equipment GmbH, located in Munich, Germany, Accuray Tibbi Cihazlar Ve Malzemeler Ithalat Ihracat Anonim Sirketi, located in Istanbul, Turkey, Accuray Mexico SA de CV located in Mexico City, Mexico and Accuray Medical Equipment Canada Ltd. located in Vancouver, Canada. The purpose of these subsidiaries is to market and/or service the Company's products in the various countries in which they are located.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation and Principles of Consolidation**

The condensed consolidated financial statements for the 2010 fiscal year include the accounts of the Company and its subsidiaries and the Company's variable interest entity, Morphormics, Inc. ( Morphormics ). As the Company is no longer considered the primary beneficiary of Morphormics, the condensed consolidated financial statements for fiscal year 2011 do not include Morphormics. Refer to Note 6. Investment . All significant inter-company transactions and balances have been eliminated in consolidation.

The accompanying condensed consolidated balance sheet as of September 30, 2010 and the condensed consolidated statements of operations for the three month periods ended September 30, 2010 and 2009 and the condensed consolidated statements of cash flows for the three month periods ended September 30, 2010 and 2009 and other information disclosed in the related notes are unaudited. The condensed consolidated balance sheet as of June 30, 2010 was derived from the Company's audited consolidated financial statements at that date. The accompanying condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes

## Edgar Filing: ACCURAY INC - Form 10-Q

contained in the Company's Annual Report on Form 10-K for the year ended June 30, 2010 filed with the Securities and Exchange Commission (the SEC).

The accompanying condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles, (GAAP), pursuant to the rules and regulations of the SEC. Certain information and note disclosures have been condensed or omitted pursuant to such rules and regulations. The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair presentation of the periods presented. The results for the three months ended September 30, 2010 are not necessarily indicative of the results to be expected for the year ending June 30, 2011 or for any other interim period or for any future year.

### **Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates.

Table of Contents

**Foreign Currency**

The Company's international subsidiaries use their local currencies as their functional currencies. For those subsidiaries, assets and liabilities are translated at exchange rates in effect at the balance sheet date and income and expense accounts at the average exchange rate. Resulting translation adjustments are excluded from the determination of net income and are recorded in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. Net foreign currency exchange transaction gains or losses are included as a component of other income, net, in the Company's condensed consolidated statements of operations for the three months ended September 30, 2010.

The majority of the Company's executed sales contracts are denominated in U.S. dollars. The CyberKnife system sales contracts denominated in local foreign currency are direct end customer transactions for international customers. At September 30, 2010, there was one sales contract for the CyberKnife system denominated in foreign currency, which was in deferred revenue in the accompanying condensed consolidated balance sheets.

**Cash and Cash Equivalents**

The Company considers all highly liquid investments with original maturities of three months or less on the date of purchase to be cash equivalents. Cash equivalents consist of amounts invested in highly liquid investment accounts and money market accounts.

**Restricted Cash**

Restricted cash has historically included amounts deposited as collateral per the terms of contracts with customers requiring that deposited cash amounts be secured via letters of credit until delivery of the CyberKnife unit occurs. The current year restricted cash balance represents funds held to guarantee funding of certain foreign taxes.

**Fair Value of Financial Instruments**

The carrying values of the Company's financial instruments including cash and cash equivalents, marketable securities, restricted cash, accounts receivable and accounts payable are approximately equal to their respective fair values due to the relatively short-term nature of these instruments.

**Marketable Securities**

## Edgar Filing: ACCURAY INC - Form 10-Q

The Company's available-for-sale securities on the condensed consolidated balance sheets include commercial paper, corporate debt and debt issued by U.S. government sponsored enterprises. All marketable securities designated as available-for-sale are reported at estimated fair value, with unrealized gains and losses recorded in stockholders' equity and included in accumulated other comprehensive income. Realized gains and losses on the sale of available-for-sale marketable securities are recorded in other income, net. The cost of available-for-sale marketable securities sold is based on the specific identification method. Available-for-sale marketable securities with original maturities greater than approximately three months and remaining maturities of one year or less are classified as short-term available-for-sale marketable securities. The Company has the ability and the intent to hold these securities for a period of time sufficient to allow for any anticipated recovery in market value.

Interest, dividends, amortization and accretion of purchase premiums and discounts on all of the Company's marketable securities are included in other income, net.

### **Other-than-Temporary Impairment Assessment**

The Company regularly reviews all of its investments for other-than-temporary declines in fair value. The review includes but is not limited to (i) the consideration of the cause of the impairment, (ii) the creditworthiness of the security issuers, (iii) the length of time a security is in an unrealized loss position, and (iv) the Company's ability to hold the security for a period of time sufficient to allow for any anticipated recovery in fair value.

### **Concentration of Credit Risk**

The Company's cash and cash equivalents are mainly deposited with two major financial institutions. At times, deposits in these institutions exceed the amount of insurance provided on such deposits. The Company has not experienced any losses in such accounts and believes that it is not exposed to any significant risk on these balances.

Table of Contents

For the three months ended September 30, 2010, there was one customer that represented 10% or more of total net revenue. For the three months ended September 30, 2009, there were no customers that represented 10% or more of total net revenue. The following summarizes the accounts receivable from customers in excess of 10% of total accounts receivable:

	September 30, 2010	June 30, 2010
Customer A	10%	
Customer B	10%	

Accounts receivable are typically not collateralized. The Company performs ongoing credit evaluations of its customers and maintains reserves for potential credit losses. Accounts receivable are deemed past due in accordance with the contractual terms of the agreement. Accounts are charged against the allowance for doubtful accounts once collection efforts are unsuccessful. Historically, such losses have been within management's expectations.

**Inventories**

Inventories are stated at the lower of cost (on a first-in, first-out basis) or market value. Excess and obsolete inventories are written down based on historical sales and forecasted demand, as judged by management. The Company determines inventory and product costs, which include allocated production overheads, through use of standard costs.

**Revenue Recognition**

The Company earns revenue from the sale of products, the operation of its shared ownership program, and the provision of related services, which include installation services, post-contract customer support ( PCS ), training and other professional services. The Company records its revenues net of any value added or sales tax. From time to time, the Company introduces customers to third party financing organizations. No amounts received from these third party financing organizations are at risk.

The Company recognizes product revenues for sales of the CyberKnife system, optional upgrades, components and replacement parts and accessories when there is persuasive evidence of an arrangement, the fee is fixed or determinable, collection of the fee is probable and delivery has occurred. Payments received in advance of product shipment are recorded as customer advances and are recognized as revenue or deferred revenue upon product shipment or installation.

For revenue arrangements with multiple elements which were entered into by June 30, 2010 and which have not subsequently been materially modified, the Company allocates arrangement consideration to each element based upon vendor specific objective evidence ( VSOE ) of fair value of the respective elements. VSOE of fair value for each element is based upon the Company's standard rates charged for the product or service when such product or service is sold separately or based upon the price established by management having the relevant authority when that product or service is not yet being sold separately. When contracts contain multiple elements, and VSOE of fair value exists for all undelivered elements, the Company accounts for the delivered elements, principally the CyberKnife system and optional product upgrades,

## Edgar Filing: ACCURAY INC - Form 10-Q

based upon the residual method. If VSOE of fair value does not exist for all the undelivered elements, all revenue is deferred until the earlier of: (1) delivery of all elements, or (2) establishment of VSOE of fair value for all remaining undelivered elements.

In the first quarter of fiscal 2011, the Company adopted Accounting Standards Update ( ASU ) 2009-13, *Multiple-Deliverable Revenue Arrangements*, (amendments to Accounting Standards Codification ( ASC ) Topic 605, *Revenue Recognition*) ( ASU 2009-13 ) (formerly Emerging Issues Task Force ( EITF ) Issue 08-1) and ASU 2009-14, *Certain Arrangements That Include Software Elements*, (amendments to Financial Accounting Standards Board ( FASB ) ASC Topic 985, *Software*) ( ASU 2009-14 ) (formerly EITF 09-3). The new standard changes the requirements for establishing separate units of accounting in a multiple element arrangement and requires the allocation of arrangement consideration to each deliverable to be based on the relative selling price. The FASB also amended the accounting standards for revenue recognition to exclude software that is contained in a tangible product from the scope of software revenue guidance if the software is essential to the tangible product s functionality. The Company adopted these new standards on a prospective basis, therefore, they apply only to revenue arrangements entered into or materially modified beginning July 1, 2010. For revenue arrangements that were entered into or materially modified after the adoption of these standards, implementation of this new authoritative guidance had an insignificant impact on the Company s reported net revenue in the first quarter of fiscal 2011 as compared to net revenue if the related arrangements entered into or modified after the effective date were subject to the accounting requirements in effect in the prior year.

Table of Contents

Under the new accounting guidance, in evaluating the revenue recognition for agreements which contain multiple deliverables, the Company determined that in certain instances it was not able to establish VSOE for all deliverables in an arrangement as the Company infrequently sells each element on a stand-alone basis, does not price products within a narrow range, or has a limited sales history. When VSOE cannot be established, the Company attempts to establish the selling price of each element based on relevant third-party evidence (TPE). TPE is determined based on competitor prices for similar deliverables when sold separately. Generally, the Company's offerings contain a significant level of proprietary technology, customization or differentiation such that the comparable pricing of products with similar functionality cannot be obtained. Furthermore, the Company is unable to reliably determine what similar competitor products' selling prices are on a stand-alone basis. Therefore, the Company typically is not able to determine TPE.

When the Company is unable to establish selling price using VSOE or TPE, the Company uses its best estimate of selling price (BESP) in the Company's allocation of arrangement consideration. The objective of BESP is to determine the price at which the Company would transact a sale if the product or service were sold on a stand-alone basis. BESP is generally used for offerings that are not typically sold on a stand-alone basis or for new or highly customized offerings. The Company determines BESP for a product or service by considering multiple factors including, but not limited to, pricing practices, internal costs, geographies and gross margin. The determination of BESP is made through consultation with and formal approval by the Company's pricing committee, taking into consideration the overall go-to-market pricing strategy.

As the Company's go-to-market strategies and other factors evolve, the Company may modify its pricing practices in the future, which could result in changes in selling prices, including VSOE, TPE and BESP. As a result, the Company's future revenue recognition for multiple element arrangements could differ materially from that recorded in the current period. The Company regularly reviews VSOE, TPE and BESP and maintains internal controls over the establishment and update of these inputs.

The Company has a limited number of software offerings which are not required to deliver the tangible product's essential functionality and can be sold separately. Revenues from sales of these software products and related post-contract support will continue to be accounted for under software revenue recognition rules. The Company's multiple-element arrangements may therefore have a software deliverable that is subject to the existing software revenue recognition guidance. The revenue for these multiple-element arrangements is allocated to the software deliverable and the non-software deliverables based on the relative selling prices of all of the deliverables in the arrangement using the hierarchy in the new revenue recognition accounting guidance.

There were no material differences between total revenue reported and pro forma total revenues that would have been reported during the three months ended September 30, 2010, if the transactions entered into or materially modified after July 1, 2010 were subject to previous accounting guidance.

The Company assesses the probability of collection based on a number of factors, including past transaction history with the customer and the credit-worthiness of the customer. The Company generally does not request collateral from its customers. If the Company determines that collection of a fee is not probable, the Company will defer the fee and recognize revenue upon receipt of cash.

The Company's agreements with customers and distributors generally do not contain product return rights.

*CyberKnife sales with legacy service plans*

For sales of CyberKnife systems with PCS arrangements entered into prior to the first quarter of fiscal 2011 that included rights to specified or committed upgrades for which the Company had not established VSOE of fair value, all revenue and cost of revenue related to the CyberKnife systems and subsequent PCS was deferred. Once all such upgrade obligations had been delivered, all accumulated and deferred revenue and cost of revenue for the CyberKnife systems and related PCS began to be recognized ratably over the remaining life of the PCS arrangement.

Sales of additional upgrades as optional extras prior to the delivery of all originally specified upgrade obligations were considered additional elements of the original arrangement and associated revenues were deferred and accounted for as described above. Sales of additional upgrades after delivery of all specified upgrade obligations, as stated in the original contract, were recognized once all revenue recognition criteria applicable to those arrangements were met.

*CyberKnife sales with nonlegacy service plans*

Currently, the Company sells CyberKnife systems with PCS contracts that provide for upgrades when and if they become available. The Company has established VSOE of the fair value of PCS in these circumstances. For arrangements entered into after June 30, 2010, with multiple elements that include the CyberKnife system, installation services, training services and a PCS service agreement, the Company recognizes revenue for the CyberKnife system and installation services, if applicable by application of the relative selling price method for all elements in the arrangement, including PCS. If the Company is responsible for installation, the Company recognizes revenue only after installation and acceptance of the system, otherwise, revenue is recognized upon delivery.



Table of Contents

*Other revenue*

Other revenue primarily consists of research and development contract revenues as well as upgrade services revenues related to the sale of specialized services specifically contracted to provide current technology capabilities for units previously sold through a distributor into the Japan market. Some upgrade sales prior to the first quarter of fiscal 2011 include elements where VSOE of fair value has not been established for the PCS. As a result, for these sales, associated revenues are deferred and recognized ratably over the term of the PCS arrangement, generally four years.

*PCS and maintenance services*

Service revenue for providing PCS, which includes warranty services, extended warranty services, unspecified when and if available product upgrades and technical support is deferred and recognized ratably over the service period, generally one year, until no further obligation exists. At the time of sale, the Company provides for the estimated incremental costs of meeting product warranty if the incremental warranty costs are expected to exceed the related service revenues. Training and consulting service revenues that are not deemed essential to the functionality of the CyberKnife system are recognized as such services are performed.

Costs associated with providing PCS and maintenance services are expensed when incurred, except when those costs are related to system upgrades where revenue recognition has been deferred. In those cases, the costs are deferred and are recognized over the period of revenue recognition.

*Distributor sales*

Sales to third party distributors are evidenced by a distribution agreement governing the relationship together with binding purchase orders or signed quotations on a transaction-by-transaction basis. The Company records revenues from sales of CyberKnife systems to distributors based on a sell-through method where revenue is only recognized upon sell-through of the product to the end user customer and once all other revenue recognition criteria are met including completion of all obligations under the terms of the purchase order or signed quotation. For sales of product upgrades and accessories to distributors, revenue is recognized on either a sell-through or sell-in basis, depending upon the terms of the purchase order or signed quotation and once all revenue recognition criteria are met. These criteria require that persuasive evidence of an arrangement exists, the fees are fixed or determinable, collection of the resulting receivable is probable and there is no right of return.

*Shared ownership program*

The Company also enters into arrangements under its shared ownership program with certain customers. Agreements under the shared ownership program typically have a term of five years, during which the customer has the option to purchase the CyberKnife system, either at the end of the contractual period or in advance, at the customer's request, at pre-determined prices. Under the terms of such program, the Company retains title to its CyberKnife system, while the customer has use of the product. The Company generally receives a minimum monthly payment and earns additional revenues from the customer based upon its use of the product. The Company may provide unspecified upgrades to

## Edgar Filing: ACCURAY INC - Form 10-Q

the product during the term of each program when and if available. Upfront non-refundable payments from the customer are deferred and recognized as revenue over the contractual period. Revenues from the shared ownership program are recorded as they become earned and receivable and are included within shared ownership program revenues in the condensed consolidated statements of operations.

Under the terms of the shared ownership program, the customer has the option to purchase the CyberKnife system at pre-determined prices based on the period the system has been in use and considering the lease payments already received. Revenue from such sales is recorded in accordance with the Company's revenue recognition policy, taking into account the PCS and any other elements that might be sold as part of the arrangement.

Table of Contents

The CyberKnife systems associated with the Company's shared ownership program are recorded within property and equipment. Effective April 1, 2009, the estimated useful life of the Company's shared ownership units was reduced from ten to seven years due to a change in management's estimate. Depreciation and warranty expenses attributable to the CyberKnife shared ownership systems are recorded within cost of shared ownership programs.

*Long-term construction and manufacturing contracts*

The Company recognizes revenue and cost of revenue related to long-term construction and manufacturing contracts using contract accounting on the percentage-of-completion or the completed contract method. The Company recognizes any loss provisions from the total contract in the period such loss is identified.

**Deferred Revenue and Deferred Cost of Revenue**

Deferred revenue consists of deferred product revenue, deferred shared ownership program revenue, deferred service revenue and deferred other revenue. Deferred product revenue arises from timing differences between the shipment of product and satisfaction of all revenue recognition criteria consistent with the Company's revenue recognition policy. Deferred shared ownership program revenue results from the receipt of advance payments that will be recognized ratably over the term of the shared ownership program. Deferred service revenue typically results from the payment for services to be delivered over a contractual service period, usually one year. Service revenue is recognized ratably over the service period. Deferred cost of revenue consists of the direct costs associated with the manufacturing of units, direct service costs for which the revenue has been deferred in accordance with the Company's revenue recognition policy, and deferred costs associated with research and development contract costs and the Japan upgrade services. Deferred revenue, and associated deferred cost of revenue, expected to be realized within one year are classified as current liabilities and current assets, respectively.

**Goodwill and Purchased Intangible Assets**

Goodwill and purchased intangible assets with indefinite lives are not amortized. Intangible assets with determinable useful lives are amortized on a straight line basis over their useful lives. Goodwill and purchased intangible assets resulted from the Company's January 2005 acquisition of the High Energy Systems Division (HES) of American Science and Engineering, Inc. (AS&E). The Company integrated this operation into its existing manufacturing operation. HES had been the sole source manufacturer of the linear accelerator used in the CyberKnife system. The Company performs an annual test for impairment of goodwill and intangible assets with indefinite lives, and interim tests if indications of potential impairment exist. As of September 30, 2010, there were no indicators of impairment.

**Stock-Based Compensation**

The Company accounts for stock-based compensation by measuring and recognizing the fair value of all stock-based payment awards made to employees based on the estimated grant date fair values, including employee stock options, restricted stock awards and the employee stock based purchase plan. The determination of fair value involves a number of significant estimates. The Company uses the Black-Scholes option pricing

model to estimate the value of employee stock options which requires a number of assumptions to determine the model inputs. These include the expected volatility of the stock's market price, the expected term of the stock-based awards, the expected risk free rate of interest and any dividend yields. As stock-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. The Company estimates and adjusts forfeiture rates based on a periodic review of recent forfeiture activity and expected future employee turnover. As the Company has been operating as a public company for a period of time that is shorter than its estimated expected option life, the Company concluded that its historical price volatility does not provide a reasonable basis for input assumptions within its Black-Scholes valuation model when determining the fair value of its stock options. As a result, the Company continues to use the simplified method for estimated term of the awards and estimated volatility, as described under ASC 718. Expected volatility was based on the historical volatility of a peer group of publicly traded companies.

### **Income and Other Taxes**

The Company is required to estimate its income taxes in each of the tax jurisdictions in which it operates prior to the completion and filing of tax returns for such periods. This process involves estimating actual current tax expense together with assessing temporary differences in the treatment of items for tax purposes versus financial accounting purposes that may create net deferred tax assets and liabilities. The Company accounts for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax bases of the Company's assets and liabilities and their financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses, research and development credit carryforwards and temporary differences.

Table of Contents

The Company records a valuation allowance to reduce its deferred tax assets to the amount the Company believes is more likely than not to be realized. Because of the uncertainty of the realization of the deferred tax assets, the Company has recorded a full valuation allowance against its domestic and certain foreign net deferred tax assets.

The calculation of unrecognized tax benefits involves dealing with uncertainties in the application of complex global tax regulations. Management regularly assesses the Company's tax positions in light of legislative, bilateral tax treaty, regulatory and judicial developments in the countries in which the Company does business. Management does not believe there will be any material changes in the unrecognized tax benefits within the next 12 months.

**Net Loss Per Common Share**

Basic net loss per common share is calculated based on the weighted-average number of shares of our common stock outstanding during the period. Common stock equivalent shares, which are based on the number of shares underlying outstanding stock options and RSUs, are not included as their effect is anti-dilutive. For the three months ended September 30, 2010 and 2009, 6,230,837 and 4,166,070 of anti-dilutive shares, respectively, were excluded from the calculation of dilutive securities.

**Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive loss. Other comprehensive loss consists of foreign currency translation adjustments and unrealized gains and losses on investments that have been excluded from the determination of net loss. Comprehensive loss for the three months ended September 30, 2010 and 2009 is as follows (in thousands):

	<b>Three Months Ended</b>			
	<b>2010</b>		<b>2009</b>	
	<b>September 30,</b>			
Net loss	\$	(4,640)	\$	(3,276)
Unrealized gain (loss) on investments		28		(23)
Foreign currency translation adjustments		89		14
Comprehensive loss	\$	(4,523)	\$	(3,285)

**Segment Information**

The Company has determined that it operates in only one segment as it only reports profit and loss information on an aggregate basis to its chief operating decision maker. The Company's long-lived assets maintained outside the United States are not material.



Table of Contents

The Company markets its products in the United States and internationally through its direct sales force and indirect distribution channels. Revenue by geographic region is based on the shipping addresses of the Company's customers. The following summarizes revenue by geographic region (in thousands):

	Three Months Ended			
	September 30,			
	2010		2009	
Americas (including Puerto Rico)	\$	23,071	\$	30,620
Europe		9,950		16,544
Asia (excluding Japan)		3,332		803
Japan		1,715		2,608
Total	\$	38,068	\$	50,575

**Recent Accounting Pronouncement**

In April, 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition (Topic 605) Milestone Method of Revenue Recognition a consensus of the FASB Emerging Issues Task Force*. ASU No. 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. This ASU is effective for interim and annual reporting periods beginning after June 15, 2010. The adoption of ASU No. 2010-17 did not have a material impact on the Company's consolidated financial statements.

In January 2010, the FASB issued ASU No. 2010-06, *Improving Disclosures about Fair Value Measurements*. ASU No. 2010-06 amends FASB ASC 820 and clarifies and provides additional disclosure requirements related to recurring and non-recurring fair value measurements and employers' disclosures about postretirement benefit plan assets. The new disclosures and clarifications under this ASU are effective over a period of two fiscal years, for interim and annual reporting periods beginning after December 15, 2009 and after December 15, 2010. The first adoption date updates under ASU No. 2010-06 did not have a material impact on the Company's consolidated financial statements. The adoption of the second date of updates is not expected to have a material impact on the Company's consolidated financial statements.

Table of Contents

**3. Collaboration Agreement**

In June of 2010, the Company entered into a Strategic Alliance Agreement, or the Alliance Agreement, with Siemens AG, or Siemens, pursuant to which (1) the Company agreed to grant Siemens certain distribution rights to CyberKnife systems, (2) Siemens agreed to incorporate certain technology of the Company into certain of its linear accelerator products, the combined products being known as the Cayman Products, and (3) a research and development relationship was created between the Company and Siemens for the pursuit and implementation of other potential collaboration opportunities in the future.

The Alliance Agreement provides that Accuray will grant Siemens distribution rights to the CyberKnife system, allowing Siemens to include the CyberKnife system in multi-product sales when it also sells its own linear accelerator products or imaging products. The Company and Siemens entered into a Multiple Linac and Multi-Modality Distribution Agreement, or Distribution Agreement, which sets forth the terms of these distribution rights. Each sale under the Distribution Agreement is subject to pre-approval by the Company. The Alliance Agreement also provides that Siemens and the Company will negotiate in good faith separate distribution agreements for the distribution by Siemens of the CyberKnife system in certain countries and regions throughout the world not currently able to be fully served by the Company.

In consideration of the Company's development efforts with respect to the first Cayman Product, Siemens has agreed to pay the Company an arrangement fee, which fee is payable in installments based on the achievement of various milestones. The Company is obligated to incur certain development costs for the first Cayman Product in excess of the arrangement fee it receives from Siemens, provided that Siemens pays the Company the full amount of the arrangement fee. The development of a second Cayman Product is contingent upon the satisfaction of certain conditions and milestones. For the three months ended September 30, 2010, no milestone payments had been received and recorded in the Company's condensed consolidated statement of operations. Research and development costs pursuant to the execution of the Agreement of \$0.1 million were incurred during the three months ended September 30, 2010.

Siemens will have the exclusive right to purchase from the Company certain technology solely for use in Cayman Products, but the Company may terminate Siemens' exclusivity if Siemens fails to meet certain specified sales targets, or if the initial shipment of a Cayman Product does not occur within a specified period of time.

Pursuant to the Alliance Agreement, Siemens and the Company agreed to develop a product concept for future joint technology development within six months following execution of the Alliance Agreement. The Company and Siemens further agree to cooperate in good faith to explore additional opportunities for ongoing collaboration on complementary technology developments.

The Alliance Agreement has a five year initial term, which will automatically renew for successive one year terms unless a party gives notice of termination to the other party at least six months before the end of a term.

**4. Financial Instruments**



## Edgar Filing: ACCURAY INC - Form 10-Q

The Company is permitted to measure many financial instruments and certain other items at fair value, with changes in fair value recognized in earnings each reporting period. The election, called the fair value option, enables entities to achieve an offset accounting effect for changes in fair value of certain related assets and liabilities without having to apply complex hedge accounting provisions.

In November 2008, the Company had entered into an agreement ( Rights Agreement ) with UBS, which provided the Company with ARS ( Auction Rate Security ) Rights ( Rights ) to sell its ARS at par value to UBS at any time during the period June 30, 2010 through July 2, 2012.

The Company elected fair value accounting for the put option recorded in connection with the Rights Agreement. This election was made in order to mitigate volatility in earnings caused by accounting for the purchased put option and underlying ARS under different methods. The initial election of fair value resulted in a gain included in Other income, net for the put option.

Additionally, the Company recorded unrealized gains of \$3.3 million related to the fair value of the put option at the time it entered into the Rights Agreement and recorded unrealized losses relating to the change in fair value of the put option beginning in November 2008. During the three months ended September 30, 2009, the Company recorded an unrealized loss of \$0.5 million, for a total fair value of the put option of \$0.9 million as of September 30, 2009. During the three months ended September 30, 2009, \$0.6 million of unrealized gain in fair value of the ARS resulted in a net unrealized gain of \$0.1 million to Other income, net .

Table of Contents

During the three months ended September 30, 2009, UBS redeemed \$0.1 million of the ARS, which generated a realized gain of \$2,000. No activity related to the fair value of the put option is included in the Company's condensed consolidated statement of operations for the three months ended September 30, 2010 due to the liquidation of the underlying ARS securities as of June 30, 2010.

The Company defines fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy contains three levels of inputs that may be used to measure fair value, as follows:

*Level 1* Unadjusted quoted prices that are available in active markets for the identical assets or liabilities at the measurement date.

*Level 2* Other observable inputs available at the measurement date, other than quoted prices included in Level 1, either directly or indirectly, including:

- Quoted prices for similar assets or liabilities in active markets;
- Quoted prices for identical or similar assets in non-active markets;
- Inputs other than quoted prices that are observable for the asset or liability; and
- Inputs that are derived principally from or corroborated by other observable market data.

*Level 3* Unobservable inputs that cannot be corroborated by observable market data and reflect the use of significant management judgment. These values are generally determined using pricing models in which management's estimate utilizes market participant assumptions.

The following tables sets forth by level within the fair value hierarchy the Company's financial instruments that were accounted for at fair value on a recurring basis at September 30, 2010 and June 30, 2010, according to the valuation techniques the Company used to determine their fair values (in thousands):

	Fair Value at September 30, 2010		Fair Value Measurements Using Inputs Considered as			
			Level 1	Level 2		
Money market funds	\$	4,835	\$	4,835	\$	
Corporate notes		35,628				35,628
Commercial paper		38,742				38,742
U.S. government agency securities		27,858				27,858
Total	\$	107,063	\$	4,835	\$	102,228

Fair Value at Fair Value Measurements  
Using Inputs Considered as

Edgar Filing: ACCURAY INC - Form 10-Q

	June 30, 2010		Level 1		Level 2	
Money market funds	\$	1,104	\$	1,104	\$	
Corporate notes		34,992				34,992
Commercial paper		22,513				22,513
U.S. government agency securities		43,774				43,774
Total	\$	102,383	\$	1,104	\$	101,279

As of September 30, 2010 and June 30, 2010, the Company had no assets or liabilities using Level 3 inputs.

## Edgar Filing: ACCURAY INC - Form 10-Q

### Table of Contents

Investments in marketable securities classified as available-for-sale by security type at September 30, 2010 and June 30, 2010, consisted of the following (in thousands):

	September 30, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Commercial paper	\$ 34,847	\$ 10	\$ (13)	\$ 34,844
Corporate notes	35,583	51	(6)	35,628
U.S. government agency securities	27,833	25		27,858
Total short-term investments	\$ 98,263	\$ 86	\$ (19)	\$ 98,330

	June 30, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Commercial paper	\$ 21,126		\$ (11)	\$ 21,115
Corporate notes	34,957	64	(29)	34,992
U.S. government agency securities	43,761	15	(2)	43,774
Total short-term investments	\$ 99,844	\$ 79	\$ (42)	\$ 99,881

As of September 30, 2010 and June 30, 2010, the Company had no long-term investments in marketable securities classified as available-for-sale by security type.

All of the Company's investments with continuous unrealized losses have been in an unrealized loss position for less than twelve months at September 30, 2010. The Company has determined that the gross unrealized losses on its marketable securities at September 30, 2010 were temporary in nature.

The following methods and assumptions were used to estimate the fair value of each class of financial instrument:

*Money market funds.* Money market funds are open-ended mutual funds that typically invest in short-term debt securities. Money market funds are classified as cash and cash equivalents on the Company's condensed consolidated balance sheets. The Company classified these funds that are specifically backed by debt securities as Level 1 instruments due to its usage of unadjusted quoted prices that are available in active markets for the identical assets or liabilities at the measurement date.

*Corporate notes.* Corporate notes are floating-rate obligations that are payable on demand. These are classified as available-for-sale within short-term marketable securities on the Company's condensed consolidated balance sheets. The market approach was used to value the Company's variable-rate demand notes. The Company classified these securities as Level 2 instruments due to either its usage of observable market prices in less active markets or, when observable market prices were not available, its use of non-binding market prices that are corroborated by observable market data or quoted market prices for similar instruments.

## Edgar Filing: ACCURAY INC - Form 10-Q

*Commercial paper.* Commercial paper is an unsecured, short-term debt instrument issued by corporations and financial institutions that generally mature within 270 days. The total fair value of commercial paper held as of September 30, 2010 of \$38.7 million includes \$3.9 million of money market funds invested in commercial paper which is classified as cash equivalents. The portion in cash and cash equivalents represents highly liquid debt instruments with insignificant interest rate risk and maturities of ninety days or less at the time of purchase. The market approach was used to value the Company's commercial paper. The Company classified these securities as Level 2 instruments due to either its usage of observable market prices in less active markets or, when observable market prices were not available, its use of non-binding market prices that are corroborated by observable market data or quoted market prices for similar instruments.

*U.S. government agency securities.* U.S. government agency securities are issued by U.S. Federal, state and local governments, government-sponsored enterprises and other governmental entities such as authorities or special districts that generally mature within two years. These are classified as short-term and long-term marketable securities on the Company's condensed consolidated balance sheets. The market approach was used to value the Company's U.S. government agency securities. The Company classified these securities as Level 2 instruments due to either its usage of observable market prices in less active markets or, when observable market prices were not available, its use of non-binding market prices that are corroborated by observable market data or quoted market prices for similar instruments.

Table of Contents

*Auction rate securities.* Prior to June 30, 2010, there was insufficient observable market information available to determine the fair value of the Company's ARS. Prior to December 31, 2008, the Company estimated Level 3 fair values for these securities based on the financial institutions broker's valuations. The financial institution broker valued student loan ARS as floating rate notes with three pricing inputs: the coupon, the current discount margin or spread, and the maturity. The coupon was generally assumed to equal the maximum rate allowed under the terms of the instrument, the current discount margin was based on an assessment of observable yields on instruments bearing comparable risks, and the maturity was based on an assessment of the terms of the underlying instrument and the potential for restructuring the ARS. The primary unobservable input to the valuation was the maturity assumption which was set at five years for the majority of ARS instruments. Through January 6, 2008, the ARS were valued at par value due to the frequent resets that historically occurred through the auction process.

As of December 31, 2008, the Company determined Level 3 fair value using an income approach. The pricing assumptions for the ARS included the coupon rate, the estimated time to liquidity, current market rates for publicly traded corporate debt of similar credit rating and an adjustment for lack of liquidity. The coupon rate was assumed to equal the stated maximum auction rate being received, which is the lesser of (i) an average trailing twelve month yield for the ARS that is equal to the average trailing twelve month 91-day U.S. Treasury rate plus 1.20% or 1.50% premium according to provisions outlined in each security's agreement, (ii) the one-month LIBOR rate as of the auction date plus 1.5%, or (iii) a maximum interest rate of either 17% or 18% (specific to each ARS). The estimated time to liquidity was 3.25 years based on (i) expectations from industry brokers for liquidity in the market and (ii) the period over which UBS and other broker-dealers that had issued ARS have agreed to redeem certain ARS at par value.

The put option gave the Company the right to sell the ARS to UBS for a price equal to par value during the period June 30, 2010 to July 2, 2012, providing liquidity for the ARS sooner than the estimated five years. Historically, the value of the put option lay in (i) the ability to sell the securities thereby creating liquidity approximately two years before the ARS market is expected to become liquid and (ii) the avoidance of receiving a below-market coupon rate while the security was illiquid and auctions were failing. The fair value of the put option represented the difference between the ARS with an estimated time to liquidity in excess of the estimated time to liquidity of the put option, which allowed for the acceleration of liquidity and the avoidance of a below market coupon rate. As of June 30, 2010, all of the underlying ARS securities were liquidated at par value.

**5. Balance Sheet Components****Accounts receivable, net**

Accounts receivable, net consists of the following (in thousands):

	September 30, 2010	June 30, 2010
Accounts receivable	\$ 36,894	\$ 37,861
Unbilled fees and services	151	209
	37,045	38,070
Less: Allowance for doubtful accounts	(266)	(115)
Accounts receivable, net	\$ 36,779	\$ 37,955

**Inventories**

Edgar Filing: ACCURAY INC - Form 10-Q

Inventories consist of the following (in thousands):

	September 30, 2010		June 30, 2010	
Raw materials	\$	15,462	\$	13,683
Work-in-process		8,477		5,987
Finished goods		6,075		8,516
Total inventories	\$	30,014	\$	28,186

Table of Contents**Property and Equipment, net**

Property and equipment, net consist of the following (in thousands):

	September 30, 2010	June 30, 2010
Furniture and fixtures	\$ 3,672	\$ 3,628
Computer and office equipment	9,306	8,297
Leasehold improvements	7,859	7,771
Machinery and equipment	16,263	15,291
CyberKnife shared ownership systems	5,248	5,216
Construction in progress	3,566	1,927
	45,914	42,130
Less: Accumulated depreciation and amortization	(28,849)	(27,446)
Property and equipment, net	\$ 17,065	\$ 14,684

Depreciation and amortization expense related to property and equipment for the three months ended September 30, 2010 and 2009 was \$1.3 million and \$1.8 million, respectively. Accumulated depreciation related to the CyberKnife systems attributable to the shared ownership program as of September 30, 2010 and June 30, 2010 was \$1.9 million and \$1.8 million, respectively.

Of the \$3.6 million recorded in construction in process, \$2.4 million relates to the Company's implementation of a new enterprise resource planning information system, which will replace its existing system, and includes capitalized costs relating to license and consulting fees.

**6. Investment**

On July 29, 2008, the Company and Morphormics entered into a Stock Purchase Agreement pursuant to which the Company agreed to purchase 120,000 shares of Morphormics Series C Preferred Stock at \$12.50 per share, for a total purchase price of \$1.5 million. In exchange, Morphormics granted the Company a non-exclusive worldwide license to integrate several of its software products into the Company's treatment planning software. The equity investment afforded the Company a voting interest of approximately 18% in Morphormics. The Company's equity was considered to be at risk and was deemed not sufficient to finance Morphormics' current product development activities without additional subordinated financial support. In addition, the Company was deemed to be Morphormics' primary beneficiary, therefore, it would absorb a majority of expected losses. The Company consolidated Morphormics in its financial results. The consolidation of Morphormics' assets and liabilities did not have a material effect on the Company's consolidated balance sheet at June 30, 2010. The Company recorded losses in fiscal years 2010 and 2009 of \$0.5 million and \$0.9 million, respectively. As of June 30, 2010, the investment amount had been substantially utilized by Morphormics.

Effective July 1, 2010, the determination of primary beneficiary status has changed from a quantitative approach to a qualitative approach in which the Company is no longer considered the primary beneficiary of Morphormics. The Company has deconsolidated Morphormics' assets and liabilities from its consolidated balance sheet as of July 1, 2010. The deconsolidation of Morphormics of approximately \$1.5 million, net of impairment charges of \$1.5 million related to the fair value of the initial investment in Morphormics, resulted in a net cumulative-effect adjustment to accumulated deficit of \$27,000 on the Company's condensed consolidated balance sheet.



As of July 1, 2010, the Company determined the fair value of the investment using an income approach. The assumptions for the valuation included historical financial data, operating projections, estimated future cash flows and an adjustment for lack of liquidity.

## **7. Contingencies**

### **Litigation**

On July 22, 2009, a securities class action lawsuit was filed in the U.S. District Court for the Northern District of California against the Company and certain of its current and former directors and officers. On August 7, 2009 and August 9, 2009, two securities class action complaints, both similar to the one filed on July 22, 2009, were filed against the same defendants in the same court. These three actions were consolidated. The consolidated complaint generally alleges that the Company and the individual defendants made false or misleading public statements regarding the Company's operations and seek unspecified monetary damages and other relief. On August 31, 2010, the Court granted defendants' motion to dismiss the consolidated

Table of Contents

complaint and granted plaintiffs leave to file an amended complaint. On September 27, 2010, plaintiffs filed an amended complaint. The amended complaint names the Company and certain of its current and former officers and directors as defendants and generally alleges that the defendants made false or misleading public statements regarding the Company's operations. The amended complaint seeks unspecified monetary damages and other relief. Defendants have filed a motion to dismiss the amended complaint.

On August 5, 2009, a shareholder derivative lawsuit was filed in Santa Clara County Superior Court against certain of the Company's current and former officers and directors. The Company is named as a nominal defendant. The complaint generally alleges that the defendants breached their fiduciary duties by misrepresenting and/or failing to disclose material information regarding the Company's business and financial performance, and seeks unspecified monetary damages and other relief. On February 25, 2010, the plaintiff dismissed the action without prejudice.

On November 24, 2009, a shareholder derivative lawsuit was filed in the U.S. District Court for the Northern District of California against certain of the Company's current and former officers and directors. The Company is named as a nominal defendant. Three other shareholder derivative lawsuits were filed in the same court on November 30, 2009, December 1, 2009 and March 16, 2010. These actions have been consolidated. The amended consolidated complaint generally alleges that the defendants breached their fiduciary duties by misrepresenting and/or failing to disclose material information regarding the Company's business and financial performance, and that certain defendants also violated federal and California securities laws. The amended consolidated complaint seeks unspecified monetary damages and other relief. On August 31, 2010, the Court granted defendants' motion to dismiss, with leave to amend. On September 27, 2010, plaintiffs filed a notice of their intent not to file an amended complaint. On October 6, 2010, judgment was entered and the action dismissed. Plaintiffs filed a notice of appeal to the U.S. Court of Appeals for the Ninth Circuit on November 5, 2010.

On September 3, 2009, Best Medical International, Inc. ( "Best Medical" ) filed a lawsuit against the Company in the U.S. District Court for the Western District of Pennsylvania, claiming the Company induced certain individuals to leave the employment of Best Medical and join the Company in order to gain access to Best Medical's confidential information and trade secrets. They are seeking monetary damages and other relief. At this time the Company does not have enough information to estimate what, if any, financial impact this claim will have.

On August 6, 2010, Best Medical filed an additional lawsuit against the Company in the U.S. District Court for the Western District of Pennsylvania, claiming the Company has infringed U.S. Patent No. 5,596,619, a patent that Best Medical alleges protects a method and apparatus for conformal radiation therapy. They are seeking declaratory and injunctive relief as well as unspecified compensatory and treble damages and other relief. At this time, the Company does not have enough information to estimate what, if any, financial impact this claim will have.

As of September 30, 2010, the Company has not recorded any liabilities for the above referenced lawsuits as we are unable to determine if a loss is probable or estimable.

**Software License Indemnity**

Under the terms of the Company's software license agreements with its customers, the Company agrees that in the event the software sold infringes upon any patent, copyright, trademark, or any other proprietary right of a third party, it will indemnify its customer licensees, against any loss, expense, or liability from any damages that may be awarded against its customer. The Company includes this infringement

## Edgar Filing: ACCURAY INC - Form 10-Q

indemnification in all of its software license agreements and selected managed services arrangements. In the event the customer cannot use the software or service due to infringement and the Company cannot obtain the right to use, replace or modify the license or service in a commercially feasible manner so that it no longer infringes, then the Company may terminate the license and provide the customer a refund of the fees paid by the customer for the infringing license or service. The Company has recorded no liability associated with this indemnification, as it is not aware of any pending or threatened actions that are probable losses as of September 30, 2010.

Table of Contents**8. Stock-Based Compensation**

The following table summarizes the stock-based compensation charges included in the Company's condensed consolidated statements of operations (in thousands):

	Three Months Ended September 30,	
	2010	2009
Cost of revenue	\$ 463	\$ 231
Selling and marketing	244	808
Research and development	674	648
General and administrative	1,115	1,418
	\$ 2,496	\$ 3,105

At September 30, 2010 and June 30, 2010, capitalized stock-based compensation costs of \$0.1 million and \$0.2 million, respectively, were included as components of inventories.

**9. Goodwill and Other Purchased Intangibles**

Goodwill and other intangible assets resulted from the Company's January 2005 acquisition of the High Energy Systems Division ( HES ) of American Science and Engineering, Inc. ( AS&E ). The Company integrated this operation into its existing manufacturing operation. HES had been the sole source manufacturer of the linear accelerator used in the CyberKnife system. The Company performed the annual test for impairment of goodwill in December 2009 concluding that there was no impairment of goodwill. At September 30, 2010, there had been no indicators to perform an interim test. The amortization expense related to intangible assets for the three months ended September 30, 2010 and 2009 was \$0.1 million and \$0.1 million, respectively. The following table represents the gross carrying amounts and accumulated amortization of amortized intangible assets at September 30, 2010 and June 30, 2010 (in thousands)::

	September 30, 2010	June 30, 2010
Complete technology	\$ 1,740	\$ 1,740
Customer contract / relationship	70	70
	1,810	1,810
Less: Accumulated amortization	(1,487)	(1,422)
Intangible assets, net	\$ 323	\$ 388

The following table represents the estimated useful life of the intangible assets subject to amortization:

	Years
Amortized Intangible Assets:	
Complete technology	7.0

Customer contract / relationship

7.0

The estimated future amortization expense of purchased intangible assets as of September 30, 2010, is as follows (in thousands):

**Year ending June 30,**

2011 (remaining nine months)	\$	194
2012		129
Total	\$	323

**10. Related Party Transactions**

The Company's former Chief Executive Officer, Dr. John R. Adler, Jr. was a member of the Company's Board of Directors until his resignation effective July 19, 2009, and is a member of the faculty at Stanford, where he holds the position of Professor of Neurosurgery and Radiation Oncology. Effective July 20, 2009, Dr. Adler was no longer a related party of the Company. During the period from June 28, 2009 through July 19, 2009, related party revenue and expense were immaterial.

Table of Contents

**Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis of our financial condition as of September 30, 2010 and results of operations for the three months ended September 30, 2010 and 2009 should be read together with our condensed consolidated financial statements and related notes included elsewhere in this report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions, including statements regarding the extent and timing of future revenues and expenses, statements regarding reimbursement rates, statements regarding regulatory requirements, statements regarding future orders, statements regarding our strategic alliance with Siemens AG, statements regarding the deployment of our products, statements regarding revenues, earnings or other financial results, and other statements using words such as anticipates, believes, could, estimates, expects, forecasts, intends, may, plans, projects, should, will and would, and words of similar import and the negatives thereof. Our actual results, performance or achievements could differ materially from those expressed or implied by the forward-looking statements on the basis of several factors, including those that we discuss in Risk Factors, set forth in Part II, Item 1A of this quarterly report on Form 10-Q. We encourage you to read that section carefully. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. All forward-looking statements included in this report are based on information available to us on the date of this report, and we assume no obligation to update any forward-looking statements contained in this report.*

*In this report, Accuray, the Company, we, us, and our refer to Accuray Incorporated.*

**Overview**

We have developed what we believe to be the first and only commercially available intelligent robotic radiosurgery system, the CyberKnife system, designed to treat solid tumors anywhere in the body as an alternative to traditional surgery. The CyberKnife system combines continuous image-guidance technology with a compact linear accelerator that has the ability to move in three dimensions according to the treatment plan. Our image-guidance technology enables the system to continuously acquire images to track a tumor's location and transmit any position corrections to the robotic arm prior to delivery of each dose of radiation. Our compact linear accelerator ( linac ) is a compact radiation treatment device that uses microwaves to accelerate electrons to create high-energy X-ray beams to destroy the tumor. This combination, which we refer to as intelligent robotics, extends the benefits of radiosurgery to the treatment of tumors anywhere in the body. The CyberKnife system autonomously tracks, detects and corrects for tumor and patient movement in real-time during the procedure, enabling delivery of precise, high dose radiation typically with sub-millimeter accuracy. The CyberKnife procedure requires no anesthesia, can be performed on an outpatient basis and allows for the treatment of patients who otherwise would not have been treated with radiation or who may not have been good candidates for surgery. In addition, the CyberKnife procedure is designed to avoid many of the potential risks and complications that are associated with other treatment options and is more cost effective than traditional surgery.

By way of an overview, in order to operate our business, we are required to first obtain regulatory clearances from governmental agencies in the United States and abroad to market our CyberKnife system, establish an effective and secure supply chain of materials and systems that we then manufacture and assemble to create the CyberKnife system, establish direct and distributor sales channels for the sales of our products, provide for ongoing sales and service supports for our products in the field and manage the attendant risks associated with our operations, including risks beyond our control, such as changes in healthcare legislation and Medicare reimbursement rates, which necessarily affect the decisions of physicians and hospitals regarding the purchase of our products.

## Edgar Filing: ACCURAY INC - Form 10-Q

In July 1999, we obtained 510(k) clearance from the United States Food and Drug Administration, or FDA, to market the CyberKnife system for the treatment of tumors and certain other conditions in the head, neck and upper spine. In August 2001, we received FDA clearance for the treatment of tumors anywhere in the body where radiation treatment is indicated. In September 2002, we received a CE mark for the sale of the CyberKnife system in Europe. CE mark is an international symbol that represents adherence to certain essential principles of safety and effectiveness mandated in the European Medical Device Directive. We received approval for full-body treatment in Japan in June 2008; previously our CyberKnife regulatory approvals in Japan were limited to treatment for indications in the head and neck. The CyberKnife system has also been approved for various indications in Korea, Taiwan, China and other countries. To date, our CyberKnife system has been used to deliver more than 100,000 patient treatments.

We manufacture and assemble our CyberKnife systems at our manufacturing facility in Sunnyvale, California. We purchase major components, including the robotic manipulator, the treatment table or robotic couch, the magnetron, which creates the microwaves for use in the linear accelerator, the imaging cameras and the computers from outside suppliers, some of which are single source. Our reliance on single source suppliers could harm our ability to meet demand for our products in a timely and cost

Table of Contents

effective manner. However, in most cases, if a supplier were unable to deliver these components, we believe that we would be able to find other sources for these components subject to any regulatory qualifications, if required. We would, however, likely suffer some delays in qualifying any new supplier. We manufacture certain other electronic and electrical subsystems, including the linear accelerator. We then assemble and integrate these components with our proprietary software and perform testing prior to shipment to customer sites.

In the United States, we sell to customers, including hospitals and stand-alone treatment facilities, directly through our sales organization. Outside the United States, we sell to customers in over 80 countries directly and through distributors. We have sales and service offices in Paris, France, Hong Kong, China, Tokyo, Japan, Madrid, Spain, New Delhi, India, Singapore, Moscow, Russia, Munich, Germany, Istanbul, Turkey and London, UK. As of September 30, 2010, we had 37 employees in our sales organization.

In addition to selling the CyberKnife system to customers through direct sales, we offer alternative arrangements to customers who may not have the financial means to purchase a CyberKnife system. For example, under our shared ownership program, we retain title to the CyberKnife system while the customer has use of the system. Our shared ownership contracts generally require a minimum monthly payment from the customer, and we may earn additional revenue through the use of the system at the site. Generally, minimum monthly payments are equivalent to the revenue generated from treating three to four patients per month, and any revenue received from additional patients is shared between us and the customer. We expect to continue to offer our shared ownership program to new customers. The shared ownership program typically has a term of five years, during which the customer has the option to purchase the system at pre-determined prices.

Our CyberKnife systems are either sold to our customers or placed with our customers pursuant to our shared ownership program. As of September 30, 2010, we had 216 CyberKnife systems installed at customer sites, including 211 sold and four pursuant to our shared ownership program. Of the 216 systems installed, 136 are in the Americas, 47 are in Asia and 33 are in Europe.

We generate revenue from sales of products and by providing ongoing services and upgrades to customers following installation of the CyberKnife system. The current United States price for the CyberKnife system typically includes initial training, installation, and a warranty up to two years. We also offer optional hardware and software when and if available, technical enhancements and upgrades to the CyberKnife system, as part of our multiyear service plans. Currently, our most comprehensive service program is our Diamond program, which consists of both our Diamond Elite multiyear service plan, or original Diamond Plan, and our new Diamond Plus multiyear service plan, or Diamond Plus plan. We introduced our Diamond Plus plan in the United States during the quarter ended September 30, 2010, and going forward, new U.S. customers may purchase the Diamond Plus plan. Under our original Diamond plan, customers are eligible to receive up to two upgrades (software and hardware only) per year, when and if available, and under our Diamond Plus plan, customers are eligible to receive up to twenty upgrades (hardware, software and services) per year, when and if available. Each upgrade available under the Diamond Plus plan has a value equal to one-tenth the value of the upgrades available under the original Diamond plan. Prior to introducing our original Diamond plan, we offered our Platinum service plan which provided specified future upgrade obligations. For systems sold with a Platinum service plan, all revenue, including CyberKnife product and service revenue, is deferred until all upgrade obligations have been satisfied and then is recognized ratably over the remaining life of the Platinum service contract. As of September 30, 2010 and 2009, 166 out of 172 and 127 out of 147, respectively, of our customers had purchased non-Platinum service plans.

The CyberKnife procedure is currently covered and reimbursed by Medicare and other governmental and non-governmental third-party payors. Medicare coverage currently exists in the hospital outpatient setting and in the freestanding clinic setting. For calendar year 2010, the national unadjusted average Medicare payment rates under Healthcare Common Procedure Coding System, or HCPCS, are \$3,572 under code G0339, the billing code for the first treatment, and \$2,488 under code G0340, the billing code for each of the second through fifth treatments. Payment for the freestanding clinic setting is governed by the final Medicare Physician Fee Schedule. For 2010, payment for CyberKnife procedures in the freestanding clinic settings for first and subsequent treatments is set by local Medicare carriers and rates may vary from low payment to a payment rate exceeding the hospital outpatient payment rates. We will continue to evaluate the impact that the new health care laws, and the



## Edgar Filing: ACCURAY INC - Form 10-Q

effect their implementation may have on Medicare reimbursement rates.

On November 2, 2010, Medicare published its final rules for hospital outpatient services, for physicians, and services performed in the freestanding center setting for 2011. The final rates in the hospital outpatient setting reflect a 4.64% decrease for G0339 (\$3,409) and a 0.7% increase for G0340 (\$2,505). Payment in the freestanding clinic setting for the first and subsequent treatments continues to be set by local Medicare carriers and rates may vary from low payment to a payment rate exceeding the hospital outpatient payment rates.

Table of Contents

In addition to Medicare reimbursement to hospitals and clinics, physicians receive reimbursement for their professional services in the hospital outpatient setting and the freestanding clinic setting. Payment to physicians is based on the Medicare Physician Fee Schedule, and payment amounts are updated on an annual basis. For 2010, Medicare adjusted reimbursement rates for the Current Procedural Terminology, or CPT, code series describing the surgeon's role in the delivery of CyberKnife cranial and spinal procedures beginning with 61796 and 63620 to varying degrees. For example, the rate for treating five simple cranial lesions was reduced by less than one percent, and the rate for treating one complex cranial lesion was increased by more than 40%. For 2011, Medicare has finalized adjustments to reimbursement rates for the CPT code series describing the surgeon's role in the delivery of CyberKnife cranial and spinal procedures beginning with 61796 and 63620 to varying degrees. These adjustments vary from a 27% increase to a 33% increase.

The 2011 Medicare Physician Fee Schedule final rules include a 30.8% reduction in the conversion factor used for rate setting for physician professional services. Faced with similar reductions in each of the last seven years, Congress took legislative action to prevent cuts to physicians. The 2011 Medicare Physician Fee Schedule rates discussed above assume similar congressional action preventing the proposed reduction for the 2011 conversion factor.

In November of 2009, we announced the introduction of the CyberKnife VSI system, which allows physicians to perform conventionally fractionated robotic image guided intensity-modulated radiation therapy, or Robotic IMRT, in addition to Robotic Stereotactic Radiosurgery procedures. Reimbursement for Robotic IMRT is expected to be similar to conventional IMRT. Medicare 2011 proposed physician fee schedule rules reflect an 11% increase in 2011 for the treatment delivery code used to report IMRT services delivered by the CyberKnife VSI system.

Our future success will depend in large part on our ability to maintain and increase our position in the market. To compete successfully, we will need to continue to demonstrate the advantages of our products and technologies over alternative procedures, products and technologies, and convince physicians and other healthcare decision makers of the advantages of our products and technologies. Our business and sales and installation cycle does not immediately create recognizable revenue. As such, we must invest in sales and marketing activities generally 1 to 2 years before we are able to generate revenue from those activities. Our ability to achieve and maintain long-term profitability is largely dependent on our ability to successfully market and sell the CyberKnife system and to control our costs and effectively manage our growth.

**Financial Condition**

*Direct Sales and Installation Cycle*

The CyberKnife system has a long sales and installation cycle because it is a major capital purchase for our typical customer and requires the approval of senior management at purchasing institutions. The sales and installation cycle is typically 1 to 2 years in duration and involves multiple steps. The cycle typically begins with customer meetings with sales and products specialists, and ends upon resolution of all contingencies and either upon shipment, if a customer is responsible for installation, or upon installation by us. Prior to installation, a purchasing institution must typically obtain a radiation device installation permit, and in some cases, a certificate of need, or CON, both of which must be granted by state and local government bodies and can add time to the cycle. Recently, as a result of healthcare cost considerations and sensitivity to the cost of major capital equipment items, some state CON boards have become more stringent in the evaluation of CON applications. This trend, if it continues, may make the CON process more protracted and uncertain. In addition, the purchasing institution must build a radiation shielded facility or upgrade an existing facility to house the CyberKnife system. We generally receive a deposit at the time the purchase agreement is entered into, or shortly thereafter, an additional payment prior to shipment and the remaining balance for the sale of the CyberKnife system after delivery and installation. The customer also typically selects a service plan at the time of signing a CyberKnife system purchase agreement and enters into the service plan agreement prior to installation of the system.

Upon installation, we typically recognize the CyberKnife system sale price less the relative selling price of at least one year of service, training and other professional services, if applicable. We recognize the relative selling price of the first year of service as revenue pro rata over the twelve months following installation, training and other professional services, as delivered. In addition, if the customer has purchased either of our Diamond service plans or our Emerald service plan and assuming annual renewals, we would receive payment at the beginning of each of the second, third, fourth and fifth years of the multiyear service plan and recognize that revenue pro rata over each year.

*Legacy Service Plans*

Prior to introducing our original Diamond plan, we offered a Platinum Elite multiyear service plan, or Platinum plan. This legacy service plan was structured so that we had an obligation to deliver two upgrades per year over the course of the multiyear service plan. If we fail to deliver the upgrades, our customers would be entitled to receive a refund of up to \$100,000 for each upgrade not offered. To date, no refunds have been required pursuant to the Platinum plan. Beginning in November 2005, we phased out offering this legacy service plan to new customers.

The Platinum plan obligates us to deliver, when available, up to two upgrades per year during the term of the contract. We have not established fair value for those future obligations; hence, generally accepted accounting principles in the United States, or GAAP, before the first quarter of fiscal 2011, requires that we cannot begin to recognize any of the revenue or cost of sales derived

Table of Contents

from the sale of the CyberKnife system sold with our Platinum plan or the associated service plan until all upgrade obligations have been fulfilled. Therefore, the payments made by our customers who have our legacy Platinum plan are categorized as deferred revenue. Once we fulfill all upgrade obligations with respect to a specific Platinum plan, we ratably recognize the revenue and related cost of sales from the sale of that specific CyberKnife system and the Platinum plan over the remaining life of the contract. As of the end of June 2010, we had installed the final upgrades on all systems sold under Platinum agreements. We anticipate that we will satisfy our final obligations under the remaining Platinum service plans during fiscal 2011.

***Warranty***

All customers purchasing a CyberKnife system receive up to a two year warranty. We recognize the CyberKnife system purchase price minus the relative selling price of support services upon installation, if we are responsible for providing installation, or delivery, and we recognize the relative selling price of the support ratably over the corresponding period following installation.

***Shared Ownership Program Revenue***

We recognize revenue, consisting of a minimum monthly payment, monthly from our shared ownership program. We also recognize usage-based revenue in excess of the monthly minimum based on usage reports from our customers. We recognized revenue from our shared ownership program of \$0.6 million and \$0.5 million for the three months ended September 30, 2010 and 2009, respectively. In limited cases, we received nonrefundable upfront payments from shared ownership program customers which are treated as deferred revenue and recognized over the term of the contract.

The CyberKnife system shared ownership systems are recorded within property and equipment and are depreciated over their estimated life of seven years. Depreciation and warranty expense attributable to shared ownership systems are recorded within cost of shared ownership program as they are incurred.

***International Sales Revenue***

We sell our products internationally through a combination of direct sales force and a network of distributors. We have strategically developed distributor relationships to serve our customers. Many of our distributors are responsible for installation and service support.

For international sales, we recognize revenue once we have met all of our obligations associated with the purchase agreement, other than for undelivered elements at their relative selling price. In situations where we are directly responsible for installation, we recognize revenue once we have installed the CyberKnife system and have confirmed performance against specification. For sales through distributors, we recognize revenue upon shipment provided that we have received proof of sell-through to the end user from the distributor and that all of our remaining obligations have been satisfied. Net revenue from international customers was \$15.0 million and \$19.9 million for the three months ended September 30, 2010 and 2009, respectively. We believe the decrease in international sales for the three months ended September 30, 2010 was a result of the different impacts of the economic downturn by country.

***Backlog***

Backlog consists of the sum of deferred revenue, future un-invoiced payments that our customers are contractually committed to make, signed, non-contingent CyberKnife system sale agreements that meet the detailed criteria set forth below, service plans and minimum payment requirements associated with our shared ownership program. In order for a CyberKnife system sale agreement to be counted as backlog under the refined definition, it must meet the following criteria:

- The contract is signed and properly executed by both the customer and us;
  
- The contract is non-contingent it either has cleared all its contingencies or contains no contingencies when signed;
  
- We have received a deposit or a letter of credit, or the sale is a direct channel sale to a government entity;
  
- The specific end customer site has been identified by the customer in the written contract or written amendment; and
  
- Less than 2.5 years have passed since the contract met all the criteria above.

Table of Contents

Included in customers' agreements to purchase a CyberKnife is an option to select the type and term of service coverage that they desire. Backlog includes the value of this service coverage selected by customers in their original agreement to purchase a CyberKnife system. Before installation of the CyberKnife is complete and service commences, the customer must complete and sign a separate service agreement for service coverage (i.e. Diamond or Emerald service). If at the time of signing the service agreement a customer selects a different type of service than the option selected in the CyberKnife system purchase agreement, our backlog is adjusted to reflect the service agreement the customer signed.

At September 30, 2010 and 2009, our backlog was approximately \$380.6 million and \$290.5 million, respectively. Of total backlog, \$136.2 million and \$98.4 million represented CyberKnife system sales at September 30, 2010 and 2009, respectively, and \$244.4 million and \$192.1 million represented revenue from service plans and other recurring revenues at September 30, 2010 and 2009, respectively. We anticipate that this backlog will be recognized over the next five years as installations occur, upgrades are delivered and services are provided.

Although our backlog includes only contractual agreements from our customers, we cannot make assurances that we will convert it into recognized revenue due to factors outside our control including without limitation, changes in customers' needs, changes in reimbursement, changes to regulatory requirements, or other cancellation of orders.

## Results of Operations

### *Overview*

Our results of operations are divided into the following components:

**Net revenue.** Our net revenue consists primarily of product revenue (revenue derived primarily from the sale of CyberKnife systems and the sale of linacs for other uses), shared ownership program revenue (revenue generated from our shared ownership program), services revenue (revenue generated from sales of post contract support service plans, installation and training) and other revenue (revenue from specialized upgrade services for units previously sold in Japan, other specialized services and other non-medical products).

**Deferred Revenue Platinum Multiyear Service Plans.** We are required to defer all of the revenue associated with our legacy multiyear service plans, including our Platinum plan, until we have satisfied all of the specified obligations related to the delivery of upgrades to the CyberKnife system during the life of the service plan. This includes deferring revenue for the cash received for the purchase of the CyberKnife system and multiyear service plans until we have delivered all upgrades which the customer is eligible to receive. Once we have satisfied our obligations for delivery of upgrades under the plan, we recognize revenue ratably over the remaining life of the service contract term. We have not offered the Platinum service plan to new customers since we phased it out when we introduced our Diamond plan in November 2005. As of the end of June 2010, we had installed the final upgrades on all systems sold under Platinum agreements.

**Cost of revenue.** Cost of revenue consists primarily of material, labor and overhead costs. Cost of revenue may fluctuate from quarter to quarter depending on system configurations ordered by our customers and overall revenue mix.

**Selling and marketing expenses.** Selling and marketing expenses consist primarily of costs for personnel and costs associated with participation in medical conferences, physician symposia, and advertising and promotional activities. We expect marketing expenses may fluctuate from quarter to quarter due to the timing of major marketing events, such as significant trade shows.

**Research and development expenses.** Research and development expenses consist primarily of activities associated with our product development, regulatory and clinical study arrangements.

**General and administrative expenses.** General and administrative expenses consist primarily of compensation and related costs for finance, in-house legal and human resources, and external expenses related to accounting, legal and other consulting fees.

**Other income, net.** Other income, net consists primarily of interest earned on our cash and cash equivalents and investments, unrealized losses on our long-term trading securities, net of unrealized gains on our put option, foreign currency transaction gains and losses, losses on fixed asset disposals, and state and local sales and use tax fines and penalties.

Table of Contents*Three Months Ended September 30, 2010 Compared to Three Months Ended September 30, 2009***Net Revenue**

(Dollars in thousands)	Three Months Ended September 30,		Variance in Dollars	Variance in Percent
	2010	2009		
Products	\$ 19,275	\$ 30,346	\$ (11,071)	(36)%
Shared ownership program	641	481	160	33%
Services	17,734	19,654	(1,920)	(10)%
Other	418	94	324	345%
Net Revenue	\$ 38,068	\$ 50,575	\$ (12,507)	(25)%

Total net revenue for the three months ended September 30, 2010 decreased \$12.5 million from the three months ended September 30, 2009. Excluding revenue recognized for systems sold under our Platinum plan, we recognized \$18.1 million and \$24.9 million of product revenue for the three months ended September 30, 2010 and 2009, respectively. Excluding revenue previously deferred under Platinum service agreements, service revenue totaled \$16.9 million for the three months ended September 30, 2010, up \$0.2 million from the three months ended September 30, 2009. Continued growth in our installed base covered by service plans resulted in a \$1.0 million increase in revenue, which was partially offset by a decline of \$0.8 million in revenue for training and other services. As of September 30, 2010 and 2009, 166 out of 172 and 127 out of 147 of our customers that had purchased service plans, respectively, had purchased non-Platinum service plans.

We recognized \$2.7 million of revenue for the three months ended September 30, 2010 from systems sold under our Platinum plan, consisting of \$1.2 million for product revenue and \$1.5 million for service revenue. All Platinum revenue for this period, except \$0.7 million of service revenue, was deferred from prior periods. By comparison, we recognized \$10.2 million of revenue for the three months ended September 30, 2009 from systems sold under our Platinum plan, including \$5.4 million for product revenue and \$4.8 million for service revenue. All Platinum revenue for this period, except \$1.8 million of service revenue, was deferred from prior periods. As of September 30, 2010, we had satisfied all upgrade delivery obligations on all units sold under our Platinum plan. Once all upgrade delivery obligations have been satisfied, revenue is recognized over the remaining term of the contract service term.

We anticipate our non-Platinum revenue to continue to grow in future periods, while we expect Platinum revenue to decrease in future periods. Additionally, we expect our service revenue to increase as our installed base continues to grow.

**Gross Profit**

	Three Months Ended September 30,			
	2010		2009	
	(Dollars in thousands)	(% of net revenue)	(Dollars in thousands)	(% of net revenue)
Gross profit	\$ 18,237	47.9%	\$ 21,619	42.7%
Products	\$ 11,950	62.0%	\$ 15,695	51.7%
Shared ownership program	\$ 469	73.2%	\$ 160	33.3%



## Edgar Filing: ACCURAY INC - Form 10-Q

Services	\$	5,934	33.5%	\$	5,734	29.2%
Other	\$	(116)	-27.8%	\$	30	31.9%

The increase in gross margin as a percentage of net revenue was primarily due to the improved gross margin of product revenue in the three months ended September 30, 2010 compared to the three months ended September 30, 2009, as a result of an increase in average selling price and decreases in manufacturing costs. Additionally, service gross margins have increased due to the increase in service revenue, especially in our international regions, and a reduction in service parts costs, which were unusually high in the quarter ended September 30, 2009.

Table of Contents**Selling and Marketing**

(Dollars in thousands)	Three Months Ended September 30,		Variance in Dollars	Variance in Percent
	2010	2009		
Sales and marketing	\$ 7,760	\$ 8,649	\$ (889)	(10)%
<i>Percentage of net revenue</i>	<i>20.4%</i>	<i>17.1%</i>		

Selling and marketing expenses for the three months ended September 30, 2010 decreased \$0.9 million compared to the three months ended September 30, 2009. The decrease was primarily attributable to reduced stock-based compensation expense of \$0.6 million and a \$0.2 million decrease in compensation and benefits related expenses as we reduced headcount in fiscal 2010.

**Research and Development**

(Dollars in thousands)	Three Months Ended September 30,		Variance in Dollars	Variance in Percent
	2010	2009		
Research and development	\$ 8,047	\$ 7,662	\$ 385	5%
<i>Percentage of net revenue</i>	<i>21.1%</i>	<i>15.1%</i>		

Research and development expenses for the three months ended September 30, 2010 increased \$0.4 million compared to the three months ended September 30, 2009 primarily due to increased consulting fees of \$0.4 million and higher spending of \$0.1 million for supplies and materials related to various research and development projects, partially offset by lower compensation and benefits related expenses of \$0.1 million. We expect research and development discretionary spending to increase in the future as we begin new development projects.

**General and Administrative**

(Dollars in thousands)	Three Months Ended September 30,		Variance in Dollars	Variance in Percent
	2010	2009		
General and administrative	\$ 8,559	\$ 8,930	\$ (371)	(4)%
<i>Percentage of net revenue</i>	<i>22.5%</i>	<i>17.7%</i>		

General and administrative expenses for the three months ended September 30, 2010 decreased \$0.4 million compared to the three months ended September 30, 2009. The decrease was primarily attributable to reduced audit and legal fees of \$1.0 million, partially offset by an increase in bad debt expense of \$0.6 million.

**Other Income, Net**

Edgar Filing: ACCURAY INC - Form 10-Q

(Dollars in thousands)	Three Months Ended September 30,		Variance in Dollars	Variance in Percent
	2010	2009		
Other income, net	\$ 1,616	\$ 485	\$ 1,131	233%
<i>Percentage of net revenue</i>	<i>4.3%</i>	<i>1.0%</i>		

Other income, net, increased \$1.1 million for the three months ended September 30, 2010 compared to the three months ended September 30, 2009. The increase was primarily attributable to an increase of \$1.6 million related to foreign currency transaction gains as a result of the appreciation of the Euro-U.S. dollar foreign exchange rate and its effects on the remeasurement of balances and translation of transactions denominated in Euros, partially offset by a decrease in interest income of \$0.3 million due to lower average interest rates earned on amounts kept in interest bearing accounts during the three months ended September 30, 2010, compared to the three months ended September 30, 2009 and a decrease of \$0.1 million related to the gain on sale of investments.

Table of Contents**Provision for Incomes Taxes**

(Dollars in thousands)	Three Months Ended September 30,		Variance in Dollars	Variance in Percent
	2010	2009		
Provision for income taxes	\$ 127	\$ 139	\$ (12)	(9)%
<i>Percentage of net revenue</i>	<i>0.3%</i>	<i>0.3%</i>		

On a quarterly basis, we provide for income taxes based upon an estimated annual effective income tax rate. This process involves estimating actual current tax expense together with assessing temporary differences in the treatment of items for tax purposes versus financial accounting purposes that may create net deferred tax assets and liabilities.

For the three months ended September 30, 2010 and 2009, the Company recorded income tax expense of \$0.1 million and \$0.1 million, respectively, primarily related to corporate earnings of our foreign subsidiaries.

**Stock-Based Compensation Expense**

Stock-based compensation expense was recorded net of estimated forfeitures for the three months ended September 30, 2010 and 2009 such that expense was recorded only for those stock-based awards that are expected to vest. For the three months ended September 30, 2010 and 2009, we recorded \$2.5 million and \$3.1 million, respectively, of stock-based compensation expense, net of estimated forfeitures, for stock options, 2007 Employee Stock Purchase Plan, or ESPP, shares issued and RSUs granted to employees.

**Liquidity and Capital Resources**

At September 30, 2010, we had \$140.9 million in cash, cash equivalents and marketable securities. We believe that we have sufficient cash resources and anticipated cash flows to continue in operation for at least the next twelve months.

**Cash Flows From Operating Activities**

Net cash used in operating activities was \$10.2 million for the three months ended September 30, 2010. Our net loss of \$4.6 million contributed to the use of cash. Negative cash flow from working capital changes includes primarily a decrease in accrued liabilities of \$3.6 million, a decrease in deferred revenue, net of deferred cost of revenue of \$4.9 million, an increase in inventories of \$3.0 million and a decrease in accounts payable of \$1.4 million. This was partially offset primarily by an increase in customer advances of \$2.5 million and a \$1.6 million decrease in accounts receivable. The decrease in deferred revenue, net of deferred cost of revenue, was primarily a result of the recognition of revenue previously deferred for systems sold under our Platinum plan, offset partially by differences between invoicing customers for products and services and the recognition of the invoicing as revenue. Non-cash charges included \$2.5 million of stock-based compensation and

\$1.4 million of depreciation and amortization expense.

#### **Cash Flows From Investing Activities**

Net cash provided by investing activities was \$6.1 million for the three months ended September 30, 2010, which was primarily attributable to net marketable security activities of \$7.4 million, which consisted of \$54.3 million of sale and maturity of marketable securities, offset by \$46.9 million in purchases, and \$1.3 million of cash used for purchases of property and equipment.

#### **Cash Flows From Financing Activities**

Net cash provided by financing activities of \$0.8 million for the three months ended September 30, 2010 was attributable to proceeds from the exercise of common stock options and the purchase of common stock under our employee stock plans.

#### **Operating Capital and Capital Expenditure Requirements**

Our future capital requirements depend on numerous factors. These factors include but are not limited to the following:

- Revenue generated by sales of the CyberKnife system, our shared ownership program and service plans;
- Costs associated with our sales and marketing initiatives and manufacturing activities;
- Facilities, equipment and IT systems required to support current and future operations;
- Rate of progress and cost of our research and development activities;

Table of Contents

- Costs of obtaining and maintaining FDA and other regulatory clearances of the CyberKnife system;
- Effect of competing technological and market developments; and
- Number and timing of acquisitions and other strategic transactions.

We believe that our current cash and cash equivalents will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for the next twelve months. If these sources of cash and cash equivalents are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned product development and marketing efforts.

**Contractual Obligations and Commitments**

We presented our contractual obligations in our Annual Report on Form 10-K for the previous annual reporting period ended June 30, 2010. There have been no material changes in those obligations during the current quarter.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

**Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these condensed consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as revenue and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.

For a description of our critical accounting policies and estimates, please refer to the *Critical Accounting Policies and Estimates* section of our Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended June 30, 2010, as filed with the SEC. In addition, please refer to Note 2, *Summary of Significant Accounting Policies*, of our condensed consolidated financial statements in Item 1 of Part I of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

For revenue arrangements that were entered into or materially modified after July 1, 2010, implementation of new revenue accounting guidance had an insignificant impact on the Company's reported net revenue in the first quarter of fiscal 2011 as compared to net revenue that would have been reported if the related arrangements were subject to the accounting requirements in effect in the prior year.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

#### ***Interest Rate Risk***

At September 30, 2010, we had \$42.5 million of cash and cash equivalents and \$98.3 million invested in other financial instruments. Our earnings are affected by changes in interest rates due to the impact those changes have on interest income generated from our cash and investment balances. We believe that while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, and except as described below, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments. However, should interest rates increase, the market value of our investments may decline, which could result in a realized loss if we are forced to sell before their scheduled maturity. If overall interest rates had risen by 100 basis points, the fair value of our net investment position at September 30, 2010 would have decreased by approximately \$0.5 million, assuming consistent levels.

Table of Contents

***Foreign Currency Exchange Rate Risk***

For the three months ended September 30, 2010, a number of our sales contracts were denominated in a foreign currency. Based on our exposure as of September 30, 2010, a 10% movement in currency rates would result in a gain or loss of \$4.3 million. Future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products outside the United States. For direct sales outside the United States, it is likely we will sell in the local currency, which could expose us to additional foreign currency risks, including changes in currency exchange rates. Some of our commissions related to sales of the CyberKnife system are payable in Euros. To the extent that management can predict the timing of payments under these or contracts we enter into that are denominated in foreign currencies, we may engage in hedging transactions to mitigate such risks in the future.

***Credit Risk***

Based on our ability to access our cash and cash equivalents, our expected operating cash flows and our other sources of cash, we do not anticipate the current lack of liquidity on these investments to have a material impact on our financial condition or results of operations.

**Item 4. Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of September 30, 2010, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of September 30, 2010 our disclosure controls and procedures were effective such that the information relating to the Company, including our consolidated subsidiaries, required to be disclosed in our SEC reports (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended September 30, 2010. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that there has not been any change in our internal control over financial reporting during the three months ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



*Inherent Limitations of Internal Controls*

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings.**

Please refer to Note 7 to the condensed consolidated financial statements above for a description of certain legal proceedings currently pending against the Company. From time to time we are involved in legal proceedings arising in the ordinary course of our business.

Table of Contents

**Item 1A. Risk Factors.**

Set forth below and elsewhere in this report and in other documents we file with the SEC are descriptions of the risks and uncertainties that could cause our actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. The descriptions below include any material changes to and supersede the descriptions of the risk factors affecting our business previously disclosed in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the fiscal year ended June 30, 2010.

**Risks Related to Our Business**

*If the CyberKnife system does not achieve widespread market acceptance, we will not be able to generate the revenue necessary to support our business.*

Achieving physician, patient, hospital administrator and third-party payor acceptance of the CyberKnife system as a preferred method of tumor treatment will be crucial to our continued success. Physicians will not begin to use or increase the use of the CyberKnife system unless they determine, based on experience, clinical data and other factors, that the CyberKnife system is a safe and effective alternative to current treatment methods. We often need to educate physicians about the use of stereotactic radiosurgery, convince healthcare payors that the benefits of the CyberKnife system and its related treatment process outweigh its costs and help train qualified physicians in the skilled use of the CyberKnife system. For example, the complexity and dynamic nature of stereotactic radiosurgery and Robotic IMRT requires significant education of hospital personnel and physicians regarding the benefits of stereotactic radiosurgery and Robotic IMRT and require departures from their customary practices. We have expended and will continue to expend significant resources on marketing and educational efforts to create awareness of stereotactic radiosurgery and Robotic IMRT generally and to encourage the acceptance and adoption of our products for these technologies.

The CyberKnife system was initially used primarily for the treatment of tumors in the brain, and the broader use of the system to treat tumors elsewhere in the body has been a more recent development. As a result, physician and patient acceptance of the CyberKnife system as a comprehensive tool for treatment of solid tumor cancers anywhere in the body has not yet been fully demonstrated, particularly as compared to products, systems or technologies that have longer histories in the marketplace. The CyberKnife system is a major capital purchase and purchase decisions are greatly influenced by hospital administrators who are subject to increasing pressures to reduce costs. These and other factors, including the following, may affect the rate and level of the CyberKnife system's market acceptance:

- The CyberKnife system's price relative to other products or competing treatments;
- Our ability to develop new products and enhancements and receive regulatory clearances and approval, if required, to existing products in a timely manner;
- Effectiveness of our sales and marketing efforts;

## Edgar Filing: ACCURAY INC - Form 10-Q

- The impact of the current economic environment on our business, including the postponement by our customers of purchase decisions or required build-outs;
- Capital equipment budgets of healthcare institutions;
- Perception by physicians and other members of the healthcare community of the CyberKnife system's safety, efficacy and benefits compared to competing technologies or treatments;
- Publication in peer-reviewed medical journals of data regarding the successful use and longer term clinical benefits of the CyberKnife system;
- Willingness of physicians to adopt new techniques and the ability of physicians to acquire the skills necessary to operate the CyberKnife system;
- Extent of third-party coverage and reimbursement rates, particularly from Medicare, for procedures using the CyberKnife system;
- Development of new products and technologies by our competitors or new treatment alternatives;

Table of Contents

- Regulatory developments related to manufacturing, marketing and selling the CyberKnife system both within and outside the United States;
- Perceived liability risks arising from the use of new products; and
- Unfavorable publicity concerning the CyberKnife system or radiation- based treatment alternatives.

If the CyberKnife system is unable to achieve or maintain market acceptance, our revenue levels would decrease and our business would be harmed.

*If we are unable to develop new products or enhance existing products, we may be unable to attract or retain customers.*

Our success depends on the successful development, regulatory clearance or approval, introduction and commercialization of new generations of products, treatment systems, and enhancements to and/or simplification of existing products. The CyberKnife system is technologically complex and must keep pace with, among other things, the products of our competitors. We are making significant investments in long-term growth initiatives. For example, in November of 2009 we announced the introduction of the CyberKnife VSI system, which allows physicians to perform conventionally fractionated robotic intensity modulated radiation therapy, or Robotic IMRT, in addition to stereotactic radiosurgery. Such initiatives require significant capital commitments, involvement of senior management and other investments on our part, which we may be unable to recover. Our timeline for the development of new products or enhancements may not be achieved and price and profitability targets may not prove feasible. Commercialization of new products may prove challenging, and we may be required to invest more time and money than expected to successfully introduce them. Once introduced, new products may adversely impact orders and sales of our existing products, or make them less desirable or even obsolete. Compliance with regulations, competitive alternatives, and shifting market preferences may also impact the successful implementation of new products or enhancements.

Our ability to successfully develop and introduce new products, treatment systems and product enhancements and simplifications, and the revenues and costs associated with these efforts, are affected by our ability to:

- Properly identify customer needs;
- Prove feasibility of new products;
- Educate physicians about the use of new products and procedures;

- Limit the time required from proof of feasibility to routine production;
- Comply with internal quality assurance systems and processes timely and efficiently;
- Limit the timing and cost of obtaining regulatory approvals;
- Accurately predict and control costs associated with inventory overruns caused by phase-in of new products and phase-out of old products;
- Price our products competitively;
- Manufacture and deliver our products in sufficient volumes on time, and accurately predict and control costs associated with manufacturing, installation, warranty and maintenance of the products;
- Manage customer acceptance and payment for products;
- Manage customer demands for retrofits of both old and new products; and
- Anticipate and compete successfully with competitors.

Even if customers accept new products or product enhancements, the revenues from these products may not be sufficient to offset the significant costs associated with making them available to customers.

Table of Contents

We cannot be sure that we will be able to successfully develop, obtain regulatory approval or clearance, manufacture or introduce new products, treatment systems or enhancements, the roll-out of which involves compliance with complex quality assurance processes, including the quality system regulation, or QSR, enforced by the FDA. Failure to complete these processes timely and efficiently could result in delays that could affect our ability to attract and retain customers, or could cause customers to delay or cancel orders, causing our backlog, revenues and operating results to suffer.

***We may face numerous risks in connection with our strategic alliance with Siemens AG, any of which could cause our expected revenues to be harmed if they were to be realized.***

In June of 2010, we entered into a Strategic Alliance Agreement with Siemens AG, or the Alliance Agreement, pursuant to which (1) we granted Siemens certain distribution rights to our CyberKnife systems, (2) Siemens agreed to incorporate certain Accuray technology into certain of its linear accelerator products, the combined products being known as the Cayman Products, and (3) we created a research and development relationship between Accuray and Siemens for the pursuit and implementation of other potential collaboration opportunities in the future. There can be no assurance that the strategic alliance with Siemens AG will be successful or that the economic terms of the Alliance Agreement will ultimately prove to be favorable to us. We are not able to control the amount and timing of resources that Siemens will devote to the development, sales or marketing of the Cayman Products, the distribution of CyberKnife systems, or to future collaboration opportunities. Our own business may be disrupted, and we may have to divert attention from our other research and development activities, in order to satisfy our obligations under the Alliance Agreement. We may incur costs in excess of the consideration to be paid to us by Siemens. Even if Siemens successfully completes the development of the Cayman Products, the Cayman Products may not receive the regulatory approvals necessary to be marketed and sold. Failure to successfully develop, market and sell the Cayman Products, failure of Siemens to distribute the CyberKnife system, and the failure of Accuray and Siemens to successfully collaborate on future opportunities could negatively impact our stock price and our future business and financial results.

***If we are unable to provide the significant education and training required for the healthcare market to accept our products, our business will suffer.***

In order to achieve market acceptance of the CyberKnife system, we often need to educate physicians about the use of stereotactic radiosurgery, convince healthcare payors that the benefits of the CyberKnife system and its related treatment process outweigh its costs and help train qualified physicians in the skilled use of the CyberKnife system. For example, the complexity and dynamic nature of stereotactic radiosurgery and Robotic IMRT requires significant education of hospital personnel and physicians regarding the benefits of stereotactic radiosurgery and Robotic IMRT and require departures from their customary practices. We have expended and will continue to expend significant resources on marketing and educational efforts to create awareness of stereotactic radiosurgery and Robotic IMRT and to encourage the acceptance and adoption of our products for these technologies. We cannot be sure that any products we develop will gain significant market acceptance among physicians, patients and healthcare payors, even if we spend significant time and expense on their education. Failure to gain significant market acceptance would adversely affect our product sales and revenues, harming our business, financial condition and results of operations.

***We have a large accumulated deficit, may incur future losses and may be unable to maintain profitability.***

As of September 30, 2010, we had an accumulated deficit of \$122.3 million. We may incur net losses in the future, particularly as we increase our manufacturing, research and development, and marketing activities in connection with, among other things, the Strategic Alliance Agreement we entered into with Siemens AG on June 8, 2010. Our ability to maintain long-term profitability is largely dependent on our ability to successfully market and sell the CyberKnife system and to control our costs and effectively manage our growth. We cannot assure you that we

will be able to maintain profitability. In the event we fail to maintain profitability, our stock price could decline.

***We face risks related to the current global economic environment, which could delay or prevent our customers from obtaining financing to purchase the CyberKnife system and implement the required facilities, which would adversely affect our business, financial condition and results of operations.***

The state of the global economy continues to be uncertain. The current global economic conditions pose a risk to the overall economy that could impact consumer and customer demand for our products, as well as our ability to manage normal commercial relationships with our customers, suppliers and creditors, including financial institutions. If the current situation deteriorates or does not improve, our business could be negatively affected, including such areas as reduced demand for our products resulting from a slow-down in the general economy, supplier or customer disruptions and/or temporary interruptions in our ability to conduct day-to-day transactions through our financial intermediaries involving the payment to or collection of funds from our customers, vendors and suppliers.

Table of Contents

In addition, due to tight credit markets and concerns regarding the availability of credit, particularly in the United States, some of our customers have been delayed in obtaining, or have not been able to obtain, necessary financing for their purchases of the CyberKnife system or for the construction or renovation of facilities to house CyberKnife systems. To date, these delays have primarily affected customers that were planning to operate freestanding CyberKnife systems, rather than hospital-based customers. These delays have in some instances led to our customers postponing the shipment and installation of previously ordered systems or cancelling their system orders, and may cause other customers to postpone their system installation or to cancel their agreements with us. An increase in delays and order cancellations of this nature would adversely affect our product sales and revenues, and therefore harm our business and results of operations.

***The high unit price of the CyberKnife system, as well as other factors, may contribute to substantial fluctuations in our operating results, which could adversely affect our stock price.***

Because of the high unit price of the CyberKnife system and the relatively small number of units installed each quarter, each installation of a CyberKnife system can represent a significant percentage of our revenue for a particular quarter. Therefore, if we do not install a CyberKnife system when anticipated, our operating results will vary significantly from our expectations. This is of particular concern in the current volatile economic environment, where we have had experiences with customers cancelling or postponing orders for our CyberKnife system and delaying the required build-outs. These fluctuations and other potential fluctuations mean that you should not rely upon our operating results in any particular period as an indication of future performance. In particular, factors which may contribute to these fluctuations include:

- Timing of when we are able to recognize revenue associated with sales of the CyberKnife system, which varies depending upon the terms of the applicable sales and service contracts;
  
- The proportion of revenue attributable to purchases of the CyberKnife system, our shared ownership program and installations, which is associated with our legacy service plans;
  
- Timing and level of expenditures associated with new product development activities;
  
- Regulatory requirements in some states for a certificate of need prior to the installation of a radiation device;
  
- Delays in shipment due, for example, to unanticipated construction delays at customer locations where our products are to be installed, cancellations by customers, natural disasters or labor disturbances;
  
- Delays in our manufacturing processes or unexpected manufacturing difficulties;



## Edgar Filing: ACCURAY INC - Form 10-Q

- Timing of the announcement, introduction and delivery of new products or product upgrades by us and by our competitors;
- Timing and level of expenditures associated with expansion of sales and marketing activities such as trade shows and our overall operations;
- Fluctuations in our gross margins and the factors that contribute to such fluctuations, as described in the Management Discussion and Analysis Results of Operations below;
- How well we execute on our strategic and operating plans;
- The extent to which our products gain market acceptance;
- Actions relating to regulatory matters;
- Demand for our products;
- Our ability to develop, introduce and market new or enhanced versions of our products on a timely basis;
- Our ability to protect our proprietary rights and defend against third party challenges;
- Disruptions in the supply or changes in the costs of raw materials, labor, product components or transportation services; and
- Changes in third party coverage and reimbursement, changes in government regulation, or a change in a customer's financial condition or ability to obtain financing.

Table of Contents

These factors are difficult to forecast and may contribute to substantial fluctuations in our quarterly revenues and substantial variation from our projections, particularly during the periods in which our sales volume is low. These fluctuations may cause volatility in our stock price.

***Because the majority of our revenue is derived from sales of the CyberKnife system, and because we experience a long and variable sales and installation cycle, our quarterly results may be inconsistent from period to period. These fluctuations in revenue may make it difficult to predict our revenue.***

Our primary product is the CyberKnife system. We expect to generate substantially all of our revenue for the foreseeable future from sales of and service contracts for the CyberKnife system. The CyberKnife system has lengthy sales and purchase order cycles because it is a major capital equipment item and requires the approval of senior management at purchasing institutions. The sales process in the United States typically begins with pre-selling activity followed by sales presentations and other sales-related activities. After the customer has expressed an intention to purchase a CyberKnife system, we negotiate and enter into a definitive purchase contract with the customer. Typically, following the execution of the contract, the customer begins the building or renovation of a facility to house the CyberKnife system, which together with the subsequent installation of the CyberKnife system, can take up to 24 months to complete. During the period prior to installation, the customer must build a radiation-shielded facility to house its CyberKnife system. In order to construct this facility, the customer must typically obtain radiation device installation permits, which are granted by state and local government bodies, each of which may have different criteria for permit issuance. If a permit were denied for installation at a specific hospital or treatment center, our CyberKnife system could not be installed at that location. In addition, some of our customers are cancer centers or facilities that are new, and in these cases it may be necessary for the entire facility to be completed before the CyberKnife system can be installed, which can result in additional construction and installation delays. Our sales and installations of CyberKnife systems tend to be heaviest during the third month of each fiscal quarter.

Under our revenue recognition policy, we generally do not recognize revenue attributable to a CyberKnife system purchase until after installation has occurred, if we are responsible for providing installation, or delivery. For international sales through distributors, we typically recognize revenue when the system is shipped with evidence of sell through to the end user. Under our current forms of purchase and service contracts, we receive a majority of the purchase price for the CyberKnife system upon installation or delivery of the system. Events beyond our control may delay installation and the satisfaction of contingencies required to receive cash inflows and recognize revenue, such as:

- Procurement delay;
  
- Customer funding or financing delay;
  
- Delay in or unforeseen difficulties related to customers organizing legal entities and obtaining financing for CyberKnife system acquisition;
  
- Construction delay;

## Edgar Filing: ACCURAY INC - Form 10-Q

- Delay pending customer receipt of regulatory approvals, including, for example, certificates of need;
- Delay pending customer receipt of a building or radiation device installation permit; and
- Delay caused by weather or natural disaster.

In the event that a customer does not, for any of the reasons above or other reasons, proceed with installation of the system after entering into a purchase contract, we would only recognize up to the deposit portion of the purchase price as revenue, unless the deposit was refunded to the customer. Therefore, the long sales cycle together with delays in the shipment and installation of CyberKnife systems or customer cancellations would adversely affect our cash flows and revenue, which would harm our results of operations and may result in significant fluctuations in our reporting of quarterly revenues. Because of these fluctuations, it is likely that in some future quarters, our operating results will fall below the expectations of securities analysts or investors. If that happens, the market price of our stock would likely decrease. These fluctuations also mean that you will not be able to rely upon our operating results in any particular period as an indication of future performance.

Table of Contents

*Our ability to increase our profitability depends in part on maintaining or increasing our gross margins on product sales and service, which we may not be able to achieve.*

A number of factors may result in adverse impacts to our gross margins, including:

- The timing of revenue recognition and revenue deferrals;
- Sales discounts;
- Changes in product configurations;
- Increases in material or labor costs;
- Increased service costs;
- Increased warranty costs;
- Excess inventory and inventory holding charges;
- Obsolescence charges;
- Our ability to reduce production costs;
- Increased price competition;

- Variation in the margins across products installed in a particular period; and
- How well we execute on our strategic and operating plans.

***If third-party payors do not provide sufficient coverage and reimbursement to healthcare providers for use of the CyberKnife system, demand for our products and our revenue could be adversely affected.***

Our customers rely significantly on reimbursement for CyberKnife procedures. Our ability to commercialize our products successfully will depend in significant part on the extent to which public and private third-party payors provide adequate coverage and reimbursement for procedures that are performed with our products. Third party payors, and in particular managed care organizations, challenge the prices charged for medical products and services and institute cost containment measures to control or significantly influence the purchase of medical products and services. If reimbursement policies or other cost containment measures are instituted in a manner that significantly reduces the coverage for or payment for our procedures that are performed with our products, our existing customers may not continue using our products or may decrease their use of our products, and we may have difficulty obtaining new customers. Such actions would likely have a material adverse effect on our operating results. In October 2009, the centers for Medicare and Medicaid Services, or CMS, issued the 2010 Medicare payment rates. The reimbursement rates are modestly lower than in the prior year, which could have a negative impact on the continued use of our products by existing customers and our ability to obtain new customers. CMS reviews such rates annually, and could implement more significant changes in future years. If in the future CMS significantly decreases reimbursement rates for stereotactic radiosurgery and Robotic IMRT services, or if other cost containment measures are implemented in the United States or elsewhere, such changes could discourage cancer treatment centers and hospitals from purchasing our products. We have seen our customers' decision making process complicated by the uncertainty surrounding the proposed reduction in Medicare reimbursement rates for radiotherapy and radiosurgery at freestanding clinics in the United States and for physician reimbursement for radiation oncology, which has resulted in delay and sometimes even failure to purchase our products.

***Our industry is subject to intense competition and rapid technological change, which may result in products or new tumor treatments that are superior to the CyberKnife system. If we are unable to anticipate or keep pace with changes in the marketplace and the direction of technological innovation and customer demands, our products may become less useful or obsolete and our operating results will suffer.***

The medical device industry in general and the non-invasive cancer treatment field in particular are subject to intense and increasing competition and rapidly evolving technologies. Because our products often have long development and government approval cycles, we must anticipate changes in the marketplace and the direction of technological innovation and customer

Table of Contents

demands. To compete successfully, we will need to continue to demonstrate the advantages of our products and technologies over well-established alternative procedures, products and technologies, and convince physicians and other healthcare decision makers of the advantages of our products and technologies. Traditional surgery and other forms of minimally invasive procedures, chemotherapy or other drugs remain alternatives to the CyberKnife system. Also, we compete directly with traditional standard linac based radiation therapy systems primarily from Elekta AB (publ), or Elekta, BrainLAB AG, the Integra Radionics business of Integra LifeSciences Holdings Corporation, or Radionics, and Varian Medical Systems, Inc., or Varian, and we believe that new competitors will enter our market.

The market for standard linear accelerators is dominated by three companies: Elekta, Siemens AG and Varian. In addition, TomoTherapy Incorporated markets and sells a radiation therapy product. The CyberKnife system has not typically been used to perform traditional radiation therapy and therefore competition has been limited with standard medical linacs that perform traditional radiation therapy. However, the CyberKnife VSI system, which we introduced in November of 2009, may be used to perform Robotic IMRT, an advanced method of traditional radiation therapy, which products of these competitors are also capable of performing. In addition, some manufacturers of standard linac based radiation therapy systems, including Varian and Elekta, have products that can be used in combination with body and/or head frames and image-guidance systems to perform radiosurgery. Furthermore, many government, academic and business entities are investing substantial resources in research and development of cancer treatments, including surgical approaches, radiation treatment, drug treatment, gene therapy, which is the treatment of disease by replacing, manipulating, or supplementing nonfunctional genes, and other approaches. Moreover, at least one other company has announced that it is developing a product that, if introduced, would be directly competitive with the CyberKnife. Successful developments that result in new approaches for the treatment of cancer could reduce the attractiveness of our products or render them obsolete.

Our future success will depend in large part on our ability to establish and maintain a competitive position in current and future technologies. Rapid technological development may render the CyberKnife system and its technologies obsolete. Many of our competitors have or may have greater corporate, financial, operational, sales and marketing resources, and more experience in research and development than we have. We cannot assure you that our competitors will not succeed in developing or marketing technologies or products that are more effective or commercially attractive than our products or that would render our technologies and products obsolete. We may not have the financial resources, technical expertise, marketing, distribution or support capabilities to compete successfully in the future. Our success will depend in large part on our ability to maintain a competitive position with our technologies.

Our competitive position also depends on:

- Widespread awareness, acceptance and adoption by the radiation oncology and cancer therapy markets of our products;
- The discovery of new technologies that improve the effectiveness and productivity of the CyberKnife system radiosurgery process;
- Product and procedure coverage and reimbursement from third-party payors, insurance companies and others;
- Properly identifying customer needs and delivering new products or product enhancements to address those needs;

## Edgar Filing: ACCURAY INC - Form 10-Q

- Published studies supporting the efficacy and safety and long-term clinical benefit of the CyberKnife system;
- Limiting the time required from proof of feasibility to routine production;
- Limiting the timing and cost of obtaining regulatory approvals;
- Our ability to attract and retain qualified personnel;
- The extent of our patent protection or our ability to otherwise develop proprietary products and processes;
- Securing sufficient capital resources to expand both our continued research and development, and sales and marketing efforts; and
- Obtaining any necessary United States or foreign marketing approvals or clearances.

Table of Contents

If customers choose not to purchase a CyberKnife system or choose to purchase our competitors' products, our revenue and market share would be adversely impacted. In addition, companies in the pharmaceutical or biotechnology fields may seek to develop methods of cancer treatment that are more effective than radiation therapy and radiosurgery, resulting in decreased demand for the CyberKnife system. Because the CyberKnife system has a long development cycle and because it can take significant time to receive government approvals for changes to the CyberKnife system, we must anticipate changes in the marketplace and the direction of technological innovation. Accordingly, if we are unable to anticipate and keep pace with new innovations in the cancer treatment market, the CyberKnife system or an aspect of its functionality may be rendered obsolete, which would have a material adverse effect on our business, financial condition and results of operations.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results. As a result, current and potential stockholders could lose confidence in our financial reporting, which could have an adverse effect on our business and our stock price.***

Effective internal controls are necessary for us to provide reliable financial reports and to protect from fraudulent, illegal or unauthorized transactions. If we cannot provide effective controls and reliable financial reports, our business and operating results could be harmed. Our management determined, as of June 30, 2008 and September 30, 2008, that we had material weaknesses in our internal control over financial reporting and that our disclosure controls and procedures were not effective. We began our remediation efforts in fiscal year 2009 and we concluded that there were no deficiencies in our internal control over financial reporting that would constitute a material weakness as of June 30, 2009 or since then. Although we are making additional improvements in our internal controls over financial reporting, in future periods we may conclude that we have one or more material weaknesses, and remedying these material weaknesses may require significant additional financial and managerial resources and could result in a loss of investor confidence in our internal controls and financial reporting.

***We may have difficulties in determining the effectiveness of our internal control due to our complex financial model.***

The complexity of our financial model contributes to our need for effective financial reporting systems and internal controls. We recognize revenue from a range of transactions including CyberKnife system sales, our shared ownership program and services. The CyberKnife system is a complex product that contains both hardware and software elements. The complexity of the CyberKnife system and of our financial model pertaining to revenue recognition requires us to process a broader range of financial transactions than would be required by a company with a less complex financial model. Accordingly, deficiencies or weaknesses in our internal controls would likely impact us more significantly than they would impact a company with a less complex financial model. If we were to find that our internal controls were deficient, we could be required to amend or restate our historical financial statements, which would likely have a negative impact on our stock price.

***Our reliance on single source suppliers for critical components of the CyberKnife system could harm our ability to meet demand for our products in a timely and cost effective manner.***

We currently depend on single source suppliers for some of the critical components necessary for the assembly of the CyberKnife system, including the robotic manipulator, imaging plates, treatment table, robotic couch and magnetron, which creates the microwaves for use in the linear accelerator. If any single source suppliers were to cease delivering components to us or fail to provide the components on a timely basis, we might be required to find alternative sources for these components. We may have difficulty or be unable to find alternative sources for these components. As a result, we may be unable to meet the demand for the CyberKnife system, which could harm our ability to generate revenue and damage our reputation. Even if we do find alternate suppliers, we will be required to qualify any such alternate suppliers and we would likely experience a lengthy delay in our manufacturing processes or a cessation in production, which would result in delays of shipment to end users. We cannot assure you that our single source suppliers will be able or willing to meet our future demands.



We generally do not maintain large volumes of inventory, which makes us even more susceptible to harm if a single source supplier fails to deliver components on a timely basis. Furthermore, if we are required to change the manufacturer of a critical component of the CyberKnife system, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements. We also will be required to assess the new manufacturer's compliance with all applicable regulations and guidelines, which could further impede our ability to manufacture our products in a timely manner. If the change in manufacturer results in a significant change to the product, a new 510(k) clearance would be necessary, which would likely cause substantial delays. The disruption or termination of the supply of key components for the CyberKnife system could harm our ability to manufacture our products in a timely manner or within budget, harm our ability to generate revenue, lead to customer dissatisfaction and damage our reputation.

Table of Contents

*It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.*

Our success depends significantly on our ability to obtain, maintain and protect our proprietary rights to the technologies used in our products. Patents and other proprietary rights provide uncertain protections, and we may be unable to protect our intellectual property. For example, we may be unsuccessful in defending our patents and other proprietary rights against third party challenges.

In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, nondisclosure agreements and other contractual provisions and technical security measures to protect our intellectual property rights. These measures may not be adequate to safeguard the technology underlying our products. If these measures do not protect our rights adequately, third parties could use our technology, and our ability to compete in the market would be reduced. Although we have attempted to obtain patent coverage for our technology where available and appropriate, there are aspects of the technology for which patent coverage was never sought or never received. There are also countries in which we sell or intend to sell the CyberKnife system but have no patents or pending patent applications. Our ability to prevent others from making or selling duplicate or similar technologies will be impaired in those countries in which we have no patent protection. Although we have several issued patents in the United States and in foreign countries protecting aspects of the CyberKnife system, our pending United States and foreign patent applications may not issue, may issue only with limited coverage or may issue and be subsequently successfully challenged by others and held invalid or unenforceable.

Similarly, our issued patents and those of our licensors may not provide us with any competitive advantages. Competitors may be able to design around our patents or develop products which provide outcomes comparable or superior to ours. Our patents may be held invalid or unenforceable as a result of legal challenges by third parties, and others may challenge the inventorship or ownership of our patents and pending patent applications. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. In the event a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against a challenge.

We also license patent and other proprietary rights to aspects of our technology to third parties in fields where we currently do not operate as well as in fields where we currently do operate. Disputes with our licensees may arise regarding the scope and content of these licenses. Further, our ability to expand into additional fields with our technologies may be restricted by our existing licenses or licenses we may grant to third parties in the future.

In October 2006, January 2007 and February 2007, we received correspondence from American Science and Engineering, Inc., or AS&E, expressing concerns that we may be using certain intellectual property we acquired from AS&E through the HES acquisition in a manner that breaches, or may breach, our contractual obligations under a license agreement with them in certain non-medical fields. The intellectual property at issue relates to the development of a next-generation linac that could be used for medical as well as non-medical purposes. We are developing the technology used in the next-generation linac independently from the intellectual property we obtained from the HES acquisition. In January of 2010, we entered into a Supply Agreement with AS&E, pursuant to which AS&E has acknowledged and agreed that our use of the intellectual property at issue did not breach or contravene the license agreement.

The policies we have in place to protect our trade secrets may not be effective in preventing misappropriation of our trade secrets by others. In addition, confidentiality agreements executed by our employees, consultants and advisors may not be enforceable or may not provide

meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. Litigating a trade secret claim is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge methods and know-how. If we are unable to protect our intellectual property rights, we may be unable to prevent competitors from using our own inventions and intellectual property to compete against us, and our business may be harmed.

*Third parties may claim we are infringing their intellectual property, and we could suffer significant litigation or licensing expenses or be prevented from selling our product.*

The medical device industry is characterized by a substantial amount of litigation over patent and other intellectual property rights. In particular, the field of radiation treatment of cancer is well established and crowded with the intellectual property of competitors and others. We also expect that other participants will enter the field in particular, at least one other company has announced that it is developing a product that would be directly competitive with the CyberKnife. A number of companies in our market, as well as universities and research institutions, have issued patents and have filed patent applications which relate to the use of stereotactic radiosurgery to treat solid cancerous and benign tumors.

Table of Contents

Determining whether a product infringes a patent involves complex legal and factual issues, and the outcome of patent litigation actions is often uncertain. We have not conducted an extensive search of patents issued to third parties, and no assurance can be given that third party patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed, or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas or fields, our competitors or other third parties may assert that our products and the methods we employ in the use of our products are covered by United States or foreign patents held by them. For example, on August 6, 2010, Best Medical International, Inc., or Best Medical, filed a lawsuit against the Company in the U.S. District court for the Western District of Pennsylvania, claiming the Company has infringed U.S. Patent No. 5,596,619, a patent that Best Medical alleges protects a method and apparatus for conformal radiation therapy. They are seeking declaratory and injunctive relief as well as unspecified compensatory and treble damages and other relief.

In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware, and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There could also be existing patents that one or more of our products or parts may infringe and of which we are unaware. As the number of competitors in the market for less invasive cancer treatment alternatives grows, and as the number of patents issued in this area grows, the possibility of patent infringement claims against us increases. Regardless of the merit of infringement claims, they can be time-consuming, result in costly litigation and diversion of technical and management personnel. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

In the event that we become subject to a patent infringement or other intellectual property lawsuit and if the relevant patents or other intellectual property were upheld as valid and enforceable and we were found to infringe or violate the terms of a license to which we are a party, we could be prevented from selling our products unless we could obtain a license or were able to redesign the product to avoid infringement. Required licenses may not be made available to us on acceptable terms or at all. If we were unable to obtain a license or successfully redesign our system, we might be prevented from selling our system. If there is an allegation or determination that we have infringed the intellectual property rights of a competitor or other person, we may be required to pay damages, or a settlement or ongoing royalties. In these circumstances, we may be unable to sell our products at competitive prices or at all, our business and operating results could be harmed.

***We could become subject to product liability claims, product recalls, other field actions and warranty claims that could be expensive, divert management's attention and harm our business.***

Our business exposes us to potential liability risks that are inherent in the manufacturing, marketing and sale of medical device products. We may be held liable if the CyberKnife system causes injury or death or is found otherwise unsuitable during usage. Our products incorporate sophisticated components and computer software. Complex software can contain errors, particularly when first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after installation. Because our products are designed to be used to perform complex surgical procedures, defects could result in a number of complications, some of which could be serious and could harm or kill patients. Any weaknesses in training and services associated with our products may also be subject to product liability lawsuits. It is also possible that defects in the design, manufacture or labeling of our products might necessitate a product recall or other field corrective action, which may result in warranty claims beyond our expectations and may harm our reputation and create bad publicity. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. The coverage limits of our insurance policies may not be adequate to cover future claims. If sales of our products increase or we suffer future product liability claims, we may be unable to maintain product liability insurance in the future at satisfactory rates or with adequate amounts. A product liability claim, any product recalls or other field actions or excessive warranty claims, whether arising from defects in design or manufacture or otherwise, could negatively affect our sales or require a change in the design, manufacturing process or the indications for which the CyberKnife system may be used, any of which could harm our reputation and business and result in a decline in revenue.

In addition, if a product we designed or manufactured is defective, whether due to design or manufacturing defects, improper use of the product or other reasons, we may be required to notify regulatory authorities and/or to recall the product, possibly at our expense. We have voluntarily conducted recalls and product corrections in the past. There were no recalls during the quarter ended September 30, 2010. A required notification to a regulatory authority or recall could result in an investigation by

Table of Contents

regulatory authorities of our products, which could in turn result in required recalls, restrictions on the sale of the products or other civil or criminal penalties. The adverse publicity resulting from any of these actions could cause customers to review and potentially terminate their relationships with us. These investigations or recalls, especially if accompanied by unfavorable publicity or termination of customer contracts, could result in our incurring substantial costs, losing revenues and damaging our reputation, each of which would harm our business.

***The safety and efficacy of our products for certain uses is not yet supported by long-term clinical data and may therefore prove to be less safe and effective than initially thought.***

Although we believe that the CyberKnife system has advantages over competing products and technologies, we do not have sufficient clinical data demonstrating these advantages for all tumor indications. For example, because our CyberKnife procedures are relatively new, we have limited clinical data relating to the effectiveness of the CyberKnife system as a means of controlling the growth of cancer at a particular body site. In addition, we have only limited five-year patient survival rate data, which is a common long-term measure of clinical effectiveness in cancer treatment. Further, future patient studies or clinical experience may indicate that treatment with the CyberKnife system does not improve patient outcomes. Such results could slow the adoption of our products by physicians, significantly reduce our ability to achieve expected revenues and could prevent us from becoming profitable. In addition, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, the FDA could rescind our clearances, our reputation with physicians, patients and others may suffer and we could be subject to significant legal liability.

***The CyberKnife system has been in use for a limited period of time for uses outside the brain, and the medical community has not yet developed a large quantity of peer-reviewed literature that supports safe and effective use in those locations in the body.***

The CyberKnife system was initially cleared by a number of regulatory authorities for the treatment of tumors in the brain and neck. More recently, the CyberKnife system has been cleared in the United States to treat tumors anywhere in the body where radiation is indicated, and our future growth is dependent in large part on continued growth in full body use of the system. Currently, however, there are a limited number of peer-reviewed medical journal publications regarding the safety and efficacy of the CyberKnife system for treatment of tumors outside the brain or spine. If later studies show that the CyberKnife system is less effective or less safe with respect to particular types of solid tumors, or in the event clinical studies do not achieve the results anticipated at the outset of the study, use of the CyberKnife system could fail to increase or could decrease and our growth and operating results would therefore be harmed.

***International sales of the CyberKnife system account for a significant portion of our revenue, which exposes us to risks inherent in international operations.***

Our international sales have increased over the last four fiscal years. To accommodate our international sales, we have invested significant financial and management resources to develop an international infrastructure that will meet the needs of our customers. We anticipate that a significant portion of our revenue will continue to be derived from sales of the CyberKnife system in foreign markets and that the percentage of our overall revenue that is derived from these markets will continue to increase. This revenue and related operations will therefore continue to be subject to the risks associated with international operations, including:

- Economic or political instability;

- Shipping delays;
- Changes in foreign regulatory laws governing the clearance, approval and sales of medical devices;
- Difficulties in enforcing agreements with and collecting receivables from customers outside the United States;
- Longer payment cycles associated with many customers outside the United States;
- Adequate reimbursement for the CyberKnife procedure outside the United States;
- Failure of local laws to provide the same degree of protection against infringement of our intellectual property;
- Protectionist laws and business practices that favor local competitors;
- The possibility that foreign countries may impose additional taxes, tariffs or other restrictions on foreign trade;

Table of Contents

- Failure of Accuray employees or distributors to comply with export laws and requirements which may result in civil or criminal penalties and restrictions on our ability to export our products;
- The expense of establishing facilities and operations in new foreign markets;
- Building an organization capable of supporting geographically dispersed operations;
- Risks relating to foreign currency; and
- Contractual provisions governed by foreign laws and various trade restrictions, including U.S. prohibitions and restrictions on exports of certain products and technologies to certain nations.

Our international operations are also subject to United States laws regarding the conduct of business overseas by U.S. companies. In particular, the U.S. Foreign Corrupt Practices Act, or FCPA, prohibits the provision of illegal or improper inducements to foreign government officials in connection with the obtaining of business overseas. Violations of the FCPA by us or any of our employees, executive officers or distributors could subject us or the individuals involved to criminal or civil liability and could therefore materially harm our business.

In addition, future imposition of, or significant increases in, the level of customs duties, export quotas, regulatory restrictions or trade restrictions could materially harm our business.

*Our results may be impacted by changes in foreign currency exchange rates.*

Currently, the majority of our international sales are denominated in U.S. dollars. As a result, an increase in the value of the U.S. dollar relative to foreign currencies could require us to reduce our sales price or make our products less competitive in international markets. Also, as our international sales increase, we may enter into a greater number of transactions denominated in non-U.S. dollars, which would expose us to foreign currency risks, including changes in currency exchange rates. If we are unable to address these risks and challenges effectively, our international operations may not be successful and our business would be materially harmed.

*We depend on third-party distributors to market and distribute the CyberKnife system in international markets. If our distributors fail to successfully market and distribute the CyberKnife system, our business will be materially harmed.*



## Edgar Filing: ACCURAY INC - Form 10-Q

We depend on a limited number of distributors in our international markets. We cannot control the efforts and resources our third-party distributors will devote to marketing the CyberKnife system. Our distributors may not be able to successfully market and sell the CyberKnife system, may not devote sufficient time and resources to support the marketing and selling efforts and may not market the CyberKnife system at prices that will permit the product to develop, achieve or sustain market acceptance. In some jurisdictions, we rely on our distributors to manage the regulatory process and we are dependent on their ability to do so effectively. For example, our regulatory approval in Japan was suspended for a period of twelve months during 2003 as a result of a failure of our former distributor to coordinate product modifications and obtain necessary regulatory clearances in a timely manner. As a result, the CyberKnife system was recalled in Japan and our former Japanese distributor was told to stop selling the CyberKnife system. In response, we retained a regulatory consultant who was not affiliated with our former Japanese distributor and worked with the Japanese Ministry of Health, Labor and Welfare and applied for, and received, approval to sell an updated version of the CyberKnife system under the name of CyberKnife II in Japan. By working with a new distributor, Chiyoda Technol Corporation, we were able to begin distributing the CyberKnife II system in 2004 with no probationary period. In addition, if a distributor is terminated by us or goes out of business, it may take us a period of time to locate an alternative distributor, to seek appropriate regulatory approvals and to train its personnel to market the CyberKnife system, and our ability to sell and service the CyberKnife system in the region formerly serviced by such terminated distributor could be materially adversely affected. Any of these factors could materially adversely affect our revenue from international markets, increase our costs in those markets or damage our reputation. If we are unable to attract additional international distributors, our international revenue may not grow. If our distributors experience difficulties, do not actively market the CyberKnife system or do not otherwise perform under our distribution agreements, our potential for revenue and gross margins from international markets may be dramatically reduced, and our business could be harmed.

Table of Contents

***We have limited experience and capability in manufacturing. If we encounter manufacturing problems, or if our manufacturing facilities do not continue to meet federal, state or foreign manufacturing standards, we may be required to temporarily cease all or part of our manufacturing operations, which would result in delays and lost revenue.***

The CyberKnife system is complex, and requires the integration of a number of components from several sources of supply. We must manufacture and assemble these complex systems in commercial quantities in compliance with strictly enforced regulatory requirements and at an acceptable cost. We have a limited history of manufacturing commercial quantities of the CyberKnife system. In particular, we manufacture compact linacs as a component of the CyberKnife system. Our linac components are extremely complex devices and require significant expertise to manufacture, and as a result of our limited manufacturing experience we may have difficulty producing needed materials in a commercially viable manner. We may encounter difficulties in scaling up production of the CyberKnife system, including problems with quality control and assurance, component supply shortages, increased costs, shortages of qualified personnel and/or difficulties associated with compliance with local, state, federal and foreign regulatory requirements. If our manufacturing capacity does not keep pace with product demand, we will not be able to fulfill orders in a timely manner which in turn may have a negative effect on our financial results and overall business. Conversely, if demand for our products decreases, the fixed costs associated with excess manufacturing capacity may adversely affect our financial results.

Our manufacturing processes and the manufacturing processes of our third-party suppliers are required to comply with the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, production processes, controls, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. We are also subject to state requirements and licenses applicable to manufacturers of medical devices, and we are required to comply with International Organization for Standardization, or ISO, quality system standards in order to produce products for sale in Europe. Because our manufacturing processes include diagnostic and therapeutic X-ray equipment and laser equipment, we are subject to the electronic product radiation control provisions of the Federal Food, Drug and Cosmetic Act, which requires that we file reports with the FDA, applicable states and our customers regarding the distribution, manufacturing and installation of these types of equipment. The FDA enforces the QSR and the electronic product radiation control provisions through periodic inspections, some of which may be unannounced. We have been, and anticipate in the future to be, subject to such inspections. Our failure or the failure of a third-party supplier to pass a QSR inspection or to comply with these, ISO and other applicable regulatory requirements could result in disruption of our operations and manufacturing delays. Our failure to take prompt and satisfactory corrective action in response to an adverse inspection or our failure to comply with applicable standards could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our products, civil or criminal penalties, or other sanctions, which would cause our sales and business to suffer. We cannot assure you that the FDA or other governmental authorities would agree with our interpretation of applicable regulatory requirements or that we or our third-party suppliers have in all instances fully complied with all applicable requirements.

If we cannot achieve the required level and quality of production, we may need to outsource production or rely on licensing and other arrangements with third parties who possess sufficient manufacturing facilities and capabilities in compliance with regulatory requirements. Even if we could outsource needed production or enter into licensing or other third party arrangements, this could reduce our gross margin and expose us to the risks inherent in relying on others. We also cannot assure you that our suppliers will deliver an adequate supply of required components on a timely basis or that they will adequately comply with the QSR. Failure to obtain these components on a timely basis would disrupt our manufacturing processes and increase our costs, which would harm our operating results.

***We depend on key employees, the loss of whom would adversely affect our business. If we fail to attract and retain employees with the expertise required for our business, we may be unable to continue to grow our business.***

We are highly dependent on the members of our senior management, operations and research and development staff. Our future success will depend in part on our ability to retain these key employees and to identify, hire and retain additional personnel. Competition for qualified

## Edgar Filing: ACCURAY INC - Form 10-Q

personnel in the medical device industry, particularly in northern California, is intense, and finding and retaining qualified personnel with experience in our industry is very difficult. We believe there are only a limited number of individuals with the requisite skills to serve in many of our key positions and we compete for key personnel with other medical equipment and software manufacturers and technology companies, as well as universities and research institutions. It is increasingly difficult to hire and retain these persons, and we may be unable to replace key persons if they leave or fill new positions requiring key persons with appropriate experience. A significant portion of our compensation to our key employees is in the form of stock option grants. A prolonged depression in our stock price could make it difficult for us to retain our employees and recruit additional qualified personnel. We do not maintain, and do not currently intend to obtain, key employee life insurance on any of our personnel. If we fail to hire and retain personnel in key positions, we may be unable to continue to grow our business successfully.

Table of Contents

*If we do not effectively manage our growth, our business may be significantly harmed.*

The number of our employees increased from 194 as of June 30, 2005 to 450 as of September 30, 2010. In order to implement our business strategy, we expect continued growth in our employee and infrastructure requirements, particularly as we expand our manufacturing and research and development capacities in connection with, among other things, our Strategic Alliance Agreement with Siemens AG. To manage our growth, we must expand our facilities, augment our management, operational and financial systems, hire and train additional qualified personnel, scale-up our manufacturing capacity and expand our marketing and distribution capabilities. Our manufacturing, assembly and installation process is complex and occurs over many months, and we must effectively scale this entire process to satisfy customer expectations and changes in demand. We also expect to increase the number of sales and marketing personnel as we expand our business. Further, to accommodate our growth and compete effectively, we will be required to improve our information systems. We cannot be certain that our personnel, systems, procedures and internal controls will be adequate to support our future operations. If we cannot manage our growth effectively, our business will suffer.

*Any failure in our physician training efforts could result in lower than expected product sales and potential liabilities.*

A critical component of our sales and marketing efforts is the training of a sufficient number of physicians to properly utilize the CyberKnife system. We rely on physicians to devote adequate time to learn to use our products. If physicians are not properly trained, they may misuse or ineffectively use our products. This may result in unsatisfactory patient outcomes, patient injury and related liability or negative publicity which could have an adverse effect on our product sales.

*Changes in interpretation or application of generally accepted accounting principles may adversely affect our operating results.*

We prepare our financial statements to conform with GAAP. These principles are subject to interpretation by the Financial Accounting Standards Board, American Institute of Certified Public Accountants, the Public Company Accounting Oversight Board, the Securities and Exchange Commission and various other regulatory or accounting bodies. A change in interpretations of, or our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. Additionally, as we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period. For example, due to the significance of the software component of the CyberKnife system, we are currently bound by the software revenue recognition rules for our business. The Company has adopted ASU 2009-13 and ASU 2009-14 in the current quarter and the impact of the adoption of ASU 2009-13 and ASU 2009-14 on the Company's consolidated financial statements has been assessed at Note 2, Summary of Significant Accounting Policies. The application of different types of accounting principles and related potential changes may make it more difficult to compare our financial results from quarter to quarter, and the trading price of our common stock could suffer or become more volatile as a result.

*As a strategy to assist our sales efforts, we may offer extended payment terms, which may potentially result in higher DSO and greater payment defaults.*

We offer longer or extended payment terms for qualified customers in some circumstances. As of September 30, 2010, customer contracts with extended payment terms of more than one year amounted to less than 5% of our accounts receivable balance. While we qualify customers to

## Edgar Filing: ACCURAY INC - Form 10-Q

whom we offer longer or extended payment terms, their financial positions may change adversely over the longer time period given for payment. This may result in an increase in payment defaults, which would affect our net earnings. Also, longer or extended payment terms have and may in the future result in an increase in our days sales outstanding, or DSO.

*Our ability to raise capital in the future may be limited, and our failure to raise capital when needed could prevent us from executing our growth strategy.*

While we believe that our existing cash and short-term and long-term investments will be sufficient to meet our anticipated cash needs for at least the next 12 months, the timing and amount of our working capital and capital expenditure requirements may vary significantly depending on numerous factors, including:

- Market acceptance of our products;
- The need to adapt to changing technologies and technical requirements;
- The existence of opportunities for expansion; and
- Access to and availability of sufficient management, technical, marketing and financial personnel.

Table of Contents

If our capital resources are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity securities or debt securities or obtain other debt financing, which could be difficult or impossible in the current economic and capital markets environments. The sale of additional equity securities or convertible debt securities would result in additional dilution to our stockholders. We have not made arrangements to obtain additional financing, and we cannot assure that financing, if required, will be available in amounts or on terms acceptable to us, if at all.

***We may attempt to acquire new businesses, products or technologies, or enter into collaborations or strategic alliances, and if we are unable to successfully complete these acquisitions or to integrate acquired businesses, products, technologies or employees, we may fail to realize expected benefits or harm our existing business.***

Our success will depend, in part, on our ability to expand our product offerings and grow our business in response to changing technologies, customer demands and competitive pressures. In some circumstances, we may determine to do so through the acquisition of complementary businesses, products or technologies, or through collaborating with complementary businesses, rather than through internal development. The identification of suitable acquisition or alliance candidates can be difficult, time consuming and costly, and we may not be able to successfully complete identified acquisitions or alliances. Other companies may compete with us for these strategic opportunities. Furthermore, even if we successfully complete an acquisition or alliance, we may not be able to successfully integrate newly acquired organizations, products or technologies into our operations, and the process of integration could be expensive, time consuming and may strain our resources, and we may not realize the expected benefits of any acquisition, collaboration or strategic alliance. Furthermore, the products and technologies that we acquire or with respect to which we collaborate may not be successful, or may require significantly greater resources and investments than we originally anticipated. In addition, we may be unable to retain employees of acquired companies, or retain the acquired company's customers, suppliers, distributors or other partners who are our competitors or who have close relationships with our competitors. Consequently, we may not achieve anticipated benefits of the acquisitions or alliances which could harm our existing business. In addition, future acquisitions or alliances could result in potentially dilutive issuances of equity securities or the incurrence of debt, contingent liabilities or expenses, or other charges such as in-process research and development, any of which could harm our business and affect our financial results or cause a reduction in the price of our common stock.

***Our liquidity could be adversely impacted by adverse conditions in the financial markets.***

At September 30, 2010, we had \$140.9 million in cash, cash equivalents and marketable securities. The available cash and cash equivalents are held in accounts managed by third party financial institutions and consist of invested cash and cash in our operating accounts. The invested cash is invested in interest bearing funds managed by third party financial institutions. These funds invest in direct obligations of the government of the United States. To date, we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurances that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial markets.

At any point in time, we also have funds in our operating accounts that are with third party financial institutions that exceed the Federal Deposit Insurance Corporation ( FDIC ) insurance limits. While we monitor daily the cash balances in our operating accounts and adjust the cash balances as appropriate, these cash balances could be impacted if the underlying financial institutions fail or become subject to other adverse conditions in the financial markets. To date, we have experienced no loss or lack of access to cash in our operating accounts.

***Our operations are vulnerable to interruption or loss due to natural disasters, epidemics, terrorist acts and other events beyond our control, which would adversely affect our business.***

## Edgar Filing: ACCURAY INC - Form 10-Q

Our manufacturing facility is located in a single location in Sunnyvale, California. We do not maintain a backup manufacturing facility, so we depend on our current facility for the continued operation of our business. In addition, we conduct a significant portion of other activities including administration and data processing at facilities located in the State of California which has experienced major earthquakes in the past, as well as other natural disasters. We do not carry earthquake insurance. In the event of a major earthquake or other disaster affecting our facilities, it could significantly disrupt our operations, delay or prevent product manufacture and shipment for the time required to repair, rebuild or replace our manufacturing facilities, which could be lengthy, and result in large expenses to repair or replace the facilities. Likewise, events such as widespread blackouts could have similar negative impacts.

Table of Contents

**Risks Related to the Regulation of our Products and Business**

***Healthcare reform legislation could adversely affect demand for our products, our revenue and our financial condition.***

Healthcare costs have risen significantly over the past decade. There have been and continue to be proposals by legislators, regulators, and third-party payors to keep these costs down. Certain proposals, if passed, may impose limitations on the amounts of reimbursement available for our products from governmental agencies or third-party payors. These limitations could have a negative impact on the demand for our products and services, and therefore on our financial position and results of operations and a material adverse effect on our financial position and results of operations.

On March 23, 2010, the Patient Protection and Affordable Care Act was signed into law, and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 was signed into law. Together, the two measures make the most sweeping and fundamental changes to the U.S. health care system since the creation of Medicare and Medicaid. The Health Care Reform laws include a large number of health-related provisions to take effect over the next four years, including expanding Medicaid eligibility, requiring most individuals to have health insurance, establishing new regulations on health plans, establishing health insurance exchanges, requiring manufacturers to report payments or other transfers of value made to physicians and teaching hospitals, modifying certain payment systems to encourage more cost-effective care and a reduction of inefficiencies and waste and including new tools to address fraud and abuse. Effective in 2013, there will be a 2.3% excise tax on the sale of certain medical devices.

In addition, various healthcare reform proposals have also emerged at the state level. We cannot predict the exact effect newly enacted laws or any future legislation or regulation will have on us. However, the implementation of new legislation and regulation may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially. In addition, the enacted excise tax may materially and adversely affect our operating expenses and results of operations.

***Modifications, upgrades and future products related to the CyberKnife system or new indications may require new FDA 510(k) clearances or premarket approvals, and such modifications, or any defects in design or manufacture may require us to recall or cease marketing the CyberKnife system until approvals or clearances are obtained.***

The CyberKnife system is a medical device that is subject to extensive regulation in the United States by local, state and the federal government, including by the FDA. The FDA regulates virtually all aspects of a medical device's design, development, testing manufacturing, labeling, storage, record keeping, adverse event, reporting, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first receive either premarket approval or 510(k) clearance from the FDA, unless an exemption exists. Either process can be expensive and lengthy. The FDA's 510(k) clearance process generally takes from three to twelve months, but it can last longer. The process of obtaining premarket approval is much more costly and uncertain than the 510(k) clearance process and it generally takes from one to three years, or even longer, from the time the application is filed with the FDA. Despite the time, effort and cost, there can be no assurance that a particular device will be approved or cleared by the FDA through either the premarket approval process or 510(k) clearance process. Even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses of the product, which may limit the market for those products.



## Edgar Filing: ACCURAY INC - Form 10-Q

Medical devices may be marketed only for the indications for which they are approved or cleared. The FDA also may change its policies, adopt additional regulations, or revise existing regulations, each of which could prevent or delay premarket approval or 510(k) clearance of our device, or could impact our ability to market our currently cleared device. We are also subject to medical device reporting regulations which require us to report to the FDA if our products cause or contribute to a death or a serious injury, or malfunction in a way that would likely cause or contribute to a death or a serious injury. We also are subject to Quality System regulations. Our products are also subject to state regulations and various worldwide laws and regulations.

A component of our strategy is to continue to upgrade the CyberKnife system. Upgrades previously released by us required 510(k) clearance before we were able to offer them for sale. We expect our future upgrades will similarly require 510(k) clearance; however, future upgrades may be subject to the substantially more time consuming and uncertain premarket approval process. If we were required to use the premarket approval process for future products or product modifications, it could delay or prevent release of the proposed products or modifications, which could harm our business.

The FDA requires device manufacturers to make their own determination of whether or not a modification requires an approval or clearance; however, the FDA can review a manufacturer's decision not to submit for additional approvals or clearances. Any modification to an FDA approved or cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new premarket approval or 510(k) clearance. We cannot assure you that the FDA will agree with our decisions not to seek approvals or clearances for particular device modifications or that we will be successful in obtaining 510(k) clearances for modifications.

Table of Contents

We have obtained 510(k) clearances for the CyberKnife system for the treatment of tumors anywhere in the body where radiation is indicated. We have made modifications to the CyberKnife system in the past and may make additional modifications in the future that we believe do not or will not require additional approvals or clearances. If the FDA disagrees and requires us to obtain additional premarket approvals or 510(k) clearances for any modifications to the CyberKnife system and we fail to obtain such approvals or clearances or fail to secure approvals or clearances in a timely manner, we may be required to cease manufacturing and marketing the modified device or to recall such modified device until we obtain FDA approval or clearance and we may be subject to significant regulatory fines or penalties.

In addition, even if the CyberKnife system is not modified, the FDA and similar governmental authorities in other countries in which we market and sell our products have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government mandated recall, or a voluntary recall by us, could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling and user manuals. There were no recalls during the fiscal quarter ended September 30, 2010. We cannot ensure that the FDA will not require that we take additional actions to address problems that resulted in previous recalls. Any recall could divert management's attention, cause us to incur significant expenses, harm our reputation with customers, negatively affect our future sales and business, require redesign of the CyberKnife system, and harm our operating results. In these circumstances, we may also be subject to significant enforcement action. If any of these events were to occur, our ability to introduce new or enhanced products in a timely manner would be adversely affected, which in turn would harm our future growth.

***We must obtain and maintain regulatory approvals in international markets in which we sell, or seek to sell, our products. If we do not obtain and maintain the necessary international regulatory approvals, we will not be able to market and sell our products in foreign countries.***

In order for us to market and sell the CyberKnife system internationally, either through direct sales personnel or through distributors, we must obtain and maintain regulatory clearances applicable to the countries and regions in which we are selling, or are seeking to sell, our products. These regulatory approvals and clearances, and the process required to obtain and maintain them, vary substantially among international jurisdictions, and can be time consuming, expensive and uncertain, which can delay our ability to market products in those countries. In some jurisdictions, we rely on our distributors to manage the regulatory process and we are dependent on their ability to do so effectively. For example, our regulatory approval in Japan was suspended for a period of twelve months during 2003 as a result of a failure of our former distributor to coordinate product modifications and obtain necessary regulatory clearances in a timely manner. As a result, the CyberKnife system was recalled in Japan and our former Japanese distributor was told to stop selling the CyberKnife system. In response, we retained a regulatory consultant who was not affiliated with our former Japanese distributor and worked with the Japanese Ministry of Health, Labor and Welfare and applied for, and received, approval to sell an updated version of the CyberKnife system under the name of CyberKnife II in Japan. By working with a new distributor, Chiyoda Technol Corporation, we were able to begin distributing the CyberKnife II system in 2004 with no probationary period. In the event that we are unable to obtain and maintain, or are unduly delayed in obtaining, regulatory clearances for the CyberKnife system, including new clearances for system upgrades and use of the system anywhere in the body, in international markets we have entered or desire to enter, or if a clearance or approval includes significant limitations on the indicated uses of the product, our international sales could fail to grow or decline.

Within the European Union, we are required under Medical Device Directive to affix the Conformité Européene, or CE, mark on our products in order to sell the products in member countries of the EU. This conformity to the applicable directives is done through self declaration and is verified by an independent certification body, called a Notified Body, before the CE mark can be placed on the device. Once the CE mark is affixed to the device, the Notified body will regularly audit us to ensure that we remain in compliance with the applicable European laws or directives. CE marking demonstrates that our products comply with the laws and regulations required by the European Union countries to allow free movement of trade within those countries. If we cannot support our performance claims and/or demonstrate compliance with the applicable European laws and directives, we lose our CE mark, which would prevent us from selling our products within the European Union.

## Edgar Filing: ACCURAY INC - Form 10-Q

Under the Pharmaceutical Affairs Law in Japan, an import approval, or *shonin*, must be obtained from the Ministry of Health, Labor and Welfare, or MHLW, for our products. Before issuing approvals, MHLW examines the application in detail with regard to the quality, efficacy, and safety of the proposed medical device. The *shonin* is granted once MHLW is content with the safety and effectiveness of the medical device. The time required for approval varies. A delay in approval could prevent us from selling our products in Japan, which could impact our ability to generate revenue and harm our business.

Table of Contents

In addition, we are subject to a variety of environmental laws regulating our manufacturing operations and the handling, storage, transport and disposal of hazardous materials, which laws impose compliance costs on our business and can also result in liability. For example, we are in the process of updating the way our products are built such that they will be compliant with the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2008, or the RoHS Regulations, upon their effectiveness. The RoHS Regulations implement EU Directive 2002/95 which bans the placing on the EU market of new electrical and electronic equipment containing more than agreed levels of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants.

*Future legislative or regulatory changes to the healthcare system may affect our business.*

Even if third-party payors provide adequate coverage and reimbursement for the CyberKnife procedure, adverse changes in third-party payors general policies toward reimbursement could preclude market acceptance for our products and materially harm our sales and revenue growth. In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposals to change the healthcare system, and some could involve changes that significantly affect our business. In addition, certain federal regulatory changes occur at least annually.

In April 2008, at the time CMS published final 2009 Medicare inpatient reimbursement rates, CMS issued final rules implementing significant amendments to the regulations under the federal Ethics in Patient Referrals Act, which is more commonly known as the Stark Law, with an effective date of October 1, 2009. These regulations, among other things, impose additional limitations on the ability of physicians to refer patients to medical facilities in which the physician has an ownership interest for treatment. Among other things, the regulations provide that leases of equipment between physician owners that may refer patients and hospitals must be on a fixed rate, rather than a per use, basis. Physician owned entities have increasingly become involved in the acquisition of medical technologies, including the CyberKnife system. In many cases, these entities enter into arrangements with hospitals that bill Medicare for the furnishing of medical services, and the physician owners are among the physicians who refer patients to the entity for services. The regulations limit these arrangements and could require the restructuring of existing arrangements between physicians owned entities and hospitals and may also discourage physicians from participating in the acquisition and ownership of medical technologies. As a result of the finalization of these regulations, some existing CyberKnife system operators may have to modify or restructure their corporate or organizational structures. In addition, certain existing customers that planned to open CyberKnife centers in the United States involving physician ownership could also have to restructure. Accordingly, these regulations could reduce the attractiveness of medical technology acquisitions, including CyberKnife system purchases, by physician-owned joint ventures or similar entities. As a result, these regulations could have an adverse impact on our product sales and therefore on our business and results of operations.

On August 3, 2010, the FDA released for public comment two internal working group reports with numerous recommendations (1) to improve the 510(k) process and (2) to utilize science in regulatory decision making in ways that encourage innovation yet maintain predictability. The public comment period closed in early October 2010 and the FDA is targeting the implementation of or setting timelines for the implementation of non-controversial recommendations by the end of the year. At the same time, the FDA acknowledges that the recommendations are preliminary and no decisions have been made on specific changes to pursue. Nevertheless, we anticipate significant changes will result in the way 510(k) programs will operate and the increased data requirements, including clinical data, to obtain 510(k) clearance or PMA approval. We cannot predict what effect these reforms will have on our ability to obtain 510(k) clearances or PMA approvals in a timely manner or the effect on our business.

On June 9 and 10, 2010, the FDA held a public meeting entitled Device Improvements to Reduce the Number of Under-doses, Over-doses, and Misaligned Exposures from Therapeutic Radiation. The expressed purpose of the meeting was to discuss steps that could be taken by manufacturers of radiation therapy devices to help reduce misadministration and misaligned exposures that have been recently reported in the

## Edgar Filing: ACCURAY INC - Form 10-Q

press. In advance of and at the meeting, the FDA requested comments in the following areas: features that should be incorporated into radiation therapy devices and their related software, user training, and quality assurance measures. It is likely that the FDA will use the information gleaned at this meeting to significantly revise the standards and requirements for designing, manufacturing and marketing devices such as ours, creating uncertainty in the current regulatory environment around our current products and development of future products. Future legislative or policy initiatives directed at reducing costs could be introduced at either the federal or state level. We cannot predict what healthcare reform legislation or regulations, if any, will be enacted in the United States or elsewhere, what impact any legislation or regulations related to the healthcare system that may be enacted or adopted in the future might have on our business, or the effect ongoing uncertainty about these matters will have on the purchasing decisions of our customers.

Table of Contents

*We are required to comply with federal and state fraud and abuse law, and if we are unable to comply with such laws, we could face substantial penalties and we could be excluded from government healthcare programs, which would adversely affect our business, financial condition and results of operations.*

We are directly or indirectly through our customers, subject to various federal, state and foreign laws pertaining to healthcare fraud and abuse. These laws which directly or indirectly affect our ability to operate our business primarily include, but are not limited to, the following:

- The federal Anti-Kickback Statute, which prohibits persons from soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- State law equivalents to the Anti-Kickback Statute, which may not be limited to government reimbursed items;
- The Ethics in Patient Referral Act of 1989, also known as the Stark Law, which prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain designated health services if the physician or an immediate family member has any financial relationship with the entity. The Stark Law also prohibits the entity receiving the referral from billing for any good or service furnished pursuant to an unlawful referral;
- State law equivalents to the Stark Law, which may provide even broader restrictions and require greater disclosures than the federal law;
- The federal False Claims Act, which prohibits the knowing filing or causing the filing of a false claim or the knowing use of false statements to obtain payment from the federal government; and
- Similar laws in foreign countries where we conduct business.

The following arrangements with purchasers and their agents have been identified by the Office of the Inspector General of the Department of Health and Human Services as ones raising potential risk of violation of the federal Anti-Kickback Statute:

- Discount and free good arrangements that are not properly disclosed or accurately reported to federal healthcare programs;

## Edgar Filing: ACCURAY INC - Form 10-Q

- Product support services, including billing assistance, reimbursement consultation and other services specifically tied to support of the purchased product, offered in tandem with another service or program (such as reimbursement guarantee) that confers a benefit to the purchaser;
- Educational grants conditioned in whole or in part on the purchase of equipment, or otherwise inappropriately influenced by sales and marketing considerations;
- Research funding arrangements, particularly post-market research activities, that are linked directly or indirectly to the purchase of products, or otherwise inappropriately influenced by sales and marketing considerations; and
- Other offers of remuneration to purchasers that is expressly or impliedly related to a sale or sales volume, such as rebates and upfront payment, other free or reduced-price goods or services, and payments to cover costs of converting from a competitor's products, particularly where the selection criteria for such offers vary with the volume or value of business generated.

We have various arrangements with physicians, hospitals and other entities which implicate these laws. For example, physicians who own our stock also provide medical advisory and other consulting and personal services. Similarly, we have a variety of different types of arrangements with our customers. For example, our shared ownership program entails the provision of our CyberKnife system to our customers under a deferred payment program, where we generally receive the greater of a fixed minimum payment or a portion of the revenues of services. Included in the fee we charge for the placement and shared ownership program are a variety of services, including physician training, educational and marketing support, general reimbursement guidance and technical support. In the past, we have also provided loans to our customers. We also provide research grants to customers to support customer studies related to, among other things, our CyberKnife systems. Certain of these arrangements do not meet Anti-Kickback Statute safe harbor protections, which may result in increased scrutiny by government authorities having responsibility for enforcing these laws.

Table of Contents

If our past or present operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, including significant civil and criminal penalties, damages, fines, imprisonment and exclusion from the Medicare and Medicaid programs. The impact of any such violations may lead to curtailment or restructuring of our operations, which could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of these laws are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. If enforcement action were to occur, our reputation and our business and financial condition may be harmed, even if we were to prevail or settle the action. Similarly, if the physicians or other providers or entities with which we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

***If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.***

There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services has promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most uses and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. Although we are not a covered entity under HIPAA, we have entered into agreements with certain covered entities under which we are considered to be a business associate under HIPAA. As a business associate, we are required to implement policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities. Our failure to protect health information received from customers could subject us to liability to both the government and the covered entity, adverse publicity, and could harm our business and impair our ability to attract new customers.

The HIPAA privacy standard was recently amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), enacted as part of the American Recovery and Reinvestment Act of 2009. HITECH significantly increases the civil money penalties for violations of patient privacy rights protected under HIPAA. Furthermore, as of February 2010, Business Associates who have access to patient health information provided by hospitals and healthcare providers are now directly subject to HIPAA, including a new enforcement scheme and inspection requirements.

Certain governmental agencies, such as the U.S. Department of Health and Human Services and the Federal Trade Commission, have the authority to protect against the misuse of consumer information by targeting companies that collect, disseminate or maintain personal information in an unfair or deceptive manner. We are also subject to the laws of those foreign jurisdictions in which we sell the CyberKnife system, some of which currently have more protective privacy laws. If we fail to comply with applicable regulations in this area, our business and prospects could be harmed.

**Risks Related to Our Common Stock**

***The price of our common stock is volatile and may continue to fluctuate significantly, which could lead to losses for stockholders.***



## Edgar Filing: ACCURAY INC - Form 10-Q

The trading prices of the stock of smaller high-technology companies can experience extreme price and volume fluctuations. These fluctuations often have been unrelated or out of proportion to the operating performance of these companies. Our stock price has experienced periods of volatility. Broad market fluctuations may also harm our stock price. Any negative change in the public's perception of the prospects of companies that employ similar technology or sell into similar markets could also depress our stock price, regardless of our actual results.

Factors affecting the trading price of our common stock include:

- Regulatory developments related to manufacturing, marketing or sale of the CyberKnife system;
- Economic changes and overall market volatility;

Table of Contents

- Political uncertainties;
- Changes in product pricing policies;
- Variations in our operating results;
- Changes in our operating results as a result of problems with our internal controls;
- Announcements of technological innovations, new services or service enhancements, strategic alliances or significant agreements by us or by our competitors;
- Recruitment or departure of key personnel;
- Changes in the estimates of our operating results or changes in recommendations by any securities analyst that elects to follow our common stock;
- Market conditions in our industry, the industries of our customers and the economy as a whole;
- Sales of large blocks of our common stock; and
- Changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results.

***Substantial sales of our common stock by our stockholders, including sales pursuant to 10b5-1 plans, could depress our stock price regardless of our operating results.***

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell shares of common stock, including sales pursuant to 10b5-1 plans, the market price of our common stock could decline significantly. These

## Edgar Filing: ACCURAY INC - Form 10-Q

sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate.

***Our directors, executive officers and major stockholders own approximately 36.1% of our outstanding common stock as of October 15, 2010, which could limit our ability to influence the outcome of key transactions, including changes of control.***

As of October 15, 2010, our directors, executive officers, and current holders of 5% or more of our outstanding common stock, held, in the aggregate, approximately 36.1% of our outstanding common stock. This concentration of ownership may delay, deter or prevent a change of control of our company and will make some transactions more difficult or impossible without the support of these stockholders.

***We have implemented anti-takeover provisions that could discourage or prevent a takeover, even if an acquisition would be beneficial in the opinion of our stockholders.***

Provisions of our certificate of incorporation and bylaws could make it more difficult for a third party to acquire us, even if doing so would be beneficial in the opinion of our stockholders. These provisions include:

- Authorizing the issuance of blank check preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- Establishing a classified board of directors, which could discourage a takeover attempt;
- Prohibiting cumulative voting in the election of directors, which would limit the ability of less than a majority of stockholders to elect director candidates;
- Limiting the ability of stockholders to call special meetings of stockholders;
- Prohibiting stockholder action by written consent and requiring that all stockholder actions be taken at a meeting of our stockholders;  
and
- Establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

Table of Contents

In addition, Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change of control of our company. Generally, Section 203 prohibits stockholders who, alone or together with their affiliates and associates, own more than 15% of the subject company from engaging in certain business combinations for a period of three years following the date that the stockholder became an interested stockholder of such subject company without approval of the board or 66<sup>2</sup>/<sub>3</sub>% of the independent stockholders. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

*We have not paid dividends in the past and do not expect to pay dividends in the future.*

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, and other factors our board of directors may deem relevant. If we do not pay dividends, a return on a stockholders' investment will only occur if our stock price appreciates.

Table of Contents

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

(a) *Sales of Unregistered Securities*

None.

(b) *Use of Proceeds from Public Offering of Common Stock*

None.

(c) *Purchases of Equity Securities by the Issuer and Affiliated Purchasers*

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. (Removed and Reserved)**

**Item 5. Other Information**

None.

**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of Registrant.
3.2	Amended and Restated Bylaws of Registrant.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.



Table of Contents

SIGNATURE

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.

ACCURAY INCORPORATED

By: /s/ Euan S. Thomson  
Euan S. Thomson, Ph.D.  
President and Chief Executive Officer

By: /s/ Derek Bertocci  
Derek Bertocci  
Senior Vice President and Chief Financial  
Officer

Date: November 8, 2010