CHAMPIONS BIOTECHNOLOGY, INC. Form 10-Q March 17, 2010

# SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549 FORM 10-Q

# **DESCRIPTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended January 31, 2010

n the q	OR	
0	TRANSITION REPORT PURSUANT TO S EXCHANGE ACT OF 1934	ECTION 13 OR 15(d) OF THE SECURITIES
	For transition period from to to Commission file nu CHAMPIONS BIOTEC	ımber <u>0-17263</u>
	(Exact name of registrant as	specified in its charter)
	Delaware	52-1401755
(Stat	te or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
855 N	N. Wolfe Street, Suite 619, Baltimore, MD	21205
(1	Address of principal executive offices) (410) 369-	(zip code) -0365

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\beta$  No o Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the registrant is a large accelerated file, 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 Accelerated filer o Non-accelerated filer o Smaller reporting filer o (Do not check if a smaller reporting company b company)

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

As of March 15, 2010, the Registrant had a total of 35,579,958 shares of common stock outstanding.

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# PART I. FINANCIAL INFORMATION

# **Item 1. Financial Statements**

# CHAMPIONS BIOTECHNOLOGY, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

	January 31, 2010 (unaudited)		April 30, 2009		
ASSETS		(			
CURRENT ASSETS Cash and cash equivalents	\$	1,479,000	\$	1,728,000	
Short term investments	φ	1,479,000	φ	1,017,000	
Accounts receivable		414,000		1 125 000	
Prepaid expenses, deposits, and other receivables		762,000		1,125,000	
Total current assets		2,655,000		3,870,000	
Property and equipment, net		97,000		81,000	
Goodwill		669,000		669,000	
TOTAL ASSETS	\$	3,421,000	\$	4,620,000	
LIABILITIES AND STOCKHOLDERS EQUITY					
CURRENT LIABILITIES					
Accounts payable	\$	886,000	\$	1,414,000	
Accrued liabilities Deferred revenue		205,000 308,000		67,000 1,223,000	
Total current liabilities		1,399,000		2,704,000	
Other		77.000			
Other		77,000			
Total liabilities		1,476,000		2,704,000	
COMMITMENTS AND CONTINGENCIES Accrued stock repurchase		219,000			
STOCKHOLDERS EQUITY					
Preferred stock, \$10 par value; 56,075 shares authorized; 0 shares issued and outstanding Common stock, \$0.001 par value; 50,000,000 shares authorized; 36,644,000 and 33,579,000 issued at January 31, 2010 and April 30, 2009, respectively, and 35,665,000 and 32,989,000 shares outstanding at January 31, 2010 and					
April 30, 2009, respectively		37,000		34,000	
		(188,000)		(1,000)	

Treasury stock, at cost, 979,000 and 590,000 shares at January 31, 2010 and April 30, 2009, respectively

TOTAL LIABILITIES AND STOCKHOLDERS EQUITY

Additional paid-in capital Accumulated deficit Accumulated other comprehensive income	14,013,000 (12,128,000) (8,000)	11,640,000 (9,757,000)
Total stockholders equity	1,726,000	1,916,000

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

\$

3,421,000

4,620,000

# CHAMPIONS BIOTECHNOLOGY, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended January 31, 2010 2009		Nine Months Ended January 31, 2010 2009				
OPERATING REVENUE		2010		2009	2010		2007
Personalized oncology services	\$	325,000	\$	901,000	\$ 1,813,000	\$	2,381,000
Preclinical eValuation services		417,000	·	83,000	1,180,000	·	320,000
<b>Total operating revenue</b>		742,000		984,000	2,993,000		2,701,000
COSTS AND OPERATING EXPENSES							
Cost of Personalized oncology services		162,000		464,000	783,000		1,059,000
Cost of Preclinical eValuation services		202,000		206,000	586,000		329,000
Research and development		566,000		435,000	1,707,000		1,072,000
General and administrative		596,000		463,000	2,293,000		1,163,000
Total costs and operating expenses		1,526,000		1,568,000	5,369,000		3,623,000
LOSS BEFORE OTHER INCOME Interest income		(784,000)		(584,000) 21,000	(2,376,000) 5,000		(922,000) 67,000
LOSS BEFORE PROVISION FOR INCOME TAXES Provision for income taxes		(784,000)		(563,000)	(2,371,000)		(855,000)
NET LOSS	\$	(784,000)	\$	(563,000)	\$ (2,371,000)	\$	(855,000)
NET LOSS PER SHARE BASIC AND DILUTED	\$	(0.02)	\$	(0.02)	\$ (0.07)	\$	(0.03)
WEIGHTED AVERAGE SHARES OUTSTANDING BASIC AND DILUTED	3	34,052,000	3	33,273,000	33,175,000	,	33,271,000

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

# CHAMPIONS BIOTECHNOLOGY, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended January 31,		
	2010	2009	
OPERATING ACTIVITIES			
Net loss	\$ (2,371,000)	\$ (855,000)	
Adjustments to reconcile net loss to net cash used in operating activities:	, ( ) , ,	(,,	
Common stock issued for patent	175,000		
Stock-based compensation	343,000	324,000	
Depreciation	24,000		
Changes in operating assets and liabilities:			
Accounts receivable	(414,000)		
Prepaid expenses, deposits, and other receivables	363,000	(628,000)	
Accounts payable	(528,000)	547,000	
Accrued liabilities and other	215,000	(361,000)	
Deferred revenue	(915,000)	925,000	
Net cash used in operating activities	(3,108,000)	(48,000)	
INVESTING ACTIVITIES			
Proceeds from certificate of deposit	1,017,000		
Purchase of certificate of deposit	, ,	(1,005,000)	
Purchase of property and equipment	(40,000)	(38,000)	
Net cash provided by (used in) investing activities	977,000	(1,043,000)	
FINANCING ACTIVITIES			
Net proceeds from private placement of common stock	2,075,000		
Purchase of treasury stock	(188,000)		
Proceeds from exercise of options and warrants	3,000	7,000	
Net cash provided by financing activities	1,890,000	7,000	
Exchange rate effect on cash and cash equivalents	(8,000)		
NET DECREASE IN CASH AND CASH EQUIVALENTS	(249,000)	(1,084,000)	
_	, ,		
CASH AND CASH EQUIVALENTS BEGINNING OF PERIOD	1,728,000	3,709,000	

# CASH AND CASH EQUIVALENTS END OF PERIOD

\$ 1,479,000 \$ 2,625,000

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

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# CHAMPIONS BIOTECHNOLOGY, INC. NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

### Note 1. Organization, Use of Estimates and Basis of Presentation

Champions Biotechnology, Inc., (the Company, or we) is a biotechnology company that is engaged in the development of advanced preclinical platforms and predictive tumor specific data to enhance and accelerate the value of oncology drugs. In March 2009, the Company formed Champions Biotechnology U.K. Limited, a wholly owned subsidiary, in order to establish operations in the United Kingdom and Israel.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates consist of share-based compensation and expenses related to personalized oncology services. During the nine months ended January 31, 2010, the Company recognized a \$218,000 reduction in expense as a result of certain obligations being canceled by various vendors that were previously accrued.

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has experienced recurring losses from operations while developing its service offerings and expanding its sales channels. These operating losses are expected to continue into the near future as the Company continues to expand. The Company will require additional capital beyond the cash currently on hand to fund these expected near term operating losses. To meet these capital needs, the Company s management is seeking to raise funds from various sources, including both the private placements and public markets. There is no assurance that the Company will succeed in these fund-raising efforts. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We evaluated subsequent events through the date the accompanying condensed consolidated financial statements were issued.

#### **Note 2. Summary of Significant Accounting Policies**

# **Unaudited Interim Financial Information**

These unaudited condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). All significant intercompany transactions and accounts have been eliminated. Certain information related to the Company significant accounting policies and footnote disclosures normally included in financial statements prepared in accordance with GAAP has been condensed or omitted. The accounting policies followed in the preparation of these unaudited condensed consolidated are consistent with those followed in the Company significant and an annual consolidated financial statements for the year ended April 30, 2009, as filed on the Company significant Annual Report on Form 10-K. In the opinion of management, these unaudited condensed consolidated financial statements contain all material adjustments necessary to fairly state our financial position, results of operations and cash flows for the periods presented and the presentations and disclosures herein are adequate when read in conjunction with the Company significant intercompany significant intercompany transactions and regulations and regulations and regulations and regulations.

# **Principles of Consolidation**

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries: Biomerk, Inc. and Champions Biotechnology U.K., Limited. All material intercompany transactions have been eliminated in consolidation.

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The local currency of the Company s foreign operations is converted to U.S. currency for the Company s condensed consolidated financial statements for each period being presented and the Company is subject to foreign exchange rate fluctuations in connection with the Company s international operations.

#### Segment Reporting

The Company operates as a single operation, using core infrastructure that serves the oncology needs of customers through both personalized oncology and preclinical services. The Company s chief operating decision maker assesses the Company s performance as a whole and no expense or operating income is generated or evaluated on any component level.

#### Reclassifications

Certain reclassifications have been made to the prior period financial statement amounts to conform to the current period presentation.

# Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less, to be cash equivalents. At various times throughout the year, the Company had amounts on deposit at financial institutions in excess of federally insured limits. Our highly liquid investments are maintained at well-capitalized financial institutions to mitigate the risk of loss.

#### Fair Value of Financial Instruments

As of January 31, 2010, the carrying value of cash and cash equivalents, accounts receivable, prepaid expenses, deposits and other receivables, accounts payable, accrued liabilities and deferred revenue approximate their fair value based on the liquidity or the short-term maturities of these instruments.

#### Goodwill

Goodwill represents the excess of the cost over the fair market value of the net assets acquired including identifiable assets. Goodwill is tested annually, or more frequently if circumstances indicate potential impairment, by comparing its fair value to its carrying amount. The determination of whether or not goodwill is impaired involves significant judgment. Although the Company believes its goodwill is not impaired, changes in strategy or market conditions could significantly impact the judgments and may require future adjustments to the carrying value of goodwill.

#### Revenue Recognition

The Company derives revenue from Personalized Oncology and Preclinical eValuation services. Personalized Oncology Services assist physicians by providing information that may enhance personalized treatment options for their cancer patients through access to expert medical information panels and tumor specific data. The Company's Preclinical eValuation services offer a preclinical tumorgraft platform to pharmaceutical and biotechnology companies using Biomerk Tumorgraft studies, which have been shown to be predictive of how drugs may perform in clinical settings. The Company recognizes revenue when the following four basic criteria are met: 1) a contract has been entered into with our customers; 2) delivery has occurred or services rendered to our customers; 3) the fee is fixed and determinable as noted in the contract; and 4) collectability is reasonably assured, as fees for services are remitted in full upon execution of the contract. The Company utilizes a proportional performance revenue recognition model for its preclinical eValuation services under which we recognize revenue as performance occurs, based on the relative outputs of the performance that have occurred up to that point in time under the respective agreement, typically the delivery of reports to our customers documenting the results of our testing protocols.

When a Personalized Oncology or Preclinical eValuation arrangement involves multiple elements, the items included in the arrangement (deliverables) are evaluated to determine whether they represent separate units of accounting. We perform this evaluation at the inception of an arrangement and as we deliver each item in the arrangement. Generally, we account for a deliverable (or a group of deliverables) separately if: (1) the delivered item(s) has standalone value to the customer, (2) there is objective and reliable evidence of the fair value of the

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undelivered items included in the arrangement, (3) if we have given the customer a general right of return relative to the delivered item(s), and (4) delivery or performance of the undelivered item(s) or service(s) is probable and substantially in our control. All revenue from contracts determined not to have separate units of accounting is recognized based on consideration of the most substantive delivery factor of all the elements in the contract.

#### Research and Development

Research and development costs represent both costs incurred internally for research and development activities as well as costs incurred externally to fund research activities. All research and development costs are expensed as incurred. Non-refundable advance payments are capitalized and recorded as expense when the respective product or services are delivered.

#### Recent Accounting Pronouncements

In June 2009, the FASB approved the FASB Accounting Standards Codification (Codification) as the single authoritative source for GAAP. The Codification, which was launched on July 1, 2009, does not change current U.S. GAAP, but is intended to simplify user access by providing all authoritative U.S. GAAP in one location. All existing accounting standards have been superseded and all other accounting literature not included in the Codification is considered non-authoritative. The Codification is effective for interim and annual periods ending after September 15, 2009. The Codification did not change GAAP and did not have a material impact on the Company s condensed consolidated financial statements.

In June 2009, the FASB issued guidance for determining whether an entity is a variable interest entity (VIE). This guidance requires an enterprise to perform an analysis to determine whether the enterprise is variable interest or interests give it a controlling financial interest in a VIE. Under this guidance, an enterprise has a controlling financial interest when it has (i) the power to direct the activities of a VIE that most significantly impact the entity is economic performance and (ii) the obligation to absorb losses of the entity or the right to receive benefits from the entity that could potentially be significant to the VIE. Enterprises are also required to assess whether they have an implicit financial responsibility to ensure that a VIE operates as designed when determining whether it has power to direct the activities of the VIE that most significantly impact the entity is economic performance. This guidance also requires ongoing assessments of whether an enterprise is the primary beneficiary of a VIE, requires enhanced disclosures and eliminates the scope exclusion for qualifying special-purpose entities. This guidance is effective for annual reporting periods beginning after November 15, 2009. We do not anticipate that the adoption of this guidance will have a material impact on our financial position or results of operations.

In August 2009, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2009-5, Measuring Liabilities at Fair Value (ASU 2009-05). ASU 2009-05 amends Accounting Standards Codification Topic 820, Fair Value Measurements. Specifically, ASU 2009-5 provides clarification that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: (i) a valuation technique that uses the quoted price of the identical liability when traded as an asset or quoted prices for similar liabilities or similar liabilities when traded as assets and/or (ii) a valuation technique that is consistent with the principles of Topic 820 of the Accounting Standards Codification (e.g. an income approach or market approach). ASU 2009-05 also clarifies that (i) when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability and (ii) that both a quoted price in an active market for an identical liability at the measurement date and a quoted price for the identical liability when traded as an asset in an active market when no adjustments to the quoted price of the asset are required are level one fair value measurements. ASU 2009-05 was adopted as of November 1, 2009 and did not have any effect on Company s condensed consolidated financial statements

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#### Note 3. Basic and Dilutive Loss Per Common Share

Basic loss per common share is computed by dividing our net loss by the weighted average number of common shares outstanding during the period excluding the dilutive effects of options and warrants. For the three and nine months ended January 31, 2010 and 2009, diluted loss per common share is computed on the same basis as basic loss per common share, as the inclusion of potential common shares outstanding would be anti-dilutive. The table below reflects the potential weighted average incremental shares of common stock that have been excluded from the computation of diluted loss per common share since their effect would be anti-dilutive.

	Three Months Ended January 31,		Nine Montl Januar	
	2010	2009	2010	2009
Stock options	506,000	343,000	472,000	355,000
Warrants	447,000	441,000	449,000	459,000
Restricted stock	9,000		5,000	
Total common stock equivalents	962,000	784,000	926,000	814,000

#### **Note 4. Property and Equipment**

Property and equipment is recorded at cost and consists of laboratory equipment, furniture and fixtures, computer hardware and software, and leasehold improvements. Depreciation is calculated on a straight-line basis over the estimated useful lives of the various assets ranging from three to seven years. Leasehold improvements are depreciated on a straight-line basis over the lesser of the lease term or estimated useful life. Property and equipment consisted of the following:

	January 31, 2010		
Laboratory equipment	\$ 36,000	\$	4,000
Furniture and fixtures	32,000		26,000
Computer hardware and software	55,000		55,000
Leasehold improvements	2,000		
Total property and equipment	\$ 125,000	\$	85,000
Less accumulated depreciation	(28,000)		(4,000)
Property and equipment, net	\$ 97,000	\$	81,000

Depreciation expense was approximately \$8,000 and \$0 for the three months ended January 31, 2010 and 2009, respectively, \$24,000 and \$0 for the nine months ended January 31, 2010 and 2009, respectively.

#### **Note 5. Licensing Agreements**

## Bithionol license agreement

In November 2009, the Company entered into a license agreement with two U.S. based companies for world-wide rights to develop and commercialize Bithionol, a drug candidate, for the treatment of various forms of cancer which include melanoma, prostate, breast and lung cancer. The Company may terminate the license agreement in whole or in part on a country-by-country basis for any reason upon sixty days prior written notice.

Under the terms of the agreement, the Company made an initial payment of \$50,000 upon execution of the agreement and is obligated to make a second payment of \$50,000 within nine months of executing the agreement. In addition, the Company will be required to pay \$6,250,000 upon successful completion of certain clinical milestones. The Company will also make royalty payments based on a percentage of net sales as defined in the license agreement. In addition,

the Company will pay annual license fee payments ranging for \$25,000 to \$100,000 until

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the minimum royalty payments outlined in the license agreement are met. The Company also agreed to pay for past patent expenses of \$29,780 incurred by the two U.S. based companies upon signing of the agreement. The initial payment of past patent expenses, initial payment due upon signing the agreement and second payment due within nine months of signing the agreement were all charged to research and development expense during the three months ended January 31, 2010. No amounts have been accrued for the annual license fees since management has determined that it is not probable that any such payments will be made in future periods.

#### TAR 1 license agreement

In October 2009, the Company entered into a license agreement with an Israeli company for world-wide rights to develop and commercialize a transactivation and apoptosis restoring (TAR-1) developmental drug candidate. The Company may terminate the license agreement in whole or in part on a country-by-country basis for any reason upon sixty days prior written notice.

Under the terms of the agreement, the Company made an initial payment of \$60,000. In addition, the Company will be required to pay \$6,140,000 upon successful completion of certain clinical milestones, \$5,000,000 upon reaching certain regulatory approvals and \$23,000,000 upon achievement of certain commercial milestones. The Company will also make royalty payments based on net sales as defined in the license agreement. In addition, the Company will pay an annual licensing fee of \$30,000 for the first three years of the agreement beginning on the second year of the agreement. The Company also agreed to pay for \$118,000 of past patent expenses incurred by the Israeli company prior to execution of the agreement. The initial payment of past patent expenses, first annual licensing fee and initial payment were all charged to research and development expense.

# Benzovlyphenylerea license agreement

In July 2009, the Company entered into a joint development and licensing agreement with a third party for the development of a soluble form of SG410, the Company s Benzoylyphenylerea (BPU) sulfur analog compound. Under the joint agreement, the third party will be entitled to milestone payments of \$2,000,000 upon the success of certain regulatory approvals and royalty payments on net sales of the licensed BPU product. No amounts were due under this agreement as of January 31, 2010.

## **Note 6. Stock-Based Compensation**

complete.

The Company may grant (i) Incentive Stock Options, (ii) Non-statutory Stock Options, (iii) Restricted Stock Awards, and (iv) Stock Appreciation Rights (collectively, stock-based compensation) to its employees, directors and non-employee consultants under a 2008 Equity Incentive Plan that has not yet been approved by the Company s shareholders. Such awards may be granted by the Company s Board of Directors. Options granted under the plan expire no later than ten years from the date of grant and the awards vest as determined by the Board of Directors. For share-based payments to non-employee consultants, the fair value of the share-based consideration issued is used to measure the transaction, as management believes this to be a more reliable measure of fair value than the services received. The fair value of the award is measured at the price of the Company s common stock or stock options on the date that the commitment for performance by the non-employee consultant has been reached or performance is

Stock-based compensation in the amount of \$159,000 and \$222,000 was recognized for the three months ended January 31, 2010 and 2009, respectively and \$343,000 and \$324,000 for the nine months ended January 31, 2010 and 2009, respectively. Stock-based compensation costs were recorded as follows:

	Three Months Ended January 31,		Nine Months Ended January 31,				
	2010		2009		2010		2009
Cost of personalized oncology services	\$ 4,000	\$		\$	15,000	\$	
Research and development	38,000		87,000		70,000		99,000
General and administrative	117,000		135,000		258,000		225,000
Total stock-based compensation expense	\$ 159,000	\$	222,000	\$	343,000	\$	324,000

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Black-Scholes assumptions used to calculate the fair value of options and warrants granted during the nine months ended January 31, 2010 and 2009 were as follows:

	Nine Months Ended January 31,				
	2010	2009			
Expected term in years	6.0	3.4 6.0			
Risk free interest rates	2.8% - 3.1%	2.1% - 2.4%			
Volatility	94%	69% - 102%			
Dividend yield	0%	0%			

#### Stock options and restricted stock

During the nine months ended January 31, 2009, options to purchase 25,000 shares of the Company s unregistered common stock were exercised resulting in the receipt by the Company of net cash proceeds of \$7,000. No options were exercised in the nine months ended January 31, 2010.

No options were granted during the three months ended January 31, 2010 or 2009.

Effective January 1, 2010 our President and Principal Executive Officer of the Company, Dr. Douglas D. Burkett, resigned and became a consultant to the Company. In conjunction with Dr. Burkett s departure, the Company amended Dr. Burkett s employment agreement to accelerate the vesting of 166,670 unvested stock options to December 31, 2009. The Company has considered this a Type III modification which resulted in the recording of an additional \$43,000 charge to compensation expense during the three months ended January 31, 2010.

#### Warrants

During the nine months ended January 31, 2010, warrants to purchase 15,408 shares of the Company s unregistered common stock were exercised resulting in the receipt by the Company of net cash proceeds of \$3,000. No warrants were issued for the nine months ended January 31, 2010. Warrants to purchase 150,000 shares of the Company s unregistered common stock were issued during the nine months ended January 31, 2009. No warrants were exercised during nine months ended January 31, 2009.

At January 31, 2010, the Company has warrants outstanding to purchase 748,983 shares of the Company s unregistered common stock with a weighted average exercise price of \$0.36 per share which expire from October 2011 through July 2014.

#### Stock option plans

On February 22, 2010, the Compensation Committee of the Board of Directors of the Company adopted the Director Compensation Plan of 2010 (the Director Plan ) to replace the Company s former compensation policy for directors, effective for the 2010 calendar year commencing January 1, 2010. Under the Director Plan, independent directors of the Company are entitled to an annual award of five-year options to purchase 50,000 shares of the Company s unregistered common stock, and the Chairman of the Board of the Company is entitled to an annual award of options to purchase 100,000 shares of the Company s unregistered common stock. Independent directors who serve on one or more Board committees will also receive an annual grant of five-year options to purchase 50,000 shares of the Company s unregistered common stock or 50,000 shares of restricted unregistered common stock. For the initial Director Plan year, an independent director can chose to receive a cash fee equal to the value of the unregistered restricted common stock that would have otherwise been granted. The Chairman of the Board is also entitled to the same arrangement for his services on Board committees at a rate of twice that of an independent director. The Company will also pay each independent director \$15,000 to offset the tax liability in respect of any unregistered restricted stock awards. All unregistered common stock options and unregistered restricted stock issued under the Director Plan vest quarterly at a rate of 25%.

#### **Note 7. Related Party Transactions**

Related party transactions include transactions between the Company and certain shareholders, management and affiliates.

Effective January 2010, the Company entered into a Consulting Agreement with David Sidransky, MD, our Chairman of the Board of Directors. The Consulting Agreement calls for compensation of \$5,000 per month plus reimbursement for reasonable expenses. The consulting services performed under the terms of this agreement are outside of the scope of services performed by Dr. Sidransky as our Chairman of the Board of Directors and include assisting the Company with new product programs and assistance with certain financial strategies. Dr. Sidransky shall devote at least 20 hours per month to his services to the Company under this agreement, which will expire on December 31, 2012, subject to certain renewal provisions.

In May 2009, the Board of Directors approved a stock repurchase agreement with a Board member which obligates the Company to purchase up to approximately \$407,000 of the Company s common stock held by the Board member over the next two years providing that the Board member continues his services under a consulting agreement executed concurrently with the stock repurchase agreement. Under the stock repurchase agreement, the Company made an initial purchase of \$125,000 of Company s shares of common stock, and may be required to make quarterly purchases of \$31,250 of the Company s common stock held by the Board member after the end of each fiscal quarter. Such purchases may occur quarterly through April 2011 provided the consulting agreement remains in effect. The purchase price per share of the common stock for each purchase is equal to the lesser price of \$0.50 or 50% of the average volume-weighted closing price of the stock as quoted on the OTC Bulletin Board for the 30 day trading period ending on the day before the date of each purchase as long as the consulting agreement remains in effect. Under the agreement, the Company has paid this Board member approximately \$188,000 for the purchase of 389,062 shares of our common stock as of January 31, 2010.

The Company accounted for its obligation to repurchase shares of its common stock under the stock repurchase agreement as a put option entered into in connection with a compensation arrangement, and valued the obligation at fair value. The fair value of the put option continues to be de minimus, as the purchase price of the shares of common stock as calculated under the agreement was less than the fair value of the Company s common stock. Because the requirement for the Company to transfer cash in exchange for the shares of common stock is not within its control, the Company has recorded an amount equal to the total purchase price required under the arrangement in temporary equity with a corresponding reduction of additional paid-in capital. As of January 31, 2010, the Company has approximately \$219,000 remaining to be paid under the stock repurchase agreement based on the stock price as of that date.

Further, under the stock repurchase agreement, the Company, at its option, may purchase all or any part of the shares that have not been previously purchased, up to but not to exceed, 2,250,000 shares of the common stock at the discretion of the Company subject to the pricing formula described above. This option may be exercised during the period of the consulting agreement or for a period up to one year following the termination of the consulting agreement. The Company has accounted for this as a purchased call option on its own stock. As this arrangement is indexed to, and will be settle in, the Company s own shares of common stock, it has recorded a decrease to stockholder s equity at the call options fair value of \$1,774,000. Additionally, because the option provides the Company the ability to repurchase its own shares of common stock at a price less than fair value and the call option was provided by a significant shareholder, the Company has recorded a corresponding contribution to stockholder s equity of \$1,774,000.

Subsequent to January 31, 2010, the Company repurchased an additional 85,227 shares of common stock for \$31,250 per the terms of the repurchase agreement noted above.

#### Note 8. Stockholders Equity

In December 2009, the Company received gross proceeds of \$2,100,000 from the private placement of 2,800,000 shares of the Company s unregistered common stock. This unregistered common stock was sold to accredited investors exempt from registration as provided by Section 4(2) of the Securities Act of 1933 and Regulation D. The Company incurred approximately \$25,000 in direct and incremental costs related to the offering. Subsequent to January 31, 2010, the Company executed additional subscription agreements for the private placement of unregistered common

stock noted above totaling \$900,000, of which \$100,000 has been received.

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In September 2009, the Company issued 250,000 shares of the Company s unregistered common stock valued at \$175,000 to the original owners of the SG 410 patent whereby the Company had previously acquired the rights to the SG 410 patent in February, 2007. The unregistered common stock was issued as the final contingent payment due upon issuance of the patent which occurred in September 2009. The \$175,000 expense is included in research and development expense in the accompanying condensed consolidated statement of operations.

# Note 9. Subsequent Events

#### Liposome option agreement

In February 2010, the Company entered into an exclusive option agreement with a Canadian company. The option agreement grants the Company the exclusive right to review Liposome, a drug candidate, for the treatment of various forms of cancer which include melanoma, prostate, breast and lung cancer, for the period of one year beginning in February 2010.

Under the terms of the agreement, the Company made a payment of \$40,000 upon execution of the agreement. In addition, the Company agreed to reimburse the Canadian company up to \$10,000 for patent costs incurred over the one year option period. All amounts paid will be recorded as research and development expense.

## Service agreement

During the fourth quarter of fiscal 2010 the Company entered into a research and development materials purchase agreement. The agreement calls for the Company to make 18 monthly payments of 25,000 commencing on March 1, 2010.

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

The following discussion of our historical results of operations and our liquidity and capital resources should be read in conjunction with the financial statements and related notes that appear elsewhere in this report.

#### **Forward-Looking Statements**

This Quarterly Report on Form 10-Q, including Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations, contains certain forward-looking statements, which include information relating to future events, future financial performance, strategies, expectations, competitive environment, regulation, and availability of resources. These forward-looking statements include, without limitation, statements regarding: proposed new programs; expectations that regulatory developments or other matters will not have a material adverse effect on our financial position, results of operations, or liquidity; statements concerning projections, predictions, expectations, estimates, or forecasts as to our business, financial and operational results, and future economic performance; and statements of management s goals and objectives and other similar expressions concerning matters that are not historical facts. Words such as may, should, could, would, predicts, potential, estimates and similar expressions, as well as statements in fut anticipates. future. intends. plans. believes. identify forward-looking statements.

Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made or management s good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements.

Forward-looking statements speak only as of the date the statements are made. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to, those described in Risk Factors in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended April 30, 2009, as updated in our subsequent reports filed with the SEC, including any updates found in Part II, Item 1A of this or other reports on Form 10-Q. You should not put undue reliance on any forward-looking statements. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions, or changes in other factors affecting forward-looking information, except to the extent required by applicable securities laws. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

#### Overview

The Company is engaged in the development of advanced preclinical platforms and predictive tumor specific data to enhance and accelerate the value of oncology drugs. Our Preclinical Platform is a novel approach based upon the implantation of primary human tumor fragments in immune deficient mice followed by propagation of the resulting engraftments (Biomerk Tumorgrafts ) in a manner that preserves the biological characteristics of the original human tumor. We believe that Biomerk Tumorgrafts closely reflect human cancer biology and their response to drugs is more predictive of clinical outcomes in cancer patients. The Company is building its Biomerk Tumorgraft platform through the procurement, development and characterization of numerous Tumorgrafts within each of several cancer types. Tumorgrafts are procured through agreements with a number of institutions in the U.S. and overseas and developed and tested through agreement with a U.S. based preclinical facility.

We are leveraging our preclinical platform to evaluate oncology drug candidates and to develop a portfolio of novel or repositioned drug candidates through pre-clinical or early clinical trials. As drugs progress through this early stage of development, the Company plans to sell, partner or license them to pharmaceutical and/or biotechnology companies, as appropriate. We believe this strategy will enable us to leverage the competencies of these partners or licensees to maximize our return on investment in a time frame that is shorter than for traditional drug development. We believe that this model is unlike that of many new biotechnology companies that look to bring the process of drug development through all phases of discovery, development, regulatory approvals, and marketing, which requires a very large financial commitment and a long development period, typically more than a decade, to commercialize. Thus far we have acquired or licensed three oncology drug candidates, SG410, TAR-1, and Bithionol. We have begun

preclinical development of the lead candidate, SG410, through the use of contract

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facilities and have secured a preclinical supply of SG410 drug substance and developed a soluble form of the compound and we intend to evaluate its efficacy in Biomerk Tumorgrafts for several cancer types. If results are promising, it is our intention to continue preclinical development and then sell, partner or license SG410 for its remaining clinical development. The Company also entered into license agreements to develop and commercialize TAR-1 and Bithionol in October, 2009 and November, 2009, respectively.

We also offer our Biomerk Tumorgraft predictive preclinical platform and tumor specific data to physicians to provide information that may enhance personalized patient care options and to companies for evaluation of oncology drugs in a platform that integrates predictive testing with biomarker discovery. We provide Personalized Oncology services to physicians in the field of oncology by establishing and administering expert medical information panels for their patients to (i) arrange for testing, analysis and study of cancer tissues, as appropriate, (ii) analyze medical records and test results, and (iii) assist in understanding conventional and research options. The Company also develops and performs testing on Personalized Tumorgrafts—to provide patients—physicians personalized data on treatment drug options.

# **Results of Operations**

#### Three Months Ended January 31, 2010 and 2009

#### Revenues

Revenues for the three months ended January 31, 2010 and 2009 were \$742,000 and \$984,000, respectively, a decrease of \$242,000 or 25%.

Revenues from Personalized Oncology Services (POS) for the three months ended January 31, 2010 and 2009 were \$325,000 and \$901,000, respectively, a decrease of \$576,000 or 64%. This decrease consisted of a \$317,000 decrease in revenues from physician panels and a \$259,000 decrease in tumorgraft implantations, tumorgraft studies, and vaccine studies. Payments for POS are generally received in advance and recorded as deferred revenue.

Revenues from Preclinical eValuation services for the three months ended January 31, 2010 and 2009 were \$417,000 and \$83,000, respectively, an increase of \$334,000 or 402%. This increase is due to growth in both the number of studies being completed and customers entering into contracts for the Company s preclinical eValuation services. The Company utilizes a proportional performance revenue recognition model for its preclinical eValuation services under which we recognize revenue as performance occurs, based on the relative outputs of the performance that have occurred up to that point in time under the respective agreement, typically the delivery of reports to our customers documenting the results of our testing protocols. Payments, or partial payments, for Preclinical eValuation services are generally received in advance and recorded as deferred revenue.

#### **Operating Expenses**

Cost of Personalized Oncology Services for the three months ended January 31, 2010 and 2009 were \$162,000 and \$464,000, respectively, a decrease of \$302,000 or 65% reflecting the \$576,000 decrease in POS revenues.

Cost of Preclinical eValuation services for the three months ended January 31, 2010 and 2009, were \$202,000 and \$206,000, respectively, a decrease of \$4,000 or 2%. During the third quarter of 2009 the Company realized lower a lower gross margin on preclinical eValuation service revenues primarily due to a contractually negotiated reduction in payments with one of the Company s customers.

Research and development (R&D) expenses for the three months ended January 31, 2010 and 2009, were \$566,000 and \$435,000, respectively, an increase of \$131,000 or 30%. This increase is primarily due to the recognition of \$130,000 in licensing fees and costs in connection with our Bithionol licensing agreement.

General and administrative expenses for the three months ended January 31, 2010 and 2009, were \$596,000 and \$463,000, respectively, an increase of \$133,000 or 29%. This increase is primarily due to our development of corporate infrastructure to support our increased generating activities of the Company and includes increased payroll, bonuses, consulting, legal, accounting, marketing, and office rent expenses.

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#### Interest Income

Interest income for the three months ended January 31, 2010 and 2009, was \$0 and \$21,000, respectively. The decrease in interest income resulted from the Company s decrease in assets held in interest bearing investments.

#### Net Loss

The Company s net loss for the three months ended January 31, 2010 and 2009, was \$784,000 and \$563,000, respectively. The \$221,000 increase in our net loss for the three months ended January 31, 2009, reflects the \$242,000 decrease in revenues and a net decline of \$21,000 in interest income offset by the \$42,000 decrease in operating expenses.

#### Nine Months Ended January 31, 2010 and 2009

#### Revenues

Revenues for the nine months ended January 31, 2010 and 2009, were \$2,993,000 and \$2,701,000, respectively, an increase of \$292,000 or 11%.

Revenues from POS for the nine months ended January 31, 2010 and 2009, were \$1,813,000 and \$2,381,000, respectively, a decrease of \$568,000 or 24%. This decrease of \$568,000 consisted of a \$1,052,000 decrease in revenues from physician panels offset by a \$484,000 increase in tumorgraft implantations, tumorgraft studies, and vaccine contracts. Payments for POS are generally received in advance and recorded as deferred revenue.

Revenues from Preclinical eValuation services for the nine months ended January 31, 2010 and 2009, were \$1,180,000 and \$320,000, respectively, an increase of \$860,000 or 269%. This increase is due to growth in both the number of studies being completed and customers entering into contracts for the Company s preclinical eValuation services. The Company utilizes a proportional performance revenue recognition model for its preclinical eValuation services under which we recognize revenue as performance occurs, based on the relative outputs of the performance that have occurred up to that point in time under the respective agreement, typically the delivery of reports to our customers documenting the results of our testing protocols. Payments, or partial payments, for Preclinical eValuation services are generally received in advance and recorded as deferred revenue.

#### **Operating Expenses**

Cost of Personalized Oncology Services for the nine months ended January 31, 2010 and 2009, were \$783,000 and \$1,059,000, respectively, a decrease of \$276,000 or 26% reflecting the \$568,000 decrease in POS revenues.

Cost of Preclinical eValuation services for the nine months ended January 31, 2010 and 2009, were \$586,000 and \$329,000, respectively, an increase of \$257,000 or 78% reflecting the increase in Preclinical eValuation revenues. During the third quarter of 2009 the Company realized lower a lower gross margin on preclinical eValuation service revenues primarily due to a contractually negotiated reduction in payments with one of the Company s customers.

Research and development expenses for the nine months ended January 31, 2010 and 2009, were \$1,707,000 and \$1,072,000, respectively, an increase of \$635,000 or 59%. This increase is due to the \$175,000 charge for the final payment made with our common stock for the acquisition of the SG410 patent, the recognition of licensing fees, and costs in connection with our TAR-1 licensing agreement of \$208,000, recognition of \$130,000 in licensing fees and costs for our Bithionol license agreement, and a \$212,000 increase in tumorgraft acquisition and testing costs, offset by the cancelation of an amounts payable of \$90,000 to certain vendors for lack of performance.

General and administrative expenses for the nine months ended January 31, 2010 and 2009, were \$2,293,000 and \$1,163,000, respectively, an increase of \$1,130,000 or 97%. This increase is primarily due to our continuing development of corporate infrastructure to support our increased revenue generating activities of the Company including increased payroll, bonuses, consulting, legal, accounting, marketing, and office rent expenses.

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#### Interest Income

Interest income for the nine months ended January 31, 2009 and 2008 was \$5,000 and \$67,000, respectively. The decrease in interest income resulted from the Company s decrease in assets held in interest bearing investments.

Net Loss

The Company s net loss for the nine months ended January 31, 2010 and 2009, was \$2,371,000 and \$855,000, respectively. The \$1,516,000 increase in our net loss for the nine months ended January 31, 2010 reflects the \$1,746,000 increase in operating expenses and a net decline of \$62,000 in interest income offset by the \$292,000 increase in revenues.

#### **Liquidity and Capital Resources**

As of January 31, 2010, our source of liquidity was cash of \$1,479,000 compared to \$1,728,000 (exclusive of a \$1,017,000 certificate of deposit) at April 30, 2009. Our cash decreased by \$249,000 during the nine months ended January 31, 2010 due primarily to our use of cash in operations of \$3,108,000 offset by the conversion to cash of our \$1,017,000 certificate of deposit upon the maturity of that instrument and the net receipt of \$2,075,000 from the private placement of our common stock. Additionally, we purchased property and equipment for \$40,000, treasury stock for \$188,000, and received cash of \$3,000 from the exercise of warrants to purchase our common stock.

The Company s working capital, defined as current assets less current liabilities, as of January 31, 2010 and April 30, 2009, was \$1,256,000 and \$1,166,000, respectively.

# **Commitments and Contractual Obligations**

There have been no material changes in our contractual obligations and other commercial commitments other than in the ordinary course of business since the end of fiscal year 2009. Information regarding our contractual obligations and commercial commitments is provided in our Annual Report on Form 10-K for the year ended April 30, 2009.

#### Ability to Continue As a Going Concern

The Company s ability to continue as a going concern is dependent upon the success of raising additional capital sufficient to meet the operating needs of the Company for at least the 12 month period subsequent to issuance of this quarterly report. In June 2009, the Company s Board of Directors authorized management to begin the process of raising additional capital. There can be no assurance that management will be successful in raising capital on terms acceptable to the Company, if at all. The Company s ability to successfully raise additional capital will depend on the condition of the capital markets and the Company s financial condition and prospects. Even if the Company is able to successfully raise additional capital, such capital could be in the form of debt and could be at high interest rates and/or require the Company to comply with restrictive covenants that limit financial and business activities. In addition, even if the Company is able to successfully raise equity capital, this could dilute the interest of existing shareholders and/or be issued with preferential liquidation, dividend or voting rights to those currently held by the Company s common stockholders.

#### **Off Balance Sheet Arrangements**

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risk, contingent liabilities, or any other obligation under a variable interest in an unconsolidated entity that provides financing and liquidity support or market risk or credit risk support to the Company.

# Item 3. Quantitative and Qualitative Disclosures About Market Risk

None

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#### **Item 4T. Controls and Procedures**

Evaluation of Disclosure Controls and Procedures

It is management s responsibility to establish and maintain disclosure controls and procedures as such term is defined in Rule 13a-15 under the Securities Exchange Act of 1934 (the Exchange Act ). Our management, including our acting principal executive officer and chief financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of a date within ninety (90) days of the filing date of this Form 10-Q quarterly report. Following this review and evaluation, management collectively determined that our disclosure controls and procedures are not effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to management, including our principal executive officer and our chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Controls

There were no changes in our internal control over financial reporting in connection with the evaluation required by Rule 13a-15(d) and 15d -15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

The Company continues to take steps to strengthen our system of internal control and disclosure control procedures in regards to the four material weaknesses as further discussed in our Annual Report on form 10-K for the fiscal year ended April 30, 2009.

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#### PART II OTHER INFORMATION

#### **Item 1. Legal Proceedings.**

From time to time we are involved in litigation incidental to the conduct of our business. While the outcome of lawsuits and other proceedings against us cannot be predicted with certainty, in the opinion of management, individually or in the aggregate, no such lawsuits are expected to have a material effect on our financial position or results of operations.

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

None

Item 3. Defaults Upon Senior Securities.

None

**Item 4. Other Information** 

None

#### Item 5. Exhibits

- Exhibit 31.1+ Certification by the Acting Principal Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- Exhibit 32.1+ Certification by the Acting Principal Executive Officer and the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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