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**Amorfix Life Sciences Ltd.**  
(a development stage company)

Financial Statements  
March 31, 2010 and 2009



10018031

June 9, 2010

**Auditors' Report**

**To the Shareholders of  
Amorfix Life Sciences Ltd.**

We have audited the balance sheets of **Amorfix Life Sciences Ltd. (the Company)** as at March 31, 2010 and 2009 and the statements of operations and comprehensive loss, shareholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with Canadian generally accepted auditing standards. Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation.

In our opinion, these financial statements present fairly, in all material respects, the financial position of the Company as at March 31, 2010 and 2009 and the results of its operations and its cash flows for the years then ended in accordance with Canadian generally accepted accounting principles.

**(Signed) "PricewaterhouseCoopers LLP"**

Chartered Accountants, Licensed Public Accountants

# Amorfix Life Sciences Ltd.

(a development stage company)

## Balance Sheets

As at March 31

	2010 \$	2009 \$
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	238,956	564,568
Marketable securities	4,159,833	4,160,798
Amounts receivable	125,998	52,663
Tax credits receivable (note 7)	431,082	211,082
Prepaid expenses and deposits	135,577	64,963
<b>Total current assets</b>	<b>5,091,446</b>	<b>5,054,074</b>
Property and equipment, net (note 3)	317,278	463,110
	<b>5,408,724</b>	<b>5,517,184</b>
<b>Liabilities</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities (note 8)	646,697	596,009
<b>Total current liabilities</b>	<b>646,697</b>	<b>596,009</b>
<b>Shareholders' Equity</b>		
Common shares	23,189,936	19,467,462
Other equity	3,778,269	3,970,704
Contributed surplus	1,535,398	225,297
Accumulated other comprehensive income	17,348	18,598
Deficit	(23,758,924)	(18,760,886)
	<b>4,762,027</b>	<b>4,921,175</b>
	<b>5,408,724</b>	<b>5,517,184</b>

Going concern (note 1)

Commitments and contingencies (note 10)

On behalf of the Board:

Director

Bob Gundel

Director

Graham Strachan

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

# Amorfix Life Sciences Ltd.

(a development stage company)

## Statements of Operations and Comprehensive Loss

	Year ended March 31, 2010 \$	Year ended March 31, 2009 \$	Period from January 23, 2004 (inception) to March 31, 2010 \$
<b>Revenues</b>			
Revenue	45,516	-	45,516
Interest earned	134,063	244,499	1,146,385
	<u>179,579</u>	<u>244,499</u>	<u>1,191,901</u>
<b>Expenses</b>			
Research and development (note 6)	3,686,663	4,126,945	18,628,584
General and administrative	1,192,527	1,040,468	4,973,489
Amortization of property and equipment	157,427	225,219	564,746
Amortization of technology rights	-	-	56,313
	<u>5,036,617</u>	<u>5,392,632</u>	<u>24,223,132</u>
<b>Loss before the undernoted</b>	<b>(4,857,038)</b>	<b>(5,148,133)</b>	<b>(23,031,231)</b>
<b>Costs related to reverse takeover</b>	<b>-</b>	<b>-</b>	<b>479,693</b>
<b>Loss for the period</b>	<b>(4,857,038)</b>	<b>(5,148,133)</b>	<b>(23,510,924)</b>
<b>Other comprehensive income (loss)</b>			
Unrealized gain (loss) on available-for-sale marketable securities	(1,250)	16,351	
<b>Comprehensive loss for the year</b>	<b>(4,858,288)</b>	<b>(5,131,782)</b>	
<b>Basic and diluted loss per common share</b>	<b>(0.10)</b>	<b>(0.12)</b>	
<b>Weighted average number of common shares outstanding</b>	<b>47,711,070</b>	<b>41,985,488</b>	
<b>Going concern (note 1)</b>			

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

**Amorfix Life Sciences Ltd.**  
(a development stage company)  
**Statement of Shareholders' Equity**

	Common shares (notes 4 and 5)		Other equity (notes 4 and 5)		Contributed surplus	Accumulated other comprehensive income (loss)	Deficit	Total
	Number	Amount \$	Number	Amount \$	Amount \$	Amount \$	Amount \$	Amount \$
<b>Balance – March 31, 2008</b>	41,678,380	19,194,840	8,315,831	2,815,838	187,777	2,247	(13,505,753)	8,694,949
Issuance of common shares for cash	862,801	272,622	-	-	-	-	-	272,622
Expiry of warrants	-	-	(23,810)	(8,662)	8,662	-	-	-
Extension of warrants	-	-	-	107,000	-	-	(107,000)	-
Expiry of stock options	-	-	(86,875)	(28,858)	28,858	-	-	-
Issuance of stock options	-	-	799,750	-	-	-	-	-
Issuance of deferred share units	-	-	346,092	191,360	-	-	-	191,360
Stock-based compensation	-	-	-	894,026	-	-	-	894,026
Other comprehensive income (loss) for the year	-	-	-	-	-	16,351	-	16,351
Loss for the year	-	-	-	-	-	-	(5,148,133)	(5,148,133)
<b>Balance – March 31, 2009</b>	42,541,181	19,467,462	9,350,988	3,970,704	225,297	18,598	(18,760,886)	4,921,175
Issuance of common shares for cash	5,146,300	2,906,371	2,573,150	174,040	-	-	-	3,080,411
Issuance of finder warrants	-	(64,491)	348,400	64,491	-	-	-	-
Exercise of stock options	355,802	416,338	(355,802)	(184,027)	-	-	-	232,311
Exercise of warrants	471,135	464,256	(471,135)	(57,205)	-	-	-	407,051
Extension of warrants	-	-	-	141,000	-	-	(141,000)	-
Expiry of warrants	-	-	(4,462,521)	(1,282,458)	1,282,458	-	-	-
Expiry of stock options	-	-	(64,656)	(27,643)	27,643	-	-	-
Issuance of stock options	-	-	1,076,125	-	-	-	-	-
Issuance of deferred share units	-	-	264,000	110,880	-	-	-	110,880
Stock-based compensation	-	-	-	868,487	-	-	-	868,487
Other comprehensive income (loss) for the year	-	-	-	-	-	(1,250)	-	(1,250)
Loss for the year	-	-	-	-	-	-	(4,857,038)	(4,857,038)
<b>Balance – March 31, 2010</b>	48,514,418	23,189,936	8,258,549	3,778,269	1,535,398	17,348	(23,758,924)	4,762,027

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

# Amorfix Life Sciences Ltd.

(a development stage company)

## Statements of Cash Flows

	Year ended March 31, 2010 \$	Year ended March 31, 2009 \$	Period from January 23, 2004 (inception) to March 31, 2010 \$
<b>Cash provided by (used in)</b>			
<b>Operating activities</b>			
Loss for the period	(4,857,038)	(5,148,133)	(23,510,924)
Amortization of property and equipment	157,427	225,219	564,746
Amortization of technology rights	-	-	56,313
Stock-based compensation	979,367	1,085,386	3,993,291
Other non-cash expenses	-	-	235,115
Changes in non-cash working capital (note 9)	(313,261)	(293,069)	(136,422)
	<u>(4,033,505)</u>	<u>(4,130,597)</u>	<u>(18,797,881)</u>
<b>Investing activities</b>			
Purchase of marketable securities	(5,337,019)	(6,159,771)	(33,170,700)
Maturity or sale of marketable securities	5,336,734	8,482,814	29,028,215
Purchase of property and equipment	(11,595)	(113,276)	(882,024)
Purchase of technology rights	-	-	(56,313)
	<u>(11,880)</u>	<u>2,209,767</u>	<u>(5,080,822)</u>
<b>Financing activities</b>			
Issuance of common shares, net of cash issue costs	-	272,622	4,655,751
Issuance of common share units, net of cash issue costs	3,080,411	-	15,053,480
Issuance of common shares on exercise of agent options and warrants	407,051	-	3,387,971
Issuance of common shares on exercise of options	232,311	-	753,679
Other financing activities	-	-	266,778
	<u>3,719,773</u>	<u>272,622</u>	<u>24,117,659</u>
<b>Net (decrease) increase in cash and cash equivalents during the period</b>	<b>(325,612)</b>	<b>(1,648,208)</b>	<b>238,956</b>
<b>Cash and cash equivalents - Beginning of period</b>	<b>564,568</b>	<b>2,212,776</b>	<b>-</b>
<b>Cash and cash equivalents - End of period</b>	<b>238,956</b>	<b>564,568</b>	<b>238,956</b>
<b>Cash and cash equivalents are comprised of:</b>			
Cash on deposit	238,956	297,068	
Short-term debt instruments	-	267,500	
	<u>238,956</u>	<u>564,568</u>	

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

# **Amorfix Life Sciences Ltd.**

(a development stage company)

Notes to Financial Statements

**March 31, 2010 and 2009**

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## **1 Nature of operations and going concern**

Amorfix Life Sciences Ltd. (the company or Amorfix) is focused on treatments and diagnostics for aggregated misfolded protein diseases. The company is considered to be in the development stage, as most of its efforts have been devoted to research and development and it has not earned any significant revenue to date.

The success of the company is dependent on obtaining the necessary regulatory approvals, bringing its products to market and achieving profitable operations. The continuation of the research and development activities and the commercialization of its products are dependent on the company's ability to successfully complete these activities and to obtain adequate financing through a combination of financing activities and operations. It is not possible to predict either the outcome of future research and development or commercialization programs, or the company's ability to fund these programs going forward.

The accompanying financial statements have been prepared using Canadian generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business as they come due. The company incurred a loss of \$4,857,038 for the year ended March 31, 2010 and has a deficit of \$23,758,924 as at March 31, 2010. These circumstances may cast significant doubt as to the ability of the company to continue as a going concern. While the company projects that its current working capital of \$4,444,749 is sufficient to fund its operations through to the end of Fiscal 2011, its ability to continue as a going concern beyond that point is dependent on its ability to generate revenues from its products or secure additional financing in order to continue its research and development activities either on its own or with partners. The company is pursuing cash flow generation activities including the out-licensing of its ALS therapeutic products and sourcing other non-dilutive funding; however, there can be no assurance that these initiatives will be successful.

These financial statements do not include any adjustments to the amounts and classifications of assets and liabilities, and the reported revenues and expenses, that might be necessary should the company be unable to continue as a going concern, and therefore, be required to realize its assets and discharge its liabilities other than in the normal course of business and at amounts different from those reflected in the accompanying financial statements. Any such adjustments could be material.

## **2 Summary of significant accounting policies**

### **Basis of preparation**

These financial statements have been prepared in accordance with Canadian generally accepted accounting principles and are presented in Canadian dollars. The significant accounting policies are noted below:

### **Use of estimates**

The preparation of financial statements in accordance with Canadian generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The most significant estimates include tax credits receivable, the valuation allowance for future income tax assets, and the fair values used to account

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for equity transactions including stock-based compensation expense, and fair values determined in connection with acquiring and granting options for technology rights. Actual results could differ from those estimates.

## Cash and cash equivalents

Cash and cash equivalents includes cash on deposit, money market funds and short-term debt instruments with maturities of less than 90 days at the time of purchase.

## Marketable securities

Marketable securities consist primarily of high credit quality corporate debt instruments with an initial maturity of 90 days or greater at the time of purchase and have an active resale market to ensure liquidity. Accordingly, all marketable securities are classified as current assets in the accompanying balance sheets.

## Financial assets and financial liabilities

Financial assets and financial liabilities are initially recorded at fair value and their subsequent measurements are determined in accordance with their classification. The classification depends on the purpose for which the financial instruments were acquired or issued and their characteristics. Cash and cash equivalents are classified as held-for-trading assets and are reported at fair value. Interest earned, interest accrued, gains and losses realized on disposal and unrealized gains and losses from market fluctuations are included in interest income or expense. Marketable securities are classified as available-for-sale and are reported at fair value. Any changes in unrealized gains and losses are recorded in accumulated other comprehensive income (AOCI) until recognized in the statement of operations and comprehensive loss, either through sale or impairment. Amounts receivable are classified as loans and receivables, and after initial recognition are accounted for at cost or amortized cost. Accounts payable and accrued liabilities are classified as other liabilities, and after initial recognition are recorded at amortized cost.

## Property and equipment

Property and equipment are stated at cost less accumulated amortization. Amortization is provided on a straight-line basis over the estimated useful lives of the assets, which are estimated as follows:

Laboratory and office equipment	2-5 years
Computer equipment	1-3 years
Leasehold improvements	lease term

## Impairment of long-lived assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying values of the related assets may not be recoverable. An impairment loss would be recognized when estimates of undiscounted future cash flows expected to result from the use of an asset and its eventual disposition are less than the carrying values. As at March 31, 2010, no impairment of long-lived assets was determined.



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## Revenue recognition

Revenue is recognized when persuasive evidence of an arrangement exists, product delivery has occurred, services have been performed, the price is fixed or determinable and collectability is reasonably assured.

## Research and development costs

Research and development costs are charged to operations as incurred, net of government assistance, if any, or related investment tax credits (ITCs), unless they meet the criteria under Canadian generally accepted accounting principles for deferral and amortization, which indicate that technical, market and financial feasibility has been established. No development costs have been deferred to date. Patent costs are expensed as incurred as the benefits to be derived from these costs are uncertain.

Refundable ITCs are recorded when the qualifying expenditures are incurred and there is reasonable assurance that these tax credits will be realized. Government assistance and refundable ITCs included in research and development costs for the year ended March 31, 2010 were \$446,000 (2009 - \$408,000).

## Income taxes

The company accounts for income taxes using the liability method. Future income tax assets and liabilities are determined based on differences between the financial statement carrying values and the respective income tax bases of assets and liabilities, measured using substantively enacted income tax rates and laws that are expected to be in effect when the differences are expected to reverse. A valuation allowance is established against future income tax assets if, based on available information, it is more likely than not that some or all of the future income tax assets will not be realized. The company takes a full valuation allowance on the future income tax assets, as the company is in the development stage and has no commercial operations.

## Stock-based compensation

Grants of stock options to employees, directors and consultants are accounted for using the fair value based method for stock-based compensation. The company uses the Black-Scholes option pricing model to establish the fair value of the stock options. The fair value of stock options awarded to employees is expensed on a straight-line basis over the vesting period and for non-employees is expensed as the services are received. Deferred share unit awards are also recorded as stock-based compensation expense. Stock-based compensation expense is recorded in general and administrative expense and research and development expense.

## Loss per share

Basic loss per share is calculated using the weighted average number of common shares outstanding during the period. Diluted loss per share is determined using the treasury stock method and is based on the weighted average number of common shares and dilutive common share equivalents during the period. All warrants and options were excluded from the calculation of diluted loss per common share as their effect was anti-dilutive.

## Foreign currency translation

Transactions denominated in foreign currencies are translated into Canadian dollars at the average rates of exchange prevailing at the time of the respective transactions. Monetary assets and liabilities are translated into

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Canadian dollars at the period-end exchange rate. Realized and unrealized foreign exchange gains and losses are recognized in general and administrative expense except for unrealized foreign exchange gains on available-for-sale marketable securities which are recorded in other comprehensive income until realized or where losses are other than temporary.

## **New accounting pronouncements:**

Effective April 1, 2009 the company adopted the Canadian Institute of Chartered Accounts (CICA) Handbook Section 3064, *Goodwill and Intangible Assets*, to replace Section 3062, *Goodwill and Other Intangible Assets*, and Section 3450, *Research and Development Costs*. Section 3064 establishes standards for the recognition, measurement and disclosure of goodwill and intangible assets. The changes relating to the definition and initial recognition of intangible assets, including internally generated intangible assets, are equivalent to the corresponding provisions of International Financial Reporting Standards (IFRS). The adoption of this standard did not have an impact on the company's financial statements.

In June 2009, the CICA issued amendments to Handbook Section 3862, *Financial Instruments – Disclosures*, enhancing disclosure requirements about liquidity risk and fair value measurements of financial instruments, effective no later than March 31, 2010. The adoption of these amendments resulted in additional disclosures in Note 11 of the financial statements.

## **Future accounting changes:**

### *International Financial Reporting Standards*

The Accounting Standards Board of Canada has announced that public companies in Canada are to adopt IFRS for fiscal years beginning on or after January 1, 2011. Effective April 1, 2011, the company will report its interim and annual financial statements under IFRS. The company is in the process of assessing the effects of the IFRS standards on its financial statements.

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Notes to Financial Statements

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## 3 Property and equipment

	<b>2010</b>		
	<b>Cost</b>	<b>Accumulated</b>	<b>Net</b>
	<b>\$</b>	<b>amortization</b>	<b>\$</b>
		<b>\$</b>	
Laboratory and office equipment	545,481	342,254	203,227
Computer equipment	114,258	104,138	10,120
Leasehold improvements	187,432	83,501	103,931
	<b>847,171</b>	<b>529,893</b>	<b>317,278</b>

	<b>2009</b>		
	<b>Cost</b>	<b>Accumulated</b>	<b>Net</b>
	<b>\$</b>	<b>amortization</b>	<b>\$</b>
		<b>\$</b>	
Laboratory and office equipment	536,846	245,422	291,424
Computer equipment	114,258	85,476	28,782
Leasehold improvements	187,432	44,528	142,904
	<b>838,536</b>	<b>375,426</b>	<b>463,110</b>

## 4 Share capital

The company has authorized an unlimited number of common shares and preferred shares and has issued 48,514,418 common shares and no preferred shares as at March 31, 2010.

- a) On April 29, 2009, the company completed a non-brokered private placement through the issuance of 5,146,300 units (Units) at a price of \$0.65 per Unit for gross proceeds of \$3,345,095 (\$3,080,411 net of cash issuance costs). Each issued Unit consisted of one common share and one-half of one common share purchase warrant (Warrant). Each whole Warrant is exercisable into one common share of Amorfix at a price of \$1.00 for a period of 24 months, subject to earlier expiry in the event (a trigger event) that the volume-weighted average price of Amorfix's common shares on the TSX for a ten-day period exceeds \$1.20. On the occurrence of a trigger event, Amorfix may give notice to warrant holders to accelerate the expiry to a date which is not less than 30 calendar days after such notice is sent to the warrant holders.

In connection with the private placement, the company issued 348,400 finder warrants having an aggregate fair value of \$68,356 estimated using a barrier option pricing model. Each finder warrant is exercisable into one common share of Amorfix at a price of \$0.68 for a period of 24 months, subject to earlier expiry on the occurrence of a trigger event on the same terms as applies to the Warrants.

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The allocation of the \$0.65 Unit issue price to the common shares and the one-half common share purchase warrants was based on the relative fair values of the common shares and warrants. The fair value of the warrant was determined using a barrier option pricing model. The common shares were allocated a price of \$0.6133 per share and the one-half common share purchase warrants were allocated a price of \$0.0367. The costs of the issue were allocated on a pro rata basis to the common shares and one-half common share purchase warrants. Accordingly, \$2,841,880 was allocated to common shares and \$170,175 to common share purchase warrants, net of issue costs. Assumptions used to determine the value of the common share purchase warrants and the finder warrants were: risk-free interest rate 0.98%; dividend yield 0%; expected volatility 77%; and expected life of 24 months.

- b) In November and December 2008, in two tranches on the achievement of the second and third research milestones under a research and option agreement, Biogen Idec subscribed for 862,801 common shares for gross proceeds to Amorfix of \$277,050 (proceeds net of cash issue costs \$272,622).

## 5 Warrants and options

The company has issued warrants and options for the purchase of common shares.

- a) As at March 31, 2010, the following warrants were outstanding:

	Exercise price \$	Number outstanding	Expiry date
Common share purchase warrants	1.00	2,302,275	April 29, 2011
Common share purchase warrants	0.68	148,140	April 29, 2011
		<u>2,450,415</u>	

On October 19, 2009, the company announced its execution of the trigger event described in Note 4(a) and accelerated expiry of the \$1.00 and \$0.68 purchase warrants from April 29, 2011 to January 19, 2010. On December 4, 2009, the company extended the expiry of the \$1.00 purchase warrants to April 29, 2011 and on February 4, 2010, the company extended the expiry of the \$0.68 purchase warrants to April 29, 2011. The company recorded an increase in other equity in the amount of \$141,000 representing the incremental fair value of the warrants at the dates of extension, with an offsetting charge recorded directly to the company's deficit. These warrants continue to be subject to earlier expiry upon the occurrence of the trigger event.

On March 8, 2009, the company extended the expiry of all of its 4,462,521 outstanding \$1.95 common share purchase warrants by one year to March 8, 2010 and recorded an increase in other equity in the amount of \$107,000 representing the incremental value of the warrants at the date of extension, with an offsetting charge recorded directly to the company's deficit. These warrants expired unexercised March 8, 2010.

- b) Under the company's 2007 Stock Option Plan, options may be granted to directors, officers, employees and consultants of the company to purchase up to 6,000,000 common shares. Stock options granted vest at various rates and have a term not exceeding ten years.

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The following table reflects the activity under the stock option plan for the years ended March 31, 2010 and 2009 and the stock options outstanding:

	2010		2009	
	Number of stock options	Weighted average exercise price \$	Number of stock options	Weighted average exercise price \$
Outstanding – Beginning of year	4,542,375	0.96	3,829,500	1.03
Granted	1,076,125	0.94	799,750	0.65
Exercised	(355,802)	0.65	-	-
Expired	(64,656)	1.09	(86,875)	0.99
Outstanding – End of year	5,198,042	0.98	4,542,375	0.96
Exercisable – End of year	4,258,428	0.99	3,271,335	0.98

The following table reflects the stock options outstanding as at March 31, 2010:

Range of exercise prices \$	Stock options outstanding			Stock options exercisable		
	Number outstanding	Weighted average contractual life (years)	Weighted average exercise price \$	Number exercisable	Weighted average exercise price \$	
0.50 - 0.68	1,598,750	4.56	0.58	1,498,750	0.58	
0.76 – 1.00	2,097,292	7.53	0.94	1,266,011	0.93	
1.14 - 1.18	65,000	4.49	1.16	65,000	1.16	
1.40 - 1.78	1,437,000	1.79	1.46	1,428,667	1.46	
0.50 - 1.78	5,198,042	4.99	0.98	4,258,428	0.99	

- c) During the year ended March 31, 2010, the company issued stock options with a fair value of \$761,181 (2009 - \$408,672) and recorded stock-based compensation expense of \$868,487 (2009 - \$894,026). The weighted average grant-date fair value of the stock options granted during the year ended March 31, 2010 was \$0.71 (2009 - \$0.51). The fair value of the stock options granted was estimated using the Black-Scholes option pricing model with the following assumptions:

	2010	2009
Risk-free interest rate	1.2-3.5%	3.0%
Dividend yield	0%	0%
Expected volatility	78%	73%
Expected life of options (years)	1.5 to 10.0	10.0

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- d) During the year ended March, 31 2009, the company adopted a deferred share unit (DSU) plan for senior officers of the company. Under the DSU plan, rights to the company's common shares (Units) may be awarded to senior officers, on a deferred payment basis, to a maximum of 1,000,000 common shares. Each Unit can be redeemed for one common share of the company by the unit holder only on cessation of employment with the company. During the year ended March 31, 2010, the company issued 264,000 fully vested Units (2009 - 346,092) with an average grant date fair value of \$0.42 (2009- \$0.55) and recorded a stock-based compensation expense of \$110,880 (2009 - \$191,360). The following table reflects the activity under the DSU plan for the years ended March 31, 2010 and 2009 and the units outstanding:

	2010	Weighted average grant date fair value \$
	Number of Units	
Outstanding, April 1, 2008	-	-
Granted	346,092	0.55
Outstanding, March 31, 2009	346,092	-
Granted	264,000	0.42
Outstanding, March 31, 2010	610,092	-

## 6 Research and development

Amorfix is developing a pipeline of diagnostic and therapeutic products for the detection and treatment of aggregated misfolded protein diseases. The diagnostic products include the development of blood screening tests for variant Creutzfeldt-Jakob Disease and Alzheimer's disease. Amorfix's therapeutics products are immunotherapies for the treatment of amyotrophic lateral sclerosis (ALS), Alzheimer's disease and cancer.

Research and development expenditures were as follows:

	Year ended March 31, 2010 \$	Year ended March 31, 2009 \$	Period from January 23, 2004 (inception) to March 31, 2010 \$
Diagnostic programs	2,888,779	3,329,459	15,455,091
Therapeutic programs	797,884	797,486	3,173,493
	<u>3,686,663</u>	<u>4,126,945</u>	<u>18,628,584</u>

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(a development stage company)

Notes to Financial Statements

March 31, 2010 and 2009

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## 7 Income taxes

- a) Income tax recoveries attributable to losses from operations differ from the amounts computed by applying the combined Canadian federal and provincial income tax rate to pre-income tax losses from operations primarily as a result of the provision of a valuation allowance on net future income tax benefits.

Significant components of the future income tax assets are as follows:

	2010	2009
	\$	\$
Future income tax assets		
Non-capital losses carried forward	1,560,000	1,422,000
Research and development expenditures	3,234,000	3,080,000
Investment tax credits	2,292,000	1,758,000
Carrying value of technology rights and property and equipment in excess of accounting basis	233,000	188,000
Ontario harmonization tax credit and other	204,000	188,000
Share issue costs	114,000	173,000
Total future income tax assets	7,637,000	6,809,000
Valuation allowance	(7,637,000)	(6,809,000)
Net future income tax assets	-	-

- b) As at March 31, 2010, the company has available research and development expenditures for income tax purposes of approximately \$12,934,000, which may be carried forward indefinitely to reduce future years' taxable income.
- c) As at March 31, 2010, the company has non-capital income tax loss carry-forwards of approximately \$6,239,000 available to reduce future years' income for income tax purposes. The income tax loss carry-forwards begin to expire in 2015.
- d) As at March 31, 2010, the company has approximately \$2,917,000 of non-refundable investment tax credits available to offset future income taxes.

# Amorfix Life Sciences Ltd.

(a development stage company)

Notes to Financial Statements

March 31, 2010 and 2009

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- e) A reconciliation of the Canadian federal and provincial statutory income tax rate applied to the net loss for the period to the income tax recovery is as follows:

	2010 \$	2009 \$
Statutory income tax rate	32.8%	33.3%
Income tax recovery based on statutory rate	(1,591,000)	(1,713,000)
Permanent differences	323,000	362,000
Net investment tax credits not recognized	(516,000)	(519,000)
Share issue costs recorded, net of equity	(66,000)	(1,000)
Change in future tax rates	950,000	181,000
Other	72,000	39,000
Change in valuation allowance	828,000	1,651,000
Income tax recovery	-	-

## 8 Related party transactions

- a) During fiscal 2008 and 2009, the company entered into three agreements with the University of British Columbia (UBC), with Dr. Neil Cashman, an officer of the company, as principal investigator, to fund research related to the company's research and development programs in the amount of \$749,799. During fiscal 2010, \$519,420 (2009- \$142,619) was paid to UBC and, as at March 31, 2010, \$87,710 (\$2009 - \$71,000) was included in accounts payable and accrued liabilities. The Company has no remaining obligations for these three agreements.
- b) In August 2009, the company entered into an assignment agreement with the University of Toronto and Dr. Neil Cashman to acquire certain technology related to its PromIS<sup>TM</sup> research program. The company paid \$2,000 for the technology and will pay royalties on the commercial sale of any product candidates developed from the technology.
- c) During the year ended March 31, 2010, the company paid a consulting fee to a director of Amorfix in the amount of \$4,500 (2009- \$nil).
- d) A company controlled by a director of Amorfix provides investment advisory services to Amorfix.



# Amorfix Life Sciences Ltd.

(a development stage company)

Notes to Financial Statements

March 31, 2010 and 2009

## 9 Supplementary cash flow information

The components of the change in non-cash working capital are as follows:

	Year ended March 31, 2010 \$	Year ended March 31, 2009 \$	Period from January 23, 2004 (inception) to March 31, 2010 \$
Amounts receivable	(73,335)	145,363	(118,951)
Tax credits receivable	(220,000)	189,000	(431,082)
Prepaid expenses and deposits	(70,614)	71,892	(135,577)
Accounts payable and accrued liabilities	50,688	(699,324)	549,188
	<u>(313,261)</u>	<u>(293,069)</u>	<u>(136,422)</u>

### Supplemental cash flow information

Common share purchase warrants issued as agents' compensation

68,356

-

417,560

No income tax or interest was paid by the company.

## 10 Commitments and contingencies

- a) The company enters into research, development and licence agreements with various parties in the ordinary course of business where the company receives research services and rights to proprietary technologies. The agreements require compensation to be paid by the company, typically, by a combination of the following methods:
- fees comprising amounts due initially on entering into the agreements and additional amounts due either on specified timelines or defined services to be provided;
  - milestone payments that are dependent on products developed under the agreements proceeding toward specified plans of clinical trials and commercial development; and
  - royalty payments calculated as a percentage of net sales, commencing on commercial sale of any product candidates developed from the technologies.

Milestone and royalty-related amounts that may become due under various agreements are dependent on, among other factors, preclinical safety and efficacy, clinical trials, regulatory approvals and, ultimately, the successful development of a new drug, the outcome and timing of which is uncertain. Amounts due per the various agreements for milestone payments will accrue once the occurrence of a milestone is likely. Amounts due as royalty payments will accrue as commercial revenues from the product are earned.

# Amorfix Life Sciences Ltd.

(a development stage company)

Notes to Financial Statements

March 31, 2010 and 2009

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- b) In February 2009, the company entered into an agreement with UBC to further the development of and to commercialize certain technology developed in part by Dr. Cashman. Under the agreement, the company is committed to make milestone payments up to \$1,400,000 per product developed using this technology based on the successful outcomes of predefined clinical and regulatory outcomes, and to make royalty payments to UBC based on revenue earned from the licensed technology. As at March 31, 2010, no payments have been made under this agreement.
- c) Under the terms of a contribution agreement with the National Research Council Canada under the Industrial Research Assistance Program (IRAP), the company received a grant to support research on its Alzheimer's disease diagnostic test. In certain limited circumstances, including where the company exports control of this technology out of Canada through sale or licence, the company may be required to repay up to two times the amount of the IRAP grant received. The company received \$265,912 in funding and has not recorded any liability for this contingent repayment as the terms for repayment have not been met.
- d) The company is committed to the following payments under the terms of its lease agreements for the years ending March 31,

	\$
2011	227,500
2012	229,300
2013	134,500

On termination of the lease for its Mississauga, Ontario premises, the landlord, at its option, may require the company to convert some or all of the leased premises to warehouse space. No liability has been recognized because the fair value of the cost of converting the premises cannot be reasonably estimated due to uncertainty about the likelihood and timing of the landlord exercising its option and the extent of the possible conversion to warehouse space if the option is exercised.

## 11 Financial instruments

### Fair Value

The CICA Handbook Section 3862 *Financial Instruments – Disclosures* requires the disclosure of the fair value of each class of financial instrument in accordance with a hierarchy that reflects the significance of the inputs used in making the measurements. Financial instruments of the company consist of cash and cash equivalents, marketable securities, amounts receivable, and accounts payable and accrued liabilities. As at March 31, 2010, there was no significant difference between the carrying values of these amounts and their estimated fair values due to their short-term nature. The company has classified its cash and cash equivalents and its marketable securities as Level 1 as fair values are determined by quoted prices of identical assets in active markets.

### Risk

The company manages its cash and cash equivalents and marketable securities in accordance with an investment policy that establishes guidelines for investment eligibility, credit quality, liquidity and foreign currency exposure. Marketable securities holdings at March 31, 2010 consist primarily of high credit quality

# Amorfix Life Sciences Ltd.

(a development stage company)

Notes to Financial Statements

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corporate debt instruments with maturities staggered over the next 17 months to provide a steady stream of cash flow for current operations. Marketable securities have an initial maturity of 90 days or greater at the time of purchase and have an active resale market to ensure liquidity. The weighted average yield of the debt instruments held at March 31, 2010 was 2.2%.

a) Credit risk

Financial instruments that potentially subject the company to credit risk consist primarily of cash and cash equivalents and marketable securities. The company manages its exposure to credit loss by placing its cash with major financial institutions and investing in high-quality government and corporate issuers with low credit risk. The company invests in commercial paper with a Dominion Bond Rating Service (DBRS) rating of R-1 Low or higher, or equivalent S Standard & Poor's (S&P) or Moody's Investor Service (Moody's) rating. The company invests in government and corporate bonds with a DBRS rating of A- or higher, or equivalent S&P or Moody's rating. The company does not hold any asset-backed commercial paper. Cash and cash equivalents held by the company are not subject to any external restrictions.

b) Liquidity risk

The company's exposure to liquidity risk is dependent on purchasing obligations and raising of funds to meet commitments and sustain operations. The company is a development stage company and is reliant on external fundraising to support its operations. Once funds have been raised, the company manages its liquidity risk by investing in highly liquid corporate and government bonds with staggered maturities to provide regular cash flow for current operations. It also manages liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors reviews and approves the company's operating and capital budgets, as well as any material transactions not in the ordinary course of business. The majority of the company's accounts payable and accrued liabilities have maturities of less than three months.

c) Market risk

The company is exposed to interest rate risk arising from fluctuations in interest rates on its cash and cash equivalents and marketable securities and to foreign exchange risk on its holdings of US dollar denominated cash and cash equivalents and marketable securities. The company manages its interest rate risk by holding its investments to maturity, where possible. The company manages its exposure to currency fluctuations by holding cash and cash equivalents and marketable securities denominated in US dollars in amounts approximating current US dollar financial liabilities and US dollar planned expenditures. As at March 31, 2010 the company held US dollar cash and cash equivalents and marketable securities in the amount of US\$126,667.

## 12 Management of capital

The company's objectives when managing capital are to ensure there are sufficient funds available to carry out its research, development and commercialization programs. To date, the programs have been funded primarily through the sale of equity securities and the conversion of common share purchase warrants and options, and stock options. The company also sources non-dilutive funding by accessing grants, government assistance and

# Amorfix Life Sciences Ltd.

(a development stage company)

Notes to Financial Statements

March 31, 2010 and 2009

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tax incentives, and through partnerships with corporations and research institutions. The company uses budgets and purchasing controls to ensure effective cost management practices are followed.

The company is not exposed to any externally imposed capital requirements.

## 13 Segmented information

The company operates in Canada within a single operating segment, being the research and development of aggregated misfolded proteins. Substantially all of the company's assets are located in Canada.

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CORPORATE FINANCIALS



## ANNUAL INFORMATION FORM

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Unless otherwise indicated  
all information in this Annual Information Form is  
presented as at and for the year ended March 31, 2010

June 9, 2010

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## CURRENCY AND MEASUREMENT

Unless otherwise indicated, all references to “dollars” or the use of the symbol “\$” are to Canadian dollars, all references to “US dollars” or “US\$” are to United States dollars.

## DOCUMENTS INCORPORATED BY REFERENCE

Information has been incorporated by reference in this Annual Information Form from documents filed with securities commissions or similar authorities in Canada. Copies of the documents incorporated herein by reference are available under the Company’s profile on the System for Electronic Document Analysis and Retrieval (“SEDAR”) which can be accessed at [www.sedar.com](http://www.sedar.com).

The management information circular of the Company dated August 24, 2009 and filed on SEDAR on September 24, 2009 is specifically incorporated by reference in this Annual Information Form.

## FORWARD LOOKING STATEMENTS

This Annual Information Form contains forward-looking statements and information that are based on the beliefs of management and reflect Amorfix’s current expectations. When used in this document, the words “estimate”, “project”, “belief”, “anticipate”, “intend”, “expect”, “plan”, “predict”, “may”, “should”, “will” and the negative of these words or such variations thereon or comparable terminology, are intended to identify forward-looking statements and information. Such statements and information reflect the current views of Amorfix with respect to risks and uncertainties that cause actual results to differ materially from those contemplated in those forward-looking statements and information.

There are a number of important factors that could cause Amorfix’s actual results to differ materially from those indicated or implied by forward-looking statements and information, including but not limited to: early stage development and scientific uncertainty, lack of product revenues and history of losses, additional financing requirements and access to capital, patents and proprietary technology, dependence on collaborative partners, licensors and others, government regulations, hazardous materials and environmental matters, rapid technological change, competition, reliance on key personnel, status of healthcare reimbursement, potential product liability and volatility of share price, absence of dividends and fluctuation of operating results. Such risks are further described under “Risk Factors” in this Annual Information Form. Potential investors and other readers are urged to consider these factors carefully in evaluating these forward-looking statements and information and are cautioned not to place undue reliance on them. Amorfix has no responsibility, nor does it intend, to update these forward-looking statements and information, unless as otherwise required by law.

Amorfix cautions that the foregoing list of material factors is not exhaustive. When relying on Amorfix’s forward-looking statements and information to make decisions, investors and others should carefully consider the foregoing factors and other uncertainties and potential events. Amorfix has assumed a certain progression, which may not be realized. It has also assumed that the material factors referred to in the previous paragraph will not cause such forward-looking statements and information to differ materially from actual results or events. However, the list of these factors is not exhaustive and is subject to change and there can be no assurance that such assumptions will reflect the actual outcome of such items or factors.

### USE OF MARKET AND INDUSTRY DATA

This Annual Information Form includes market and industry data that has been obtained from third party sources, including industry publications, as well as industry data prepared by the Company's management on the basis of its knowledge of and experience in the industry in which the Company operates (including management's estimates and assumptions relating to the industry based on that knowledge). Management's knowledge of the industry has been developed through its experience and lengthy participation in the industry. Management believes that its industry data is accurate and that its estimates and assumptions are reasonable, but there is no assurance as to the accuracy or completeness of this data. Third party sources generally state that the information contained therein has been obtained from sources believed to be reliable, but there is no assurance as to the accuracy or completeness of included information. Although management believes it to be reliable, the Company's management has not independently verified any of the data from third party sources referred to in this Annual Information Form or ascertained the underlying economic assumptions relied upon by such sources.



## **CORPORATE STRUCTURE**

### **Name, Address and Incorporation**

Amorfix was incorporated on January 23, 2004 under the name 4203801 Canada Inc. pursuant to the *Canada Business Corporations Act*. The Company changed its name to Amorfix Life Sciences Ltd. on August 24, 2004.

Amorfix's registered office is at Suite 1500, 1055 West Georgia Street, Vancouver, British Columbia, V6E 4N7, and its head office is at 3403 American Drive, Mississauga, Ontario, L4V 1T4. The Company's telephone number is (416) 847-6898, its fax number is (416) 847-6899 and the address of its web site is [www.amorfix.com](http://www.amorfix.com).

In this document, the "Company," "Amorfix," "we," "us," and "our" refer to Amorfix Life Sciences Ltd.

### **Intercorporate Relationships**

The Company does not have any subsidiaries.

## **GENERAL DEVELOPMENT OF THE BUSINESS**

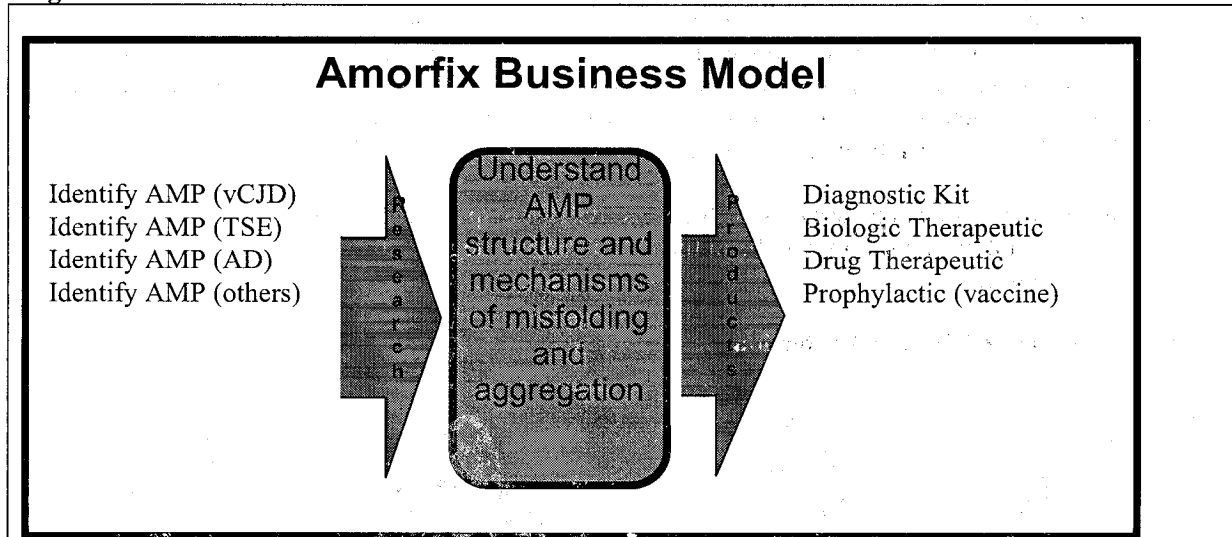
### **Three Year History**

On September 20, 2005 Amorfix amalgamated with Luxor Developments Inc. ("Luxor") under the reverse take-over rules of the TSX Venture Exchange (the "TSX-V") whereby common shares of both companies were exchanged for shares of the amalgamated company. The amalgamated company was continued under the name Amorfix and listed for trading on the TSX-V on October 3, 2005. The Company listed its shares for trading on the Toronto Stock Exchange (TSX) on July 25, 2007.

### ***Principal Products***

The mechanisms of template-induced misfolding of proteins in TSE diseases and the formation of aggregates in all Aggregated Misfolded Protein (AMP) diseases are unknown. The detection and characterization of AMPs is a first step in understanding their creation and evolution and ultimately to finding ways to prevent their formation. Amorfix intends to build on its novel mechanism to detect AMPs to fully understand their formation, structure and function. With this knowledge, Amorfix intends to develop diagnostic kits, biological and therapeutics and finally prophylactics such as vaccines (Figure 1).

Figure 1: Overall Business Model



### *AMP Detection Technology*

Amorfix's technology is based upon the detection of AMPs, which are leaked from the central nervous system of a human or animal into that species' bloodstream. The brain-to-bloodstream route is mediated by the brain's arachnoid villi, which are essentially microscopic one-way valves. AMPs known as "prions" can also enter the bloodstream through infection of the gut and the lymphatic tissue.

There are no definitive diagnostic tests for AMP diseases prior to death. Current diagnostic testing is limited because the species being tested require invasion into the central nervous system by means of the spinal column. Detecting the presence of AMPs in living organisms becomes risky, expensive and medically problematic. Therefore, until now, all such testing has occurred in a post mortem environment through the use of medical autopsies. Post mortem testing, while scientifically and medically interesting, does little for the patient who suffered and ultimately passed away from the presence of such neurodegenerative diseases. The challenge is to discover human or animal predispositions to such neurodegenerative diseases by detecting the presence of AMPs in the organisms when they are alive and the related potential predisposition to such fatal diseases without risky invasion to the host organism.

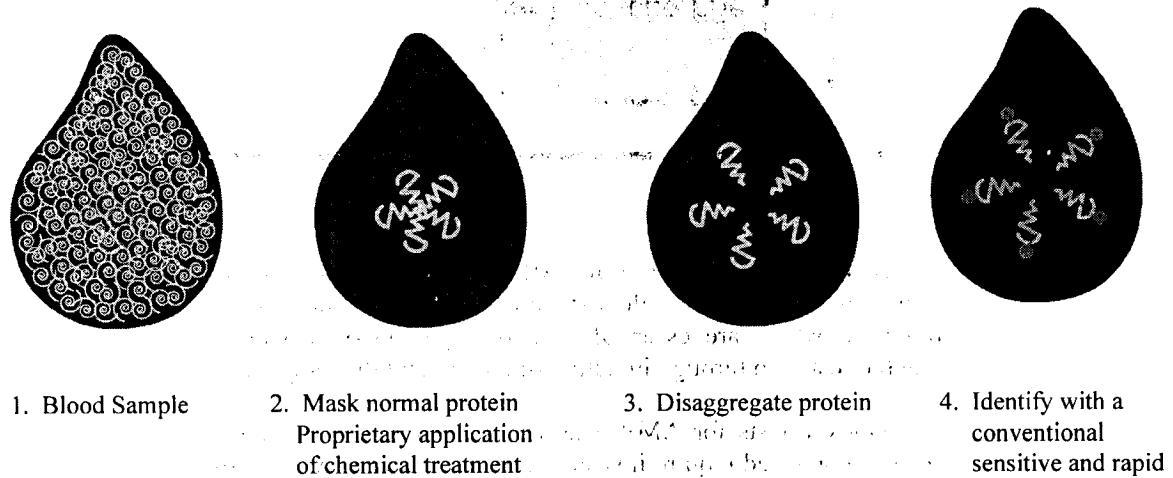
Amorfix has developed as a diagnostic platform to find and confirm the presence of these misfolded protein aggregates in living, functioning and cognitive humans and animals. The Amorfix diagnostic technology called "Epitope Protection" (EP) is designed to detect misfolded protein molecules by discovering their sequestration into misfolded aggregates, thereby protecting them from chemical modification. Until Dr. Neil Cashman's (the Company's Chief Scientific Officer) recent discoveries, seeking and finding these aggregated misfolded proteins in blood where the normal proteins are present was like trying to find the proverbial needle in a hay stack since both conformations of the protein (normal and AMP) are made up of the identical proteins. Amorfix's technology overcomes the limitations associated with current commercial immunological detection tests where direct antibody testing cannot efficiently differentiate between normal and aggregated proteins. Furthermore, their binding ability is affected by blood-based inhibitors making the detection of these misfolded protein aggregates extremely difficult.

The basic principal of EP is that the proteins within AMPs are sequestered or "protected" from chemical modification agents, while non-aggregated proteins are not protected. Thus, when reagents are used to

modify the epitopes on the normal and singular misfolded proteins, the epitopes within the AMPs are unchanged except for the small number exposed at the surface of the aggregate. When the sample is disaggregated following chemical modification, those protected, chemically unmodified epitopes can then be detected by conventional immunoassay procedures against a black background of immunoreactive normal protein. Without the use of Amorfix's EP technology, conventional antibody detection methods do not effectively distinguish between normal and aggregated proteins. See Figure 2.

Amorfix is seeking to develop assays with the sensitivity and specificity to detect AMPs in blood. To date, AMPs have not been confirmed to be in the blood in neurodegenerative and TSE diseases other than vCJD, CWD and scrapie.

**Figure 2: Concept of Epitope Protection**



Amorfix is developing assays for AMPs based upon its EP technology platform. AMPs have not been measured in blood before and so the concentrations in patients are unknown. The detection process is similar to many broadly used immunoassays, with certain modifications by Amorfix scientists to achieve a very high level of sensitivity. Fluorescence and luminescence-based clinical testing methodologies are commonly used worldwide, and the EP technology could be integrated into such existing systems for clinical testing in major research laboratories, large-scale clinical reference laboratories, and hospital laboratories.

**Research and Development**

The stage of development for each product is given in Figure 3. The market entry of the products will depend upon regulatory approval processes which vary from country to country and depend upon the product's use for agricultural or human applications.

**Figure 3: Product Development Pipeline**

Diagnostic Products	Research	Validation Pre-commercial	Commercial/ Regulatory
	A <sup>4</sup> Abeta assay - animal	[Shaded bar spanning Research and Validation]	
A <sup>4</sup> Abeta assay - human	[Shaded bar spanning Research and Validation]		
Liver cancer screening assay*	[Shaded bar spanning Research and Validation]		
EP-vCJD™ blood screening assay	[Shaded bar spanning Research and Validation]		Development on hold
Sheep scrapie	[Shaded bar spanning Research and Validation]		Development on hold

Therapeutic Products	Research	Preclinical	Clinical
	ALS - antibodies	[Shaded bar spanning Research and Preclinical]	
ALS - vaccines	[Shaded bar spanning Research and Preclinical]		
Alzheimer's disease	[Shaded bar spanning Research and Preclinical]		
Cancer	[Shaded bar spanning Research and Preclinical]		

\*This assay is being developed by Amorfix in collaboration with BioMosaics (see below).

***Early Diagnosis and Treatment for Alzheimer's Patients (EP-AD™ Test / A<sup>4</sup> Amyloid Assay)***

Alzheimer's disease (AD), ALS and Parkinson's disease are chronic neurodegenerative illnesses which are associated with neural deposits of AMPs. Unlike the TSE diseases, these diseases are not thought to be infectious and it is believed that their AMPs result from abnormal synthesis or metabolism of the normal neural proteins. Currently, the only definitive diagnostic for these diseases is post-mortem examination of brain tissue. There are currently approximately 5 million people in North America with AD and an equal number with dementia who may be suffering from AD but an accurate diagnosis is impossible due to the lack of a blood test. A sensitive and specific diagnostic blood test could allow earlier treatment for AD patients and would lead to the development of better therapies as patients could be accurately screened into clinical drug trials. It is not known whether aggregated proteins from these diseases are present in blood as there is no test currently that could detect them. Worldwide there are 460 million people over the age of 65 who should be tested annually for AD. There are an estimated 1.6 million people in North America with Parkinson's disease and an estimated 33,000 people with ALS. The Company has the potential to develop diagnostics and therapeutics for each of these neurodegenerative diseases.

Development History

In January 2006, the Ontario Genomics Institute (OGI) committed \$100,000 of funding through the subscription of common shares and warrants to support the initiation of an Alzheimer's disease blood diagnostic research and development program incorporating the EP platform. OGI invested \$50,000 on signing the agreement and invested a further \$50,000 in September 2006 when Amorfix established the

proof of concept of its Epitope Protection technology using Abeta aggregates, the protein known to misfold and aggregate in Alzheimer's disease. This achievement was validated by an expert scientific panel convened by OGI that reviewed the Amorfix data. On the strength of this data and the development plan, Amorfix was awarded an Industrial Research Assistance Program (IRAP) grant from the Government of Canada in December 2006. Amorfix received \$265,912 of support over the two year term of the grant under this IRAP program.

From December 2006 to March 2008, the Company initiated and progressed its AD diagnostic assay development by screening and selecting monoclonal antibodies, establishing a sample preparation protocol to enrich for the Abeta proteins, assessing several different assay formats and optimizing the assay conditions. The Company developed the assay using synthetic Abeta protein and subsequently demonstrated the ability of the assay to detect Abeta aggregates from AD brain spiked into normal plasma.

In June 2008, the AD test achieved its target sensitivity in being able to detect aggregated Abeta protein of 1 in 1,000,000 dilution of a 10% AD brain homogenate in a plasma sample. At this level of sensitivity, the Amorfix test was not able to detect aggregated Abeta in human blood plasma or cerebral spinal fluid samples.

In September 2009, the Company received a second grant from the National Research Council Canada Industrial Research Assistance Program (NRC-IRAP) of \$50,000 to continue development of an assay to measure Alzheimer's-related amyloid in blood. The sensitivity of the assay has increased and the Company will try again to detect amyloid in AD blood. The Company will first test blood from animal models which is readily available. There continues to be a need for a simple screening test for AD to identify patients, conduct clinical trials of new treatments, and to monitor disease progression.

The Company assessed other potential commercial applications for this very sensitive aggregated Abeta protein assay and identified a commercial market to assay the brain tissue of human transgenic AD mice to assist in the assessment of drug efficacy in these models. The Company's A<sup>4</sup> assay can detect Abeta amyloid in human and animal brain tissue and has been shown to detect amyloid build up in animals much earlier than conventional methods. The Company believes that the A<sup>4</sup> test will accelerate the development and evaluation of new treatments for AD.

On July 25, 2009, the Company presented validation results for the A<sup>4</sup> assay at the International Congress on AD. In October 2009, the Company promoted its A<sup>4</sup> assay service at the Society for Neuroscience meeting in Chicago, Illinois. The Company is seeking collaborations and offering the A<sup>4</sup> test as a service to drug discovery companies and academic researchers working to discover new treatments for AD.

In December 2009, the Company announced that it is conducting pilot studies with several pharmaceutical companies engaged in developing new treatments for AD and one company has publicly announced their results verifying their novel drug's ability to reduce amyloid formation in animal models of AD. The Company has recorded its first sales for this service and expects additional customers to order the test as the pilot studies are completed and the test is integrated into their standard testing protocols. The Company estimates the market for this service to be 50,000 tests per year.

In May 2010, the Company announced the A<sup>4</sup> assay could detect AD-associated aggregated Beta-amyloid in the blood from a mouse model of AD. This achievement represents the first time that aggregated ABeta has been measured in blood plasma from any animal model. The A<sup>4</sup> assay detects both oligomeric and fibrillar aggregates of ABeta, which are generally considered to be the toxic forms and major contributors to brain dysfunction in AD. The quantitative measurement of aggregated ABeta in plasma was obtained using the A<sup>4</sup> on samples from Tg2576 transgenic mice as early as 3 months of age. The Tg2576 mouse is the most commonly used transgenic model for preclinical evaluation of potential AD therapeutics. The aggregated peptide was detected in the blood from transgenic mice, but not in blood

from non-transgenic age-matched control mice. This breakthrough will now allow scientists to monitor levels of aggregated Abeta in the blood of individual AD mice as they age and to detect the impact of treatments with novel AD medications. The Company has also added the detection of aggregated Abeta in plasma to its A<sup>4</sup> service offering.

The Company is continuing to develop an AD blood screening test for humans for early diagnosis and monitoring of disease progression.

#### ***Early Diagnosis for Liver Cancer Patients***

The Company believes that its expertise in the development of highly sensitive and specific diagnostic tests can be applied to the benefit of other potential biomarkers. In early fiscal 2010, the Company announced a collaboration with BioMosaics Inc, a privately-held cancer biomarker development company, to develop and commercialize a blood-based assay for the early detection of hepatocellular carcinoma (HCC) or primary liver cancer. The Company is developing an assay incorporating the existing technology for the blood test licensed to BioMosaics, plus new material from the Sunnybrook Research Institute needed to improve the test. The Company will receive royalties on commercial product sales, and an option to manufacture the assay kits and reagents for global distribution. BioMosaics is responsible for product commercialization. This project is funded by an "Intellectual Property Development and Commercialization Program" investment of \$280,000 from the Ontario Institute for Cancer Research to the Sunnybrook Research Institute. To March 31, 2010, the Company has received funding of \$127,308 out of the \$200,000 it is eligible to receive.

HCC is the fifth most common cancer in the world, with approximately 600,000 new cases every year. It is the third most common cause of cancer-related death. Early detection could significantly improve treatment outcomes.

In December 2009, the Company announced that it has completed the development of a prototype test and will now start testing clinical samples to determine sensitivity and specificity. A key issue is the ability to differentiate between cirrhosis, hepatitis and HCC.

#### ***Protecting the Blood Supply (EP-vCJD™ Blood Screening Assay)***

To date a few hundred people have been diagnosed with vCJD due to consumption of BSE-infected meat, but it is estimated that up to 23,000 people are incubating the disease in the UK alone. Four people have been infected through blood transfusions and thousands of people have received blood fractions made from vCJD-infected plasma pools. There is a general concern in the medical community that vCJD is now within the blood transfusion systems and a screening assay for blood is required to protect everyone from a secondary epidemic.

Globally, approximately 100 million units of blood are collected annually and tested for infectious agents, such as HIV-1 and hepatitis viruses at a cost of US\$4 billion. The market for a blood test for vCJD is estimated to be at least \$500 million per year based on the existing prices for blood tests for other infectious agents.

The Company believes that with its Epitope Protection (EP) platform technology it has developed the most sensitive and specific assay to detect AMPs in blood. Conventional scientific methods to date have been unable to adequately address a fundamental problem in the detection of AMPs in blood which is the presence of the normal protein at a million-fold higher relative concentration to the misfolded protein. The Company's EP platform technology specifically addresses this issue by chemically modifying the normal proteins while protecting the misfolded aggregates.

#### **Development History**

In late 2005, the United Kingdom National vCJD Surveillance Unit and National Institute for Biological Standards and Control (NIBSC) released a series of steps that a blood test for vCJD must pass in order to be accepted. Amorfix entered into this process and from January to June 2006, increased the sensitivity of its vCJD assay using human blood samples spiked with vCJD brain prions. Amorfix and its competitors developed their assays by detecting vCJD brain prions spiked into normal human plasma rather than directly using plasma samples from people who were afflicted by the disease due to the scarcity and unavailability of these patient plasma samples. The culmination of the NIBSC process was to allow developers to gain access to some of these scarce patient plasma samples to validate their tests using clinical samples. In June 2006, Amorfix received a blinded panel from NIBSC of plasma samples containing spiked brain and spleen prions from vCJD patients, and normal controls from blood donors. Amorfix's results on the blinded panel matched internal results and demonstrated leading sensitivity over all companies or academic laboratories that had published results. This significant technical milestone provided independent validation of the Company's research program and provided rationale that an assay for detecting human vCJD prions could be developed.

From July 2006 to June 2007, Amorfix made significant progress in advancing the vCJD prion detection assay towards commercialization. The Company converted the research-based vCJD assay to a commercial 96-well high-throughput platform producing a more sensitive, specific and reproducible assay. A commercial team was hired with in vitro diagnostic device experience, critical vendors were selected and final equipment configurations were established. The Company also established a quality management system and received ISO 13485:2003 certification for its EP-vCJD™ Blood Screening Assay. During this period, the Company made advances in the NIBSC process and applied to access the vCJD patient blood samples. The Company believes that the NIBSC process was subsequently discontinued until it was determined that there would be sufficient human vCJD blood samples available to clinically validate all manufacturers' assays.

In February 2007, the UK National Health Protection Agency (HPA) issued a tender for the supply of 60,000 Research-Use-Only (RUO) tests for blood screening for vCJD prions as part of the UK's effort to understand the prevalence of vCJD in the UK blood donor population. Amorfix applied and qualified to be a potential supplier of products to the UK government. By June 1, 2007 Amorfix had produced sufficient RUO kits to test 60,000 UK blood samples. Amorfix believes that many of its competitors were unable to rapidly meet the requirements of the tender to produce 60,000 tests by June 2007 and subsequently ceased working on development of their vCJD blood screening assays. Ultimately, the UK HPA did not proceed with this tender.

In February 2008, Amorfix reported the results of a second blinded panel of normal human blood samples spiked with human vCJD brain and spleen prions at different dilutions, and normal human controls provided by NIBSC. Amorfix demonstrated a 10-fold improved sensitivity and improved reproducibility with its commercial high-throughput assay on this 2008 blinded panel compared to its research grade assay blinded panel results from a year earlier.

In July 2007, the Company began adapting its human vCJD blood screening assay into a blood screening test for sheep scrapie to support the clinical validation of the human vCJD assay. In October 2007, the Company announced the completion of an independent blinded panel of sheep blood where the Amorfix sheep scrapie assay (EP-TSE™) was able to detect prion disease in symptomatic sheep. In April 2008, the sheep scrapie blood screening assay was successful at detecting prion disease in presymptomatic scrapie sheep.

In February 2008, the Oversight Committee of NIBSC established a new process to verify the performance of an acceptable blood test for vCJD. Amorfix received and accepted an invitation to further qualify our EP-vCJD™ Blood Screening Assay using British blood samples. NIBSC set out three steps: the first would involve the completion of a blinded panel that contains blood plasma from symptomatic diseased and normal sheep; the second step will be a large panel of normal human blood samples to

assess the assay's specificity; and the third step will be a blinded panel that contains among other samples, blood from people who had contracted vCJD. In the first quarter of fiscal 2009, the Company completed a sheep scrapie blinded panel and submitted the results to NIBSC for assessment.

In the second quarter of fiscal 2009, the Company received and accepted an invitation from the British government to further qualify the specificity of its EP-vCJD™ Blood Screening Assay using UK blood donor samples to be supplied by the National Blood Service. The Company completed a blinded study of 1,000 normal and spiked fresh human plasma samples at the Prion Laboratory of NIBSC. On October 8, 2008, the Company announced the results of the study demonstrating 100% sensitivity for all spiked samples. The specificity for all samples was 99.3% on initial testing and 100% on repeat reactive testing.

NIBSC asked the Company to continue testing samples to verify the results and to determine if frozen samples can similarly be used, as all vCJD patient samples are frozen. In the third quarter of fiscal 2009, the Company completed the testing of 500 frozen blinded human plasma samples provided by NIBSC which included some samples spiked with vCJD brain prions. The EP-vCJD™ test successfully detected all (100% sensitivity) of the spiked samples down to a 1 in 100,000 dilution of 10% brain homogenate (1/1,000,000 dilution of vCJD brain).

In April 2009, the Company announced that it was advised that it is required to test additional prion-infected animal samples, supplied by NIBSC, prior to being granted access to the human vCJD blood samples.

In December 2008, the UK Spongiform Encephalopathy Advisory Committee (SEAC) announced the first clinical case of vCJD in a patient with an MV genotype (all previous vCJD clinical cases were MM genotype) and suggested that 50 to 250 further cases might arise in the UK. This was consistent with an editorial in a leading medical journal, *Lancet Neurology*, suggesting "waves" of vCJD cases could be expected. This first MV case of vCJD now shows people with MV genotypes are not resistant to vCJD, but may incubate the disease for a longer time before developing neurological symptoms.

In January 2009, the Company announced that it has initiated large-scale testing of French blood donors to demonstrate the feasibility of routine testing of blood donations for vCJD. The first 20,000 blood samples were completed by June 30, 2009 and were collected using standard procedures from routine blood donors, and anonymously tested for vCJD by staff at the EFS-Alsace Blood Transfusion Centre in Strasbourg, France. Six blood samples were repeat positive, consistent with a specificity of 99.94%, assuming the six samples were in fact negative and falsely scored positive. This specificity for the 1st-generation Amorfix test is equivalent to the specificity achieved by the current 3rd-generation blood screening tests for HIV antibodies currently in use worldwide in blood transfusion centres to assure the safety of blood. The European Union's In Vitro Diagnostics Technical Group has recommended testing a minimum of 5,000 samples to verify specificity of at least 99.5% for a vCJD blood test. The complete Strasbourg study was presented in July 2009 at le Congrès 2009 de la Société Française de Transfusion Sanguine.

On March 18, 2009, the UK National Health Service published a framework tender under which, when awarded, the NHS may request the supply of blood test kits for a 10,000 sample assessment panel, a 50,000 sample prevalence study, and unlimited kits for routine testing. On July 17, 2009 the contract award was published on the European Tenders Electronic Daily website indicating that Amorfix and one competitor were successful.

On October 29, 2009 the Company announced it has achieved 100% specificity (no reproducible false positive results) upon testing 19,000 blood donations for variant Creutzfeldt-Jakob Disease ("vCJD") with the EP-vCJD™ Blood Screening Assay at l'Établissement Français du Sang de Pyrénées Méditerranée ("EFS-PM") in Montpellier, France. The study in Montpellier included testing of fresh blood within 24 hours of collection and processing of the plasma with an automated sample handling system. This is the



same process that would be used in routine blood testing. These results should give governments confidence that very few blood donors will be falsely identified as potentially having vCJD during routine blood screening. Using the settings for maximum sensitivity of 1:1,000,000 dilution of vCJD brain, as verified by testing at the NIBSC in the UK, the test in EFS-PM was 100% specific. Including these 19,000 blood samples collected and tested at EFS-PM, a total of 39,000 blood donations have now been tested at two blood transfusion centers in France. 99.90% specificity was previously reported for 20,000 samples tested at EFS-Alsace in Strasbourg. In both blood transfusion centers using two lots of kits, the EP-vCJD™ test performed better than the 99.85% specificity required by the UK Blood Transfusion Service.

On October 27, 2009, the Company announced the detection of prions in blood from non-human primates that were orally-infected with BSE and developed a primate version of vCJD. These results are promising although from a small number of tested samples due to the limited number of these very rare primate samples that Amorfix could access. The Company made minor modifications to its EP-vCJD™ blood screening assay in order to test the primate samples.

In December 2009, the Company announced that NIBSC provided three plasma samples from three different vCJD patients which the Company tested using the first generation of the EP-vCJD™ test. The UK experts estimated based on the concentration of prions in animal blood and brain that the concentration of prions in human blood would be 1:100,000th of that in brain. Since the Amorfix test measures 1:1,000,000th, the Company was confident that the test would be able to identify human vCJD plasma samples from a blinded panel. The samples tested negative and the UK authorities have now concluded that the first generation test is not sufficiently sensitive to detect infected human blood samples.

In December 2009, the Company announced that it was attempting to obtain additional vCJD samples from other countries, and also from individuals with the disease.

During the third and fourth quarter of fiscal 2010, The Company continued development activities to improve the sensitivity of its EP-vCJD™ blood screening test. In May 2010, the Company announced that it was successful in developing versions 2 and 3 of the test, which differ in the sample preparation steps, and both are four times more sensitive than the first version which underwent testing with vCJD patient blood in December 2009. The Company obtained a rare blood sample from a person in the clinical phase of vCJD and used the new versions of the EP-vCJD tests to test this sample and it was scored negative by both versions of the test. Although the Company was successful in developing a 2<sup>nd</sup> and 3<sup>rd</sup> generation of the test with significantly increased sensitivity these subsequent improvements to the test did not yield positive results in plasma from one human vCJD sample or animal models of the disease, and the Company has reached an impasse until scientific understanding improves or more vCJD patient blood is available. Accordingly, the Company has suspended the commercialization of the vCJD allowing a more focussed effort on its other research programs. Future research may prompt reevaluation of this assessment.

### ***Protecting the Food Supply (TSE Tests)***

The first case of BSE in cattle emerged in the United Kingdom 17 years ago and there has been a concern about the food supply ever since. The disease has spread to 21 countries and may have crossed over to other species such as sheep and goats. Post-mortem testing of brain tissue has been the only way to accurately detect any of the TSE diseases. The Company believes its Epitope Protection (EP) technology can be used to develop assays for the ante-mortem testing of animals with TSE diseases and remove them from the food chain. The Company has applied its EP technology and developed an assay to detect sheep scrapie. During 2008, Amorfix adapted its vCJD blood screening assay to detect endogenous prions in symptomatic sheep and in the first quarter of fiscal 2009 detected endogenous prions in presymptomatic sheep. Current ante-mortem testing methods for sheep scrapie are not commercializable at scale and may

not be accurate enough for broad application where a simple blood test could be adopted quickly and easily.

Scrapie-infected lambs as early as 17 months of age were detected by the Amorfix EP-TSE™ test. Sheep normally show symptoms of scrapie at 3 to 5 years of age. Detection of infected sheep 2 to 3 years prior to symptoms would allow effective removal of infected animals before they have the ability to infect other sheep in the flock. There are over 2,450 sheep ranchers in the United States who have joined the voluntary Scrapie Flock Certification Program which began in 1992 after attempts to eradicate scrapie starting in 1952 were unsuccessful. To date, approximately 500 flocks have been certified as it requires 5 years of continuous monitoring and verification of absence of disease. Similar eradication programs are ongoing in Europe with significant subsidies by the European Commission to eradicate scrapie through genetic testing and culling of susceptible sheep. Current European post-mortem testing of scrapie is labour-intensive as it requires extensive brain tissue preparation. A simple blood test could be used for surveillance as well as eradication and would lead to the identification of animals earlier.

The Company's analysis of the market opportunity for a scrapie test suggests scrapie must be recognized as a public health issue before it would be widely used to eliminate scrapie-infected sheep. Accordingly, the Company has focused its resources on projects with greater market potential at this time and will consider further development with a partner or at a time that scrapie becomes a human health concern.

#### ***Treatment for ALS Patients***

ALS belongs to a family of fatal neurodegenerative diseases, which includes Alzheimer's and Parkinson's diseases, and in which AMPs are thought to be a major pathway in the progressive killing of brain cells. In ALS, also known as "Lou Gehrig's disease," muscles throughout the body weaken and atrophy, due to degeneration of motor nerve cells that supply them from the spinal cord and brain. Symptoms can start with limb weakness or muscle twitching, stiffness and muscle cramps from ages 40 to 70 years. ALS is a fatal disease in which half of affected people die within three years after diagnosis. The protein that is believed to misfold and aggregate in the central nervous system of ALS patients is called superoxide dismutase-1 (SOD1).

Amorfix's technology targets misfolded SOD1 through two approaches: a passive infusion of manufactured monoclonal antibodies and an active immunization approach designed to elicit the production of similar antibodies by the patient's own body. Amorfix's technology is based on the premise that the misfolding and aggregation of SOD1 is a principal agent in the death of neurons that occurs in brain-wasting diseases. Amorfix believes that if misfolded SOD1 can be specifically recognized and its toxic activity neutralized by antibodies, brain-wasting diseases could be effectively treated.

#### **Development History**

In February and April 2006 in a series of agreements, the Company acquired certain SOD1 technologies and exclusively licensed additional SOD1 technologies owned by Dr. Neil Cashman, the Company's Chief Scientific Officer, and his co-inventors for diagnostic and therapeutic applications for ALS disease. A research plan was established to enable proof-of-concept studies to validate the Company's therapeutic approach to the treatment of ALS and potential development partners were contacted.

In August 2006, the Company signed a research and investment agreement with Biogen Idec MA (Biogen) which included an option for Biogen to license the exclusive worldwide rights to certain Amorfix technology to develop and commercialize therapeutic products directed against ALS. Over the following 28 months, Biogen contributed US\$750,000 (Cdn\$860,207) in funding support for the ALS program through subscriptions for 1,243,433 common shares of the Company in an initial investment and

three additional investment transactions made on the achievement of predefined research milestones by Amorfix.

In July 2007, the Company achieved the first research milestone, the development of disease-specific antibodies to misfolded SOD1. In October 2008, the Company achieved the second research milestone; the DSE monoclonal antibody treatments demonstrated statistically significant improvement in survival over controls in a mouse model of ALS. In December 2008, the Company announced the achievement of the third research milestone with the completion of the final study report. In February 2009, Biogen allowed its option to license the SOD1 technologies for use in the treatment of ALS to lapse. The Company is seeking to partner with a biopharmaceutical company to humanize the antibodies and initiate clinical trials. As vaccines have different development timelines and require special expertise compared to the antibodies, Amorfix is seeking other partners to develop the vaccines.

In November 2007, Amorfix announced the discovery of misfolded SOD1 protein in the brains of people with Alzheimer's Disease (AD). This breakthrough result suggests that SOD1 is a common link between the two brain-wasting diseases, Alzheimer's and ALS. SOD1 has a "Jekyll-and-Hyde" nature as it normally plays an important protective role in detoxifying free radicals in the body, but when misfolded can create lethal oxidative free radicals.

In July 2008, the Company announced a research collaboration to develop Alzheimer's treatments based upon the discovery of misfolded SOD1 protein in the brains of people with Alzheimer's disease. The research program includes preclinical efficacy studies for both antibody treatments and vaccines and is being conducted in Dr. Cashman's laboratory at the Brain Research Center at the University of British Columbia in collaboration with Amorfix scientists, and is supported by a \$227,500 grant from the Canadian Institutes for Health Research (CIHR). The Company has completed its funding of its \$540,000 cash and in-kind contribution commitment to the program. The Company expects results from the first animal series in this study this summer.

Amorfix's technology related to the role of SOD1 in ALS and Alzheimer's is covered by patent applications including one recently published entitled, "Methods and Compositions to treat and Detect Misfolded-SOD1 Mediated Diseases". The patent applications relate to the methods and two compositions for treating and detecting conditions, disease, and disorders mediated by non-native SOD1. In December 2008, Amorfix received its first issued patent from the U.S. Patent and Trademark Office titled "ALS-Specific Peptide Composition". This patent covers one of the key disease specific epitopes in the SOD1 "Jekyll and Hyde" protein which Amorfix has shown is exposed when it misfolds and becomes toxic for nerve cells. Amorfix DSE<sup>TM</sup> antibodies bind to this region and we believe neutralize the toxic effects of SOD1 giving the longevity extension Amorfix has previously reported in animal models of ALS.

#### **New Misfolded Protein Diagnostics and Therapeutics**

The Company has expanded its research program to identify novel disease-specific epitopes on misfolded proteins. The Company licensed the exclusive rights to the ProMIS<sup>TM</sup> target identification technology from the University of British Columbia, to predict novel disease specific epitopes on the molecular surface of misfolded proteins. ProMIS<sup>TM</sup> is an "in silico" rational selection approach that can be applied to any protein where the normal folding structure is at least partially known and predicts how the protein will misfold. There are 57,000 such protein structures currently available in public databases. ProMIS<sup>TM</sup> has already been used to identify potential DSE's on three known target proteins likely to be misfolded in cancer and the development of novel immunotherapeutics and companion diagnostics for these diseases has begun.

It is well established that protein misfolding is a central pathological event in many fatal neurodegenerative diseases including Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis. Recently, intriguing evidence for a role of misfolded proteins in cancer has been identified. Studies in our laboratories and others have confirmed this role and there is a growing body of published literature on this topic providing further support for our scientific rationale. The focus on misfolded proteins represents an entirely new approach to the identification of cancer targets and may allow for the development of very selective therapeutics offering greater efficacy and less toxicity.

Cancer cells are stressed by uncontrolled growth, rapid cell division and oxidative damage which can induce protein misfolding, unfolding and partial loss of native protein structure. In some cases, the ability of cancer cells to effectively evade the immune system and continue to grow and spread throughout the body may depend on aberrant signaling by incorrectly folded proteins. It appears that misfolded proteins are tolerated more in cancer cells compared to normal cells where they are either refolded into their proper configuration or discarded. Indirect evidence for the importance of protein misfolding in cancer is derived from the demonstration of increased sensitivity of cancer cells to proteasome inhibitors suggesting the production of a larger quantity of unfolded or misfolded protein compared to normal cells. The selective targeting of cancer cells based on expression of misfolded proteins represents an entirely new avenue for therapeutic intervention.

The primary issues associated with the failure of new therapeutics in the clinic fall into three general categories:

1. The target selected for therapeutic intervention is not causal to the pathogenesis of the disease.
2. The drug being tested fails to either effectively neutralize the disease target; and
3. The drug has off target side effects that make it toxic and prevent its use at therapeutic levels.

Amorfix's strategy to identify novel DSE's on well validated targets using the ProMIS™ technology may solve these problems and provides the Company with the opportunity to produce highly selective and potent proprietary therapeutics with greater efficacy and safety while greatly reducing the risk of failure.

Recent studies with a monoclonal antibody to an undisclosed DSE site on one of the selected proteins confirmed that the misfolded protein is present on cancer cells but not on normal cells. The antibody targets a specific DSE region of the misfolded protein that is not present on the normally folded protein. This new finding indicates that the antibody has potential to be developed for both diagnostic uses and therapeutic treatments for several cancers. The Company is in the process of producing antibodies to these targets for further validation and development.

Amorfix plans to target proteins which may be misfolded in diseases where cells are under stress and more likely to produce misfolded proteins like cancer. Once a protein has been identified, antibodies and vaccines can be developed and assessed for therapeutic and diagnostic use. The Company is establishing strategic alliances to expand its capabilities to develop immunotherapeutics to numerous proteins and is also exploring partnerships with other companies to accelerate the development and expand its program to other proteins of interest.

In May 2010, Amorfix entered into an agreement with Epitomics, Inc. to develop high-affinity monoclonal antibodies against a number of DSE targets for cancer predicted by Amorfix's proprietary ProMIS™ computational platform discovery technology. Epitomics, together with its partners, has successfully generated over a dozen humanized therapeutic antibody drug leads targeting immune diseases and cancers using RabMAb® technology and its proprietary Mutation Lineage Guided humanization technology.

In May 2010, Amorfix also entered into an agreement with Aragen BioScience, Inc. to develop high affinity monoclonal antibodies against a number of targets for cancer predicted by ProMIS™. Amorfix has identified several DSEs on misfolded Fas receptor which is a well characterized target on cells that, when activated, causes programmed cell death, or apoptosis. Previous attempts by others to use Fas receptor as a therapeutic target for the development of new anti-cancer therapeutics have failed because its expression and function leads to undesirable side effects on normal cells. Using our ProMIS™ technology, we believe we have identified DSEs on Fas receptor that will provide the required specificity for our mAbs to target and kill tumor cells while leaving normal cells intact.

### **Significant Acquisitions**

Amorfix made no significant acquisitions during fiscal year 2010 and 2009 for which disclosure is required under Part 8 of National Instrument 51-102.

## **DESCRIPTION OF BUSINESS**

### **Business of the Company**

Amorfix Life Sciences Ltd. is a theranostics company developing therapeutic products and diagnostic devices targeting misfolded protein diseases including ALS, cancers, and Alzheimer's Disease (AD). Amorfix utilizes its computational discovery platform, ProMIS™, to predict novel Disease Specific Epitopes ("DSE") on the molecular surface of misfolded proteins. Amorfix's lead programs include therapeutics and companion diagnostics for cancers and antibodies and vaccines to DSEs in ALS and AD. Amorfix's proprietary technology enables it to specifically identify very low levels of misfolded proteins in a normal sample. The Company's diagnostic programs include an ultrasensitive method for the detection of aggregated Beta-Amyloid in brain tissue and blood of animal models of AD, months prior to observable amyloid formation, and a blood screening test for liver cancer.

Amorfix has developed a key expertise in the field of protein misfolding with its ability to identify regions on proteins that are unique in a diseased state and not in a normal healthy state. These unique regions are called Disease Specific Epitopes™ (DSE) and are selected by Amorfix due to their potential to provide for highly specific diagnostic assessments as well as targets for potential therapeutic drug development.

Amorfix is developing diagnostic products with the goal of detecting the presence of AMPs in tissue, blood or other biofluids. Earlier detection of people with neurodegenerative diseases or cancer has the potential to significantly change the prognosis for these patients and allow for earlier application of emerging therapies. Detection of vCJD prions would improve the safety of blood transfusions and thereby avert the unintended human transmission of prion-contaminated blood. Detection of prions in animals would enable the protection of the food supply.

Amorfix technologies are also being used to develop antibody and vaccine therapies that target Disease Specific Epitopes (DSE) on disease-relevant proteins as an innovative approach to treat these currently incurable disorders.

### **Operations**

All Amorfix products will be required to be manufactured under applicable regulatory guidelines including ISO quality management system or GMP guidelines. Amorfix intends to outsource the physical manufacturing of its products to a manufacturer with the infrastructure and reputation to ensure highest

quality manufacturing at an economical cost. This will allow Amorfix to focus on continued innovation and development to strengthen the product pipeline. Amorfix qualifies all suppliers under its quality management system to ensure they meet the established criteria for supply.

Since a percentage of the future Amorfix product revenues are expected to be derived from sales outside the U.S., international regulatory bodies often establish varying regulations governing product standards, packaging and labelling requirements, import restrictions, tariff regulations, duties and tax requirements. As a result of sales potential in Europe, for example, Amorfix will need to contract with a manufacturer which has obtained ISO certification and a "CE" mark certification, an international symbol of quality and compliance with applicable European medical directives.

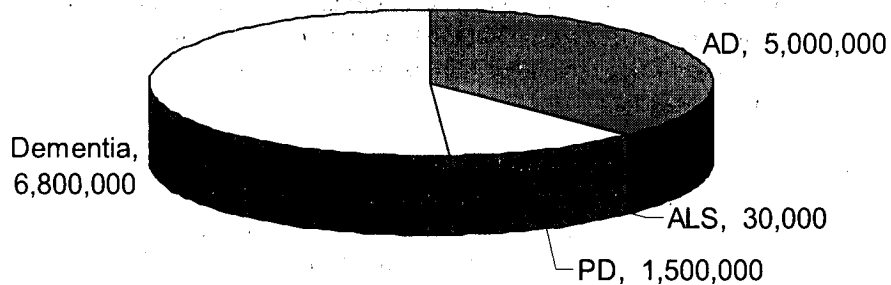
### **Market**

Amorfix's products seek to diagnose, to detect and then ultimately treat AMPs in diseases such as AD, ALS, cancer, and PD. Amorfix technology can also target TSE diseases such as vCJD, Scrapie, BSE and Chronic Wasting Disease.

### **AMP Neurodegenerative Diseases**

Three significant human AMP diseases are Alzheimer's Disease (AD), Parkinson's Disease (PD) and Amyotrophic Lateral Sclerosis (ALS). Estimates of the world market for these diseases are given in Table 1. Age is a risk factor for all these diseases. Between 1994 and 2020, America's 85 and older population is projected to double to seven million and grow to between 19 and 27 million by 2050, making these seniors the fastest growing segment of the population.<sup>1</sup> One in 10 persons over 65 and nearly half of those over 85 have Alzheimer's Disease,<sup>2</sup> the most common form of dementia, accounting for over 60% of cases.<sup>3</sup> It is estimated that as many as 6.8 million Americans have dementia, all of whom would benefit from a correct diagnostic test (Figure 4)<sup>4</sup>.

**Figure 4: Distribution of Neurodegenerative Diseases (North America Prevalence)**



The growing number of aged and particularly those suffering from dementia will increase demand for long-term care and particularly dementia care. This may be compounded by social factors including the increased number of females in the workforce and necessarily the decreased availability of family home

<sup>1</sup> U.S. Bureau Census. Current Population Reports, Special Studies, P23-190. April 1996.

<sup>2</sup> Alzheimer's Association – Statistics Available.

<sup>3</sup> Canadian Study of Health and Aging Working Group (1994) Canadian Study of Health and Aging: Study methods and prevalence of dementia. Canadian Medical Association Journal, 150: 899-913.

<sup>4</sup> *Losing a Million Minds: Confronting the Tragedy of Alzheimer's Disease and Other Dementias*. U.S. Congress Office of Technology Assessment; U.S. Government Printing Office, 1987.

care. In addition, the proportion of older people requiring support from adults of working age is expected to increase from 12% to 17% in 2025 putting increased pressure on both financial and human resources.<sup>5</sup>

**Table 1: Diagnostic Markets (If a screening test was available)**

Application	Test Subject	Canada +USA	World Prevalence	Current World Market	World Market in 5 years	Comments
Alzheimer's Disease	People over 65 years old	40 million	460 million	US\$1-10 billion	US\$10B	Assumes test price similar to PSA test
Parkinson's Disease	People over 65 years old	1.6 million	16 million	US\$900 million	US\$1.5B	Assumes test price similar to PSA test
Amyotrophic Lateral Sclerosis	People with some symptoms of ALS	70,000	0.7 million	US\$30 million	US\$0.05B	Assumes test would also be used for monitoring therapy

Amorfix is focused on diagnostic tests for these AMP diseases and has begun development of novel therapeutic approaches based on its understanding of the structure of misfolded proteins.

### ***Alzheimer's Disease***

Alzheimer's disease (AD) is a progressive, neurodegenerative disease characterized in the brain by abnormal aggregates (amyloid plaques) and tangled bundles of fibres (neurofibrillary tangles) composed of misplaced proteins. One of the more common forms of dementia, specific symptoms of AD include memory loss, language deterioration, impaired ability to mentally manipulate visual information, poor judgment, confusion, restlessness, and mood swings. Eventually AD destroys cognition, personality, and the ability to function. The early symptoms of AD, which include forgetfulness and loss of concentration, are often missed because they resemble natural signs of aging. There are no blood or laboratory tests available to accurately diagnose AD.

AD is one of the most obvious and near-term human healthcare applications for the Amorfix technology. AD is a common form of dementia and is characterized by loss of mental function in elderly people.<sup>6</sup> Global statistics show that while 1 out of 10 people over the age of 60 suffer from this disease, only 1 in 3 of those afflicted by AD are currently undergoing any form of treatment.<sup>7</sup> There are currently 5 million AD patients in the North America and 2001 sales of AD treatment drugs were estimated at roughly US\$1.2 billion.<sup>8</sup> Datamonitor expects the global AD treatment market to achieve sales of US\$3.4 billion by 2008, resulting in a compound annual growth rate of approximately 16%.<sup>9</sup> Worldwide there are 460 million people over the age of 65 who should be tested annually for AD. The worldwide market for such a screening test would be more than US\$1B annually.

<sup>5</sup> The World Health Report; The World Health Organization; 1998.

<sup>6</sup> *US Neurodegenerative Disease Treatment Market*, March, 2003.

<sup>7</sup> *Healthcare Review: CNS*. Datamonitor. September, 2002.

<sup>8</sup> *Alzheimer's Treatment Alternative Set to Expand Lucrative Market*. Datamonitor. May 9, 2002.

<sup>9</sup> *Alzheimer's Treatment Alternative Set to Expand Lucrative Market*. Datamonitor. May 9, 2002.

Diagnosis is perhaps one of the key issues from a therapeutic standpoint since the disease begins slowly. Therefore, the time from initial symptoms to diagnosis may span several years and even then neurologists and geriatricians can only diagnose AD correctly around eighty to ninety percent of the time using costly time-consuming or technology-driven assessment measures such as neuropsychological tests coupled with computerized tomography ("CT"), magnetic resonance imaging ("MRI") and positron emission tomography ("PET"). The Company believes the first application for an AD diagnostic test may be to assist drug developers in screening patients for entrance into AD clinical trials.

To the knowledge of Amorfix, there is not a simple, reliable or accepted diagnostic assay for Alzheimer's disease. The current diagnosis of Alzheimer's disease is based on psychometric testing in conjunction with MRI testing or functional brain imaging (i.e. PET scans). This is akin to a pregnancy test that relied upon visual assessment of belly size by a physician. Amorfix's goal is to develop a test based on a marker or set of markers that predicts disease in individuals that are pre-symptomatic. Thus, the Amorfix assay is expected to be marketed as predicative rather than confirmatory. This distinction is critical since the symptomatic patient is unlikely to be cured as neuronal damage is irreversible.

The first generation Amorfix AD test achieved its target sensitivity in F2009 in being able to detect aggregated Abeta protein of 1 in 1,000,000 dilution of a 10% AD brain homogenate in a plasma sample. At this level of sensitivity, the Amorfix test was not able to detect aggregated Abeta in human blood plasma or cerebral spinal fluid samples. The Company assessed other potential commercial applications for this very sensitive aggregated Abeta protein assay and identified a market to assay the brain tissue of human transgenic AD mice to assist in the assessment of drug efficacy in these models. The Company's A<sup>4</sup> assay can detect Abeta amyloid in human and animal brain tissue and has been shown to detect amyloid build up in animals months earlier than conventional methods. The Company launched the A<sup>4</sup> test service in F2010 and has generated its first revenues. The Company believes that the A<sup>4</sup> test will accelerate the development and evaluation of new treatments for AD.

The Company estimates the market for this test to be 50,000 mice used annually in Alzheimer disease preclinical studies. The current standard for analyzing mouse brains for the presence of Abeta plaques is immunohistochemistry (IHC) which is market priced between \$200 - \$600. The Company also sells its assay in this price range as it complements the existing IHC test, provides quantitative measurement data and can be used to detect aggregated Abeta significantly earlier providing significant advantage in shortening the time course of preclinical studies.

In May 2010, the Company determined the A<sup>4</sup> assay could detect AD-associated aggregated Beta-amyloid in the blood from a mouse model of AD. This achievement represented the first time that aggregated ABeta was measured in plasma from any animal model. The A<sup>4</sup> assay detects both oligomeric and fibrillar aggregates of ABeta, which are generally considered to be the toxic forms and major contributors to brain dysfunction in AD. The quantitative measurement of aggregated ABeta in plasma was obtained using the A<sup>4</sup> on samples from Tg2576 transgenic mice as early as 3 months of age. The Tg2576 mouse is the most commonly used transgenic model for preclinical evaluation of potential AD therapeutics. The aggregated peptide was detected in the blood from transgenic mice, but not in blood from non-transgenic age-matched control mice. This breakthrough will now allow scientists to monitor levels of aggregated Abeta in the blood of individual AD mice as they age and to detect the impact of treatments with novel AD medications. The Company has also added the detection of aggregated Abeta in plasma to its A<sup>4</sup> service offering.

The sensitivity of the A<sup>4</sup> assay has significantly increased through further development since the first generation AD test was completed in F2009. Based on the success of detecting aggregated Abeta in plasma of transgenic AD animal models, the Company is continuing to validate the assay in progressively larger animal models and is developing an AD blood screening test for humans for early diagnosis and monitoring of disease progression based on this improved assay.



### ***Amyotrophic Lateral Sclerosis***

ALS is a fatal, neuromuscular disease which affects 1 in 1,000 adults over a lifetime. There are 30,000 people in North America suffering with ALS with approximately 5,000 new cases per year. A differential process is currently used to diagnosis ALS, which presents its symptoms through progressive weakness, muscle atrophy and spasticity. These neurodegenerative and neuromuscular disease presentations arise due to the ultimate degeneration of neurons in the spinal cord, the brain stem and in the brain cortex. Incurable and usually fatal within five years, ALS gradually robs a patient of the ability to walk, talk and breathe. There is no confirmatory test for ALS and many people go undiagnosed at early phases of the disease. Global statistics indicate that this disease progresses slowly, similar to AD. ALS occurs throughout the world with no racial, ethnic or socioeconomic boundaries.

The biological mechanisms that cause ALS are only partially understood. The only known cause of ALS is a mutation of a specific gene, the superoxide dismutase-1 (SOD1) gene. This mutation is believed to make a defective protein that misfolds and aggregates in the nervous system.

Approximately two thirds of those afflicted by ALS are currently undergoing a form of treatment. In 2002, the sales of Rilutek, the principal ALS treatment drug sold by Aventis, were estimated at roughly US\$35 million in North America. Given the lack of effective treatments available, the therapeutic market has been estimated to be greater than US\$300 million per year for an effective treatment.

### ***TSE - Human Market***

There is a general concern that vCJD is now within the blood transfusion systems and a screening assay to detect prions in human blood is urgently required to protect everyone from a secondary (after oral infection by consuming BSE-positive beef) vCJD epidemic. The global market for blood products is large and growing as more countries establish blood transfusion services<sup>10</sup>. Approximately 81 million units of blood are collected annually and tested for infectious agents, such as HIV-1 and hepatitis viruses at a cost of US\$4B per year worldwide. Of the estimated 81 million units of blood donated annually worldwide<sup>11</sup>, less than 40 per cent are collected in the developing world where 82 per cent of the planet's population lives. As these blood transfusions services expand, so will the blood screenings market.

Demand for blood products continues to increase as the supply of blood is constrained by increasingly restrictive donor selection and other blood safety policies. Blood safety concerns caused by transfusion-transmitted diseases such as AIDS and Hepatitis C have made a "zero-defect" international blood supply the goal of regulators around the world, including the US Food and Drug Administration ("FDA"). Amorfix believes these dynamics create significant demand for products that make blood safer on an international basis.

Blood safety remains a significant concern as new pathogens are discovered and the demand for blood products continues to increase. To reduce the risk of contamination of the blood supply with pathogens, blood banks currently screen donors using detailed questionnaires and screen the donated blood for five known pathogens. Although these safety measures have increased the safety of blood products overall, the risk of transmitting pathogens remains.

Blood banks collect, separate and process whole blood from donors at either mobile or fixed collection sites. After collection, whole blood is usually separated into three components, which are then distributed

<sup>10</sup> [http://www.who.int/bloodsafety/global\\_database/en/SumRep\\_English.pdf](http://www.who.int/bloodsafety/global_database/en/SumRep_English.pdf)

<sup>11</sup> <http://www.ifrc.org/docs/news/04/04040601/>

to hospitals for storage and transfusion: red blood cells, plasma and platelets. Maintaining adequate supplies of safe blood products is an increasing challenge for blood centers around the world.

Most blood centers rely on volunteer donors to donate blood for transfusion, but less than five percent of healthy Americans eligible to donate blood do so each year. More rigorous screening and stricter donor exclusion criteria have reduced the number of previously eligible donors. The FDA guidelines currently exclude potential donors who have spent a total of three months or more in the United Kingdom between 1980 and 1996, or a cumulative five years in other countries in Europe. The FDA estimates that approximately five percent of currently eligible donors are excluded due to these rules.

In 2002, the FDA and the Center for Disease Control ("CDC") reported on 13 cases of suspected transmission of West Nile Virus via blood transfusion. The West Nile Virus is an example of the vulnerability of the world's blood supply to emerging pathogens. However, medical science has attempted to develop approaches to combat serious contamination to the world's blood supply. Unfortunately, each of the current approaches is limited in its scope, effectiveness, or practicality as noted below:

- Donor Exclusions. Although donor screening has been used for decades, it remains limited because it relies heavily on the honesty and the cooperation of the donor. In addition, it is only designed to exclude donors who are more likely to be at risk for diseases known to be transmissible through blood.
- Screening Donated Blood. The principal limitation on current screening procedures is the limited scope – in the U.S, Europe and Japan, blood is only screened for six pathogens – HIV, HBV, HCV, HTLV and syphilis. Therefore, current screening methods are not used to detect other known pathogens. In addition, they cannot detect unknown or emerging pathogens, which have historically presented a threat to the blood supply.
- Donation Strategies. Autologous donation is impractical for most patients and impossible when a transfusion is required due to trauma. Quarantining depends on the donor's timely return for additional testing, cannot be applied to red blood cells or platelets because of their limited shelf life and remains subject to limitations associated with blood screening.
- Leukocyte Reduction and Gamma Irradiation. Leukocyte reduction is effective at removing white blood cells, but does little to reduce the existence of other pathogens in blood products other than cytomegalavirus.
- Blood Substitutes or Temporary Oxygen Carriers. Blood substitutes are being developed to simulate specific therapeutic characteristics of blood and are not intended to replace whole blood components, such as red blood cells, for most conditions. The few substitutes available today remain effective for only approximately 24 to 48 hours in the blood, making the substitutes inadequate for treatment of indications requiring chronic transfusion.
- Pathogen Inactivation. There is currently no pathogen inactivation process available for red blood cells. Additionally, existing pathogen inactivation approaches are only applicable to plasma and are limited in the scope of pathogens they can inactivate.
- Blood filtration: Prometic Pharma in partnership with MacoPharma have developed a prion capture filter that claims to remove 90% of endogenous prions from leucodepleted red cell concentrates based on a hamster bioassay model. This product is currently being tested in a clinical setting. As this product can only be used for red blood cells and not plasma, and has a

limited removal capacity, its potential market utility is uncertain. The Company also believes that there are at least two other blood filters in development that claim to remove prions from red cell concentrates.

Data from 2002 indicates it costs US\$40-\$50 to test each blood donation<sup>12</sup>. Chiron, Inc. had 80% of the market share in North America and had US\$500 million/yr in sales for HIV, HBV and HCV testing only in 2004<sup>13</sup>. Assuming a reasonable price of US\$10 per test for the vCJD assay, the world market for a blood screening test would be US\$810 million with an addressable market in North America, EC and Asia-Pacific of approximately US\$500 million per year (Table 2).

**Table 2: Blood Screening Market (If a screening test was available)**

Application	Test Subject	Canada and USA	World Prevalence	Current World Market	World Market in 5 years	Comments
Screen blood for vCJD	Blood donations	15 million	81 million	US\$810 million	US\$1B	Assumes vCJD prevalence continues

Adoption of a blood screening test for vCJD would be done on a national basis and it would be expected to be introduced rapidly due to ethical and litigation concerns. The blood transfusion services have had the experience in the mid 1980s with HIV testing where countries that failed to implement the test spent hundreds of dollars per donation in subsequent legal and settlement costs.

The Company has reached an impasse on the development of its EP-vCJD™ Blood Screening Assay until scientific understanding improves or more vCJD patient blood is available. Accordingly, the Company has suspended the commercialization of this program. Future research may prompt reevaluation of this assessment.

**TSE - Animal Markets**

In 1997, Stanley Prusiner, a University of California at San Francisco neurologist and researcher, who coined the term "prions", was awarded the Nobel Prize in Medicine for delineating the basic principle of prion infections.

BSE is one of several different forms of Transmissible Spongiform Encephalopathies (TSE) affecting a number of animal species. Scrapie is a common disease in sheep and goats, while Chronic Wasting Disease (CWD) affects deer and elk. Public awareness of prion diseases is rising as an outbreak of Chronic Wasting Disease (CWD) devastates herds of deer and elk in the Western U.S. and Canada. CWD clearly threatens to undermine economies supported by hunting revenues, but in addition, there is concern that the CWD prion infecting these wild herds might be capable of infecting cattle, deer farms or even humans. Extensive research remains to be done to understand CWD and its threat to health and consumer safety. Creutzfeld-Jakob disease (CJD) is the prototype human TSE, affecting approximately one person in every one million worldwide each year. Typically, it occurs in patients over the age of 60, and 90% die within one year. There are three major categories of CJD: approximately 5-10% of CJD occurs in a form associated with a hereditary predisposition; less than 5% of CJD results from the accidental transmission of the causative agent via contaminated surgical equipment or transplant material; a sporadic form accounts for 85-90% of cases.

<sup>12</sup> [http://www.priondata.org/data/A\\_mktblood.html](http://www.priondata.org/data/A_mktblood.html)

<sup>13</sup> <http://www.chiron.com/investors/shareholder/index.html>

### ***Sheep Scrapie***

Scrapie is a fatal, progressive neurological disorder of sheep thought to be caused by an infectious protein or prion. Once infected the disease is always fatal. Scrapie has a very long incubation period. Infected animals rarely show clinical signs of scrapie before 2 years of age, with the average age being 4 years.<sup>14</sup> Sheep producers with high infectivity in their flock face steep production losses as the number of infected animals increases over a number of years while the average age of onset of Scrapie symptoms decreases.<sup>15</sup>

A US Department of Agriculture (USDA) study in 2002-2003 determined the scrapie prevalence to be 0.2% of the sheep population in the US. There are over 2,450 sheep ranchers in the United States who have joined the voluntary Scrapie Flock Certification Program which began in 1992 after attempts to eradicate scrapie starting in 1952 were unsuccessful. Under this program sheep producers can over a five year period certify their flocks as scrapie free and increase the economic value of their flock from maintaining a scrapie-free status. To date, approximately 500 flocks have been certified. Similar eradication programs are ongoing in Europe with significant subsidies by the European Commission to eradicate scrapie through genetic testing and culling of susceptible sheep. Current European post-mortem testing of scrapie is labour-intensive as it requires extensive brain tissue preparation. A simple blood test could be used for surveillance as well as eradication and would lead to the identification of animals earlier.

Scrapie disease in sheep has been known for at least the last 200 years. Health authorities have traditionally been less concerned about Scrapie relative to BSE since there have been no recorded instances of transmission of the disease to humans. However, new strains of scrapie (atypical, BSE) have surfaced leading some in the scientific community to have concern that certain strains of scrapie may eventually be shown to have human health implications similar to BSE in cattle. Results from recently published scientific studies have shown that atypical scrapie is not zoonotic, or infectious to humans. The Company's analysis of the market opportunity for a scrapie test suggests scrapie must be recognized as a human health issue before it would be widely used to eliminate scrapie-infected sheep. Accordingly, the Company has focused its resources on projects with greater market potential at this time and will consider further development with a partner or at a time that scrapie becomes a public health concern.

### ***Bovine Spongiform Encephalopathy***

Mad Cow Disease or Bovine Spongiform Encephalopathy ("BSE") is a transmissible, slowly progressive, degenerative, fatal disease affecting the central nervous system of cattle. The disease was first diagnosed in 1986 in Great Britain.<sup>16</sup> The evidence suggests that BSE is spread through animal feed containing BSE-contaminated meat and bone meal as a protein source. There is no evidence that BSE spreads through contact between unrelated adult cattle or contact between cattle to other species.<sup>17</sup> BSE is the bovine-specific form of a family of diseases known as transmissible spongiform encephalopathies (TSEs). The BSE agent causes no detectable immune or inflammatory response in the host and has yet to be recognized microscopically. There is no test to detect the disease in live animals.<sup>18</sup>

Amorfix has demonstrated the proof of concept of using its Epitope Protection technology for the development of an ante-mortem blood test for BSE. Further development of this BSE test by Amorfix will be made in conjunction with a commercial partner.

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<sup>14</sup> Scrapie Prevention and Awareness on U.S. Sheep Operations (January 2004). USDA Web site.

<sup>15</sup> Scrapie Program. USDA Web site.

<sup>16</sup> Bovine Spongiform Encephalopathy (February 2002). USDA Web site.

<sup>17</sup> Bovine Spongiform Encephalopathy (BSE). USDA Web site.

<sup>18</sup> USDA News Release No. 0432.03. USDA Makes Preliminary Diagnosis of BSE. USDA Web site.

### ***Chronic Wasting Disease***

The presence of Chronic Wasting Disease ("CWD") is most pronounced in North America, particularly in the inter-mountain west. CWD exists most notably in deer and elk. This is a small market with no central point of testing and will not be addressed by the Company unless the EP-BSE™ test or EP-TSE™ test is also able to detect CWD, or support is received from a partner to develop the test.

### ***Marketing Plans and Milestones***

Because the Amorfix technology has many applications including human and animal for both diagnostic and therapeutic uses, its development, marketing and commercial launch schedule must be planned in relation to its available resources. Amorfix intends to out-license the marketing and sales of its product applications to major international healthcare firms for commercial exploitation. Accordingly, the business objectives which Amorfix expects to accomplish over the next 24-month period, provided resources are available, are as follows:

### ***Research and Development***

1. Continue validation of the A<sup>4</sup> assay on larger AD animal models and develop a human Alzheimer's test using CSF and/or plasma;
2. Generate high-affinity antibodies to DSEs on at least three new misfolded protein targets for both diagnostic and therapeutic applications in cancer and achieve proof of concept in animal models;
3. In collaboration with PREVENT advance the ALS vaccine program through preclinical development and initiate a Phase I clinical trial;
4. Complete proof-of-concept preclinical studies for Alzheimer's Disease targeting misfolded SOD1 using passive and active immunization targeting the misfolded SOD1 protein;
5. Complete development of a screening test for liver cancer in collaboration with BioMosaics;

### ***Marketing and Sales***

6. Continue marketing the A<sup>4</sup> assay through service contracts to increase revenues and establish collaborations to expand the utility and further validate the benefits of the A<sup>4</sup> assay;
7. Engage a partner for the ALS DSE antibody program;
8. Engage partners in the therapeutic development of novel DSE targets on misfolded proteins;

### ***Manufacturing***

9. Maintain and further develop manufacturing relationships with suppliers of antibodies for our diagnostic and therapeutic programs; and

### ***General and Administrative***

10. Perform all general and administrative functions necessary to accomplish the foregoing milestones.

### ***Regulatory Approval and Certification***

All commercial applications of the Amorfix technology will be subject to substantial regulation and certification in the jurisdictions in which Amorfix or its strategic partners intend to sell these diagnostic and therapeutic products. Since the markets for the Amorfix diagnostic and therapeutic applications are both animal and human, different regulatory requirements exist.

The initial markets for Amorfix's product candidates are located in the United States and because the Canadian healthcare (diagnostic and therapeutic) market place is regulated in a similar manner as in the United States, Amorfix intends to conform its regulatory and certification scheme to the more rigorous standards imposed by the U.S. Food and Drug Administration (FDA). Many countries through the world provide reciprocal approval based upon the receipt by an innovator of an FDA approval.

### ***Human Diagnostic Products***

#### **United States**

In the United States, medical diagnostic products are classified by the FDA into one of three classes (Class I, II or III) on the basis of controls deemed necessary by the FDA to ensure their safety and effectiveness in a reasonable manner. Class I diagnostics are subject to general controls (e.g., labelling, pre-market notification and adherence to QSR requirements). Class II diagnostics are subject to general and special controls (e.g., performance standards, post-market surveillance, patient registries and FDA guidelines). Generally, Class III diagnostics are those that must receive pre-market approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable devices or new devices that have been found not to be "substantially equivalent" to existing marketed devices). Most of Amorfix's product applications under development are expected to be classified as Class I or Class II (diagnostic) devices.

Before a new device can be introduced in the market, Amorfix must obtain FDA clearance or approval through either clearance of a 510(k) pre-market notification to the FDA or approval by the FDA of a product marketing approval ("PMA") application, which is a more extensive and costly application. Amorfix expects that its future diagnostic products may qualify for clearance using a 510(k) application but some of its product applications, due to their uniqueness, may require PMA approval from the FDA.

Diagnostic devices related to blood collection and processing procedures (our EP-vCJD™ test) and cellular products are regulated by the Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH) divisions of the FDA. CBER reviews new products, by evaluating scientific and clinical data submitted by manufacturers to determine whether the product meets its standards for approval. After a thorough assessment of the data, CBER makes a decision based on the risk-benefit for the intended population and the product's intended use. Since vCJD is a suspected transfusion transmitted disease, the Company expects the EP-vCJD™ test will be classified as a Class III device in the US.

There can be no assurance that Amorfix will be able to obtain the necessary regulatory approvals or clearances for its products from the FDA on a timely basis, if at all. Delays in receipt of or failure to receive such approvals or clearances, the loss of previously received approvals or clearances, limitations on intended use imposed as a condition of such approvals or clearances, or failure to comply with existing or future regulatory requirements, could also have a material adverse effect on the business, financial condition and results of operations of Amorfix. PMA approvals can require up to 18 months or longer from the FDA. Similar regulatory procedures are in place in countries outside the United States.

Customers using Amorfix's diagnostic tests for clinical purposes in the United States would also be regulated under the Clinical Laboratory Information Act of 1988 ("CLIA"). CLIA is intended to ensure the quality and reliability of all medical testing in laboratories in the United States by requiring that any health care facility in which testing is performed meets specified standards in the areas of personnel qualification, administration, participation in the proficiency testing, patient test management, quality control, quality assurance and inspections.

**Human Therapeutic Products**

The Amorfix human therapeutic product applications will also be subject to rigorous preclinical and clinical testing and other approval procedures by the FDA and similar regulatory agencies in other countries. The regulatory process for human therapeutic products is more rigorous than for human diagnostic products.

First, pre-clinical testing of human therapeutics is conducted on animals in the laboratory to evaluate the potential efficacy and the safety of a potential pharmaceutical product. The results of these studies are submitted to the FDA as part of an Investigational New Drug ("IND") application, which must be approved by the FDA before clinical testing in humans can begin in the U.S. Typically, the clinical evaluation process involves three phases. In Phase I, clinical trials are conducted with a small number of healthy human subjects to determine the early safety profile, the pattern of therapeutic drug distribution and metabolism. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease to determine preliminary evidence of efficacy, the optimal dosages, and more extensive evidence of safety. In Phase III, large scale, statistically-driven multi-center, comparative clinical trials are conducted with patients afflicted with a target disease in order to provide enough data to demonstrate the efficacy and safety required by the FDA.

Pre-clinical and clinical results are submitted to the FDA in the form of a New Drug Application ("NDA") for approval before the product can commence commercial sales. In responding to an NDA, the FDA may grant marketing approval, request additional information, or deny the application if the FDA determines that the application does not satisfy its regulatory approval criteria. Amorfix cannot provide assurance that approvals from the FDA for any of its therapeutic product candidates will be granted on a timely basis, if at all. Similar regulatory procedures are in place in countries outside the United States.

**Animal Diagnostic Products**

Most diagnostic tests for animal health applications are veterinary biological products that are regulated in the U.S. by the Center for Veterinary Biologics within the United States Department of Agriculture (USDA), specifically, the USDA Animal and Plant Health Inspection Service ("APHIS"). This regulatory approval process involves the submission of product performance data and manufacturing documentation. Following regulatory approval to market a product, APHIS requires that each lot of product be submitted for review before the release to customers. In addition, APHIS requires special approval to market products where test results are used in part for government-mandated disease management programs. A number of foreign governments accept APHIS approval as part of their separate regulatory approvals.

In the EU, the European Food Safety Authority (EFSA) is responsible for making a preliminary scientific evaluation of ante-mortem TSE tests for ruminant animals and has established an annual call for expression of interest for companies to submit tests for evaluation and potential approval to be used within the framework of EU wide TSE monitoring. Annex X to Regulation (EC) No 999/2001 sets out the rules for tests that prevent, control and eradicate certain transmissible spongiform encephalopathies which may be used within the framework of the EU monitoring programs. Evaluation of tests is based on protocols developed by experts and includes an assessment of the application dossier, a laboratory trial

and a field trial. Given the current stage of scientific knowledge about preclinical TSE disease, EFSA has not yet established binding performance requirements for ante-mortem tests.<sup>19</sup>

### ***Environmental Regulation***

Amorfix may also be subject to foreign and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. There can be no assurance that Amorfix will not incur significant costs to comply with laws and regulations in the future or that such laws or regulations will not have a material adverse effect upon Amorfix's business, financial condition and results of operations.

### ***Pricing and Reimbursement***

The payment for Amorfix's human diagnostic and therapeutic products by the end user or consumer is largely based on third party payer reimbursement. For diagnostic products, it is anticipated that every laboratory that performs a test will submit an invoice to the patient's insurance provider (or the patient if not covered by a program). Each diagnostic procedure (and in some instances, a specific technology) is assigned a current procedural terminology ("CPT") code by the American Medical Association. Each CPT code is then assigned a reimbursement level by CMS. Third party insurance payers typically establish a specific fee to be paid for each code submitted. Third party payer reimbursement policies are generally determined with reference to the reimbursement for CPT codes for Medicare patients, which themselves are determined on a national basis by CMS.

Similarly, therapeutic products are largely paid for based on third party payer reimbursement, similar to diagnostic products. However, concurrent with approval for commercialization of such therapeutic products by the FDA, each therapeutic product is assigned a product code. Each product code is then assigned a reimbursement level by CMS. Third party insurance payers typically establish a specific fee to be paid for each code submitted. Third party payer reimbursement policies are generally determined with reference to the reimbursement for CPT codes for Medicare patients which themselves are determined on a national basis by CMS.

In parallel with this regulatory reimbursement scheme in the United States, other countries also regulate reimbursement similar to the U.S. Therefore, it is important that Amorfix establish for its human diagnostic and therapeutic products reimbursement schemes which provide ultimate financial payment for Amorfix's products consistent with its business plan.

### ***Commercial Marketing Plans and Strategies***

Amorfix markets its A<sup>4</sup> diagnostic services directly to customers and plans to also market and potentially offer these services through contract research organizations that currently provide services to common customers. Amorfix does not intend to market diagnostic or therapeutic products it develops that require extensive distribution channels. Instead, Amorfix intends to license to, or enter into strategic alliances with, larger pharmaceutical and animal veterinary companies that are equipped to manufacture and/or market Amorfix's products through their well developed distribution networks. Amorfix may license some or all of its patent rights to more than one company to achieve the fullest development, marketing and distribution of its products. To this end, Amorfix intends to continue to develop and improve its proprietary technologies and to expand the applications of its technologies in the healthcare markets. Amorfix is pursuing this objective with the strategies below.

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<sup>19</sup> *The EFSA Journal* (2007) 540, 1-12



### ***Generate Product Revenues***

Amorfix has begun to generate revenues by performing A<sup>4</sup> services which are expected to increase over time as results are published by collaborators and customers, and as greater market penetration occurs. Further product revenues, if any, will principally derive from sales of its aggregated misfolded proteins ("AMP") detecting technology through partnerships with larger human and animal life science corporations. Revenues, if any, from its therapeutic pipelines are expected to be generated from research funding, license fees, milestone payments, co-development funding, and royalties from partnerships to be completed by Amorfix with selected third-party, multi-national health care firms. As of the date of this form, Amorfix has not generated any significant product revenues.

### ***Develop Collaborative Customer-Funded Commercialization Agreements***

In order to increase market exposure of its products and to capitalize on a partners' clinical development competencies, market position, and distribution capabilities, Amorfix intends to develop its projects with collaborative commercial partners which will fund further product development projects incorporating the Amorfix technology. These collaborative arrangements typically will provide for a jointly-funded development project and contemplate a licensing arrangement (which may be entered into at the same time as the development project or at a later date) under which, if a project is commercialized by the collaborative partner, Amorfix would potentially receive license fees, royalty payments from product sales and manufacturing revenue. Amorfix believes that such arrangements with major commercial partners will serve to validate its proprietary technologies in human and animal healthcare areas and thereby assist Amorfix in attracting additional licensing arrangements on favourable terms.

In order to pursue enhanced royalty or marketing terms over those obtained under customary development and licensing agreements, Amorfix intends to develop drug formulations through internally-funded projects in market segments where Amorfix believes there is strong market potential and that its technology may provide a significant competitive advantage. After carrying such projects to an appropriate development stage, Amorfix will offer companies that are seeking to maintain or expand their market share an opportunity to enter into partner agreements covering such internally-funded Amorfix products.

### ***Enhance Out-licensing of Amorfix Requirements***

Where practical, Amorfix will outsource its manufacturing and thereby out-license the manufacturing rights to its products to capture greater revenue and generate production economies that may not be available to healthcare companies seeking to apply Amorfix's technology to only one or a few products. Amorfix has explored and will continue to evaluate the possibility of entering into strategic manufacturing alliances with appropriate third parties.

### ***Recruit and Retain Key Amorfix Personnel***

Amorfix will seek to hire qualified scientists and key employees as needed to maintain and strengthen its operations, while also seeking to retain current personnel.

### ***Competitive Conditions***

Amorfix faces competition from large biotechnology and pharmaceutical companies in blood safety and early diagnosis of neurodegenerative diseases. In addition, there are a number of companies both large and small who are attempting to develop therapeutic and prophylactic products for humans and animals as these are large unmet medical needs. Each of these markets will be discussed below.

### ***Neurodegenerative Diseases Competition***

There are three main categories of potential biomarkers for AD: genetic and proteomic; imaging; and body fluid analysis. The genetics of familial early-onset AD do not address the more common form of sporadic AD. The ApoE genotype is of some predictive value and may be useful in combination with the development of new biomarkers. Structural and metabolic neuroimaging is improving and may be a powerful addition to a screening assay for biomarkers. A recent report<sup>20</sup> from Predictive Diagnostics found large-scale proteomics was capable of finding a unique fingerprint of proteins in AD patients compared to normal controls. This is very much a brute force method and will not be cost-effective unless it can be converted to a simple procedure. Cerebral spinal fluid (CSF) A $\beta$  and tau are still variable in AD and less invasive measurements in plasma and urine can be expected to be less consistent. Urine analysis of other elements, such as isoprostanes and sulfatides are currently inconclusive. None of the above approaches has been sufficient to definitively diagnose or predict the therapeutic response in AD.

Competition in the human medical diagnostics industry is significant. Potential competitors to Amorfix range from development stage diagnostics companies to major domestic and international healthcare firms. Many of these businesses have substantially greater financial, technical, marketing, sales, manufacturing, distribution and other resources. In addition, many of these companies have name recognition, established positions in the market and long standing relationships with customers and distributors.

The diagnostics industry also continues to experience significant consolidation in which many of the large domestic and international healthcare companies have been acquiring small to mid-sized diagnostics companies, further increasing the concentration of diagnostic resources. However, competition in diagnostic medicine is highly fragmented, with no firm holding a dominant position in neurodegenerative disease. The Amorfix competitors in the diagnostic area could include Elan Pharmaceuticals, Eli Lilly and Company, Merck Research Laboratories, Celera Diagnostics, Inova Diagnostics, Inc., Abbott Laboratories, Johnson & Johnson, Biorad Laboratories, Roche, Applied NeuroSolutions, Predictive Diagnostics, IDEXX Laboratories, DIASORIN, Diagnostica Stago, American Bioproducts, Organon Teknika, Helix Diagnostics, Heamagen Diagnostics, Sigma Diagnostics and IVAX Diagnostics.

### ***Human Healthcare Products Competition***

Amorfix will compete with many large and small human pharmaceutical companies that are developing and/or marketing therapeutic compounds similar to those that Amorfix plans to develop. Many large pharmaceutical companies and smaller biotechnology companies maintain well-funded research departments concentrating on therapeutic approaches to neurodegenerative diseases. Amorfix expects substantial competition from these companies as they develop different and/or novel approaches to the treatment of these diseases. Some of these approaches may directly compete with the technology that Amorfix is currently developing.

In the intense competitive environment that is the human pharmaceutical industry, those companies that complete clinical trials, obtain regulatory approval and commercialize their therapeutic products first will enjoy competitive advantages. Amorfix believes that it will develop compounds with characteristics that may enable them, if fully developed, to have a market impact. A number of major human pharmaceutical companies have significant programs to develop drugs for the treatment of neurodegenerative disease.

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<sup>20</sup> <http://www.predictivediagnostics.com/041905.html>

These companies include Warner-Lambert, Eisai/Pfizer, Novartis, Merck, Novartis, Genentech, Amgen and Johnson & Johnson.

### ***Animal Healthcare Products Competition***

Amorfix competes with many companies focused on animal health ranging from small businesses to large pharmaceutical companies. Its competitors vary in its different markets. Academic institutions, governmental agencies and other public and private research organizations also conduct research activities and may commercialize products which could compete with Amorfix's products, on their own or through joint ventures. Some of Amorfix's animal health competitors have substantially greater capital, manufacturing, marketing and research and development resources.

Amorfix will face intense competition within the markets in which its animal healthcare technology is sold. Future competition will become even more intense and Amorfix will have to compete with changing technologies, which could affect the marketability of Amorfix's animal products. Amorfix's competitive position also will depend on its ability to develop proprietary products, attract and retain qualified scientific and other personnel, develop and implement production and marketing plans, obtain patent protection and obtain adequate capital resources. In the animal diagnostic products markets, Amorfix will compete primarily on the basis of the specificity and ability to measure AMPs ease of use, speed, accuracy and other performance characteristics of its products, the breadth of its product line, the effectiveness of its strategic partners, sales and distribution channels, and the quality of its technical staff.

### ***Future Development***

Amorfix believes that other diseases will be identified as AMP diseases and expand the applications for diagnostic, therapeutic and prophylactic products that can be developed from its core technology and know-how. To date, diabetes, multiple sclerosis, schizophrenia and some cancers are thought to have protein aggregates as hallmarks of the disease. Amorfix's ProMIS™ and EP technologies may have the potential to validate or refute these claims as well as to discover AMPs in many other disorders.

### ***Proprietary Protection***

Amorfix has acquired the rights to certain proprietary discovery platforms for the identification of proteins involved in misfolding diseases embodied in various national and international patent applications. Amorfix has also filed international patent applications related to SOD1-based immunotherapy to further protect its intellectual property rights related to its therapeutic programs. In addition Amorfix has obtained proprietary rights to a computational algorithm (ProMIS™) for identification of Disease Specific Epitopes (DSEs) in protein misfolding diseases as well as predicted DSEs against several disease targets such as cancer. Amorfix intends to aggressively protect the commercial applications for diagnostic, therapeutic and prophylactics of these discoveries. In addition, Amorfix has developed know-how which it may elect to keep as trade secrets and not publicly disclose them in patent applications.

### ***Risk Factors***

Prospects for companies in the biotechnology industry generally may be regarded as uncertain given the nature of the industry and, accordingly, investments in biotechnology companies should be regarded as speculative. Biotechnology research and development involves a significant degree of risk. An investor should carefully consider the risks and uncertainties described below, as well as other information contained in this Annual Information Form. The risks and uncertainties described below are not an exhaustive list. Additional risks and uncertainties not presently known to the Company or that the

Company believes to be immaterial may also adversely affect the Company's business. If any one or more of the following risks occur, the Company's business, financial condition and results of operations could be seriously harmed. Further, if the Company fails to meet the expectations of the public market in any given period, the market price of the Company's common shares could decline.

**Early Stage Development and Scientific Uncertainty.** Several of Amorfix's products are at an early stage of development. Significant additional investment in research and development, product validation, technology transfer to manufacturing, production scale-up, manufacturing, clinical testing, and regulatory submissions of such product candidates is required prior to commercialization. There can be no assurance that any such products will actually be developed. The development and regulatory processes may require access to rare biofluid and tissue samples from people and animals with AMP diseases which may not be available to the Company in sufficient amounts or in a timely fashion to allow Amorfix to complete the development or receive regulatory approval of any product or process. The presence of AMPs in human blood has never been measured and so may be not present or at levels so low as to be unmeasurable. A commitment of substantial time and resources is required to conduct research and clinical trials if Amorfix is to complete the development of any product. It is not known whether any of these product or process candidates will meet applicable health regulatory standards and obtain required regulatory approvals, or whether such products can be produced in commercial quantities at reasonable costs and be successfully marketed, or whether ante-mortem diagnostic tests for AMP diseases will achieve market acceptance, or if Amorfix's investment in any such products will be recovered through sales or royalties.

**Lack of Product Revenues and History of Losses.** To date, Amorfix has not recorded any revenues from the sale of biopharmaceutical products. As at March 31, 2010, Amorfix has a deficit of \$23,758,924. Amorfix expects to incur additional losses during the periods of research and development, clinical testing, and application for regulatory approval of its product candidates. Amorfix expects to incur losses unless and until such time as payments from corporate collaborations, product sales and/or royalty payments generate sufficient revenues to fund its continuing operations.

**Additional Financing Requirements and Access to Capital.** Amorfix will require substantial additional funds for further research and development, planned clinical testing, regulatory approvals, establishment of manufacturing capabilities and, if necessary, the marketing and sale of its products. Amorfix may attempt to raise additional funds for these purposes through public or private equity or debt financing, collaborations with other biopharmaceutical companies and/or from other sources. There can be no assurance that additional funding or partnerships will be available on terms acceptable to Amorfix and which would foster successful commercialization of Amorfix's products.

**Patents and Proprietary Technology.** Amorfix's success will depend in part on its ability to obtain, maintain, and enforce patent rights, maintain trade secret protection and operate without infringing the proprietary rights of third parties. There can be no assurance that pending patent applications will be allowed, that Amorfix will develop additional proprietary products that are patentable, that issued patents will provide Amorfix with any competitive advantage or will not be challenged by any third parties, or that patents of others will not have an adverse effect on the ability of Amorfix to do business. Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of Amorfix's products, or design around the products patented by Amorfix. In addition, Amorfix may be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any licenses required under such patents or proprietary rights will be available on terms acceptable to Amorfix. If Amorfix does not obtain such licenses it could encounter delays in introducing one or more of its products to the market, while it attempts to design around such patents, or could find that the development, manufacturing or sale of products requiring such licenses could be foreclosed. In addition, Amorfix could incur substantial costs in defending itself in suits brought against it on such patents or in suits where it attempts to enforce its own patents against other parties.

Until such time, if ever, that patent applications are filed, the ability of Amorfix to maintain the confidentiality of its technology may be crucial to its ultimate possible commercial success. While Amorfix has adopted procedures designed to protect the confidentiality of its technology, no assurance can be given that such arrangements will be effective, that third parties will not gain access to Amorfix's trade secrets or disclose the technology, or that Amorfix can meaningfully protect its rights to its trade secrets.

**Dependence on Collaborative Partners, Licensors and Others.** Amorfix's activities will require it to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, manufacturing, marketing and commercialization of its products. Amorfix intends to attract corporate partners and enter into additional research collaborations. There can be no assurance, however, that Amorfix will be able to establish such additional collaborations on favorable terms, if at all, or that its current or future collaborations will be successful. Failure to attract commercial partners for its products may result in the Company incurring substantial clinical testing, manufacturing and commercialization costs prior to realizing any revenue from product sales or result in delays or program discontinuance if funds are not available in sufficient quantities.

Should any collaborative partner fail to develop, manufacture, or commercialize successfully any product to which it has rights, or any partner's product to which Amorfix will have rights, Amorfix's business may be adversely affected. Failure of a collaborative partner to continue to participate in any particular program could delay or halt the development or commercialization of products generated from such program. In addition, there can be no assurance that the collaborative partners will not pursue other technologies or develop alternative products either alone or in collaboration with others, including Amorfix's competitors, as a means for developing treatments for the diseases targeted by Amorfix's programs.

Furthermore, Amorfix will hold licenses for certain technologies and there can be no assurance that these licenses will not be terminated, or that they will be renewed on conditions acceptable to Amorfix. Amorfix intends to negotiate additional licenses in respect of technologies developed by other companies and academic institutions. Terms of license agreements to be negotiated may include, inter alia, a requirement to make milestone payments, which may be substantial. Amorfix will also be obligated to make royalty payments on the sales, if any, of products resulting from licensed technology and, in some instances, may be responsible for the costs of filing and prosecuting patent applications.

**Government Regulations.** Biotechnology and pharmaceutical companies operate in a high-risk regulatory environment. The manufacture and sale of animal and human diagnostic and therapeutic products is governed by numerous statutes and regulations in the United States, Canada and other countries where Amorfix intends to market its products. The subject matter of such legislation includes approval of manufacturing facilities, controlled research and testing procedures, review and approval of manufacturing, preclinical and clinical data prior to marketing approval, as well as regulation of marketing activities, notably advertising and labelling.

The process of completing clinical testing and obtaining required approvals is likely to take several years and require the expenditure of substantial resources. Furthermore, there can be no assurance that the regulators will not require modification to any submissions which may result in delays or failure to obtain regulatory approvals. Any delay or failure to obtain regulatory approvals could adversely affect the ability of Amorfix to utilize its technology, thereby adversely affecting operations. Further, there can be no assurance that Amorfix's diagnostic product candidates will achieve levels of sensitivity and specificity sufficient for regulatory approval or market acceptance, or that its therapeutic product candidates prove to be safe and effective in clinical trials, or receive the requisite regulatory approval. There is no assurance that the Company will be able to timely and profitably produce its products while complying with all the

applicable regulatory requirements. Foreign markets, other than the United States and Canada, impose similar restrictions.

**Hazardous Materials and Environmental Matters.** Certain of Amorfix's research and development processes will involve the controlled use of hazardous materials. Amorfix is subject to federal, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although management of Amorfix believes that its procedures for handling and disposing of such materials comply with the standards prescribed, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, Amorfix could be held liable for damages and such liability could exceed the resources of Amorfix. Amorfix is not specifically insured with respect to this liability. Although management of Amorfix believes that Amorfix currently complies in all material respects with applicable environmental laws and regulations, Amorfix may be required to incur significant costs to comply with environmental laws and regulations in the future. Furthermore, there can be no assurance that the operations, business or assets of Amorfix will not be materially adversely affected by current or future environmental laws or regulations.

**Rapid Technological Change.** The biotechnology and pharmaceutical industries are characterized by rapid and substantial technological change. There can be no assurance that developments by others will not render Amorfix's products or technologies non-competitive, or that Amorfix will keep pace with technological developments. Competitors have developed or are developing technologies that could be the basis for competitive products. Some of these products have an entirely different approach or means of accomplishing the desired diagnostic or therapeutic effect as compared with products to be developed by Amorfix, and could be more effective and less costly than the products to be developed by Amorfix. In addition, alternative forms of medical treatment may be competitive with Amorfix's products.

**Competition.** Technological competition from pharmaceutical companies, biopharmaceutical companies and universities is intense and is expected to increase. Potential competitors of Amorfix have or may develop product development capabilities or financial, scientific, marketing and human resources exceeding those of Amorfix. Competitors may develop products before Amorfix develops its own products, obtain regulatory approval for such products more rapidly than Amorfix, or develop products which are more effective than those which Amorfix intends to develop. Research and development by others may render Amorfix's technology or products obsolete or non-competitive or produce treatments or cures superior to any therapy developed or to be developed by Amorfix, or otherwise preferred to any therapy developed by Amorfix.

**Reliance on Key Personnel.** Amorfix is dependent on certain members of its management and scientific staff, the loss of services of one or more of whom could adversely affect Amorfix. In addition, Amorfix's ability to manage growth effectively will require it to continue to implement and improve its management systems and to recruit and train new employees. There can be no assurance that Amorfix will be able to successfully attract and retain skilled and experienced personnel.

**Status of Healthcare Reimbursement.** Amorfix's ability to successfully market certain diagnostic or therapeutic products may depend in part on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Significant uncertainty exists as to whether newly approved healthcare products will qualify for reimbursement. Furthermore, challenges to the price of medical products and services are becoming more frequent. There can be no assurance that adequate third-party coverage will be available to establish price levels, which would allow Amorfix to realize an acceptable return on its investment in product development.

**Potential Product Liability.** Pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. Product liability insurance is costly, availability is limited and may not be available on terms which would be acceptable to Amorfix, if at all. An inability to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of Amorfix's potential products. A product liability claim brought against Amorfix, or withdrawal of a product from the market, could have a material adverse effect upon Amorfix and its financial condition.

**Volatility of Share Price, Absence of Dividends and Fluctuation of Operating Results.** Market prices for the securities of biotechnology companies, including the Company, have historically been highly volatile. Factors such as fluctuation of the Company's operating results, announcements of technological innovations, patents or new commercial products by Amorfix or competitors, results of clinical testing, regulatory actions, or public concern over the safety of biopharmaceutical products and other factors could have a significant effect on the share price or trading volumes for the common shares. The Company's common shares have been subject to significant price and volume fluctuations and may continue to be subject to significant price and volume fluctuations in the future. Amorfix has not paid dividends to date and does not expect to pay dividends in the foreseeable future.

#### **DIVIDENDS**

There are no restrictions in Amorfix's articles or elsewhere which would prevent Amorfix paying dividends. No dividends have been declared or paid on the common shares of Amorfix in the last three fiscal years, and it is not expected that dividends will be declared or paid in the immediate or foreseeable future. The policy of the Board of Directors of the Company (the "Board") is to reinvest all available funds in operations. The Board will reassess this policy from time to time. Any decision to pay dividends on the common shares of Amorfix will be made by the Board based on the assessment of, among other factors, earnings, capital requirements and the operating and financial condition of the Company.

#### **DESCRIPTION OF CAPITAL STRUCTURE**

The Company is authorized to issue an unlimited number of voting and participating common shares without par value and an unlimited number of non-voting and participating preferred shares without par value. As at March 31, 2010, 48,514,418 common shares and no preferred shares were issued and outstanding.

Each common share carries one vote at all general meetings of Amorfix whether ordinary or special, and may participate in any dividends declared by the directors of Amorfix. The common shares carry the right to receive a proportionate share of Amorfix's assets available for distribution to the holders of Amorfix shares upon liquidation, dissolution or winding up of Amorfix. The common shares do not have any special liquidation, pre-emptive or conversion rights.

The Amorfix preferred shares may be issued in one or more series and the directors are authorized to fix the number of shares in each series and to determine the designation, rights, privileges, restrictions and conditions attached to the shares of each series. The Amorfix preferred shares rank on parity with the Amorfix common shares with respect to the payment of dividends unless one or more series of Amorfix preferred shares are entitled to cumulative dividends. The Amorfix preferred shares also rank on parity with the preferred shares of every other series and are entitled to a priority over any other class of shares ranking junior to the Amorfix preferred shares with respect to the distribution of assets upon the liquidation, dissolution or winding-up of Amorfix.

## MARKET FOR SECURITIES

### Trading Price and Volume

The Company's common shares are listed under the symbol "AMF" and during the financial year traded on the TSX-V from April 1, 2007 to July 24, 2007 and the TSX since July 25, 2007. The following table sets out the high and low sale prices and the volume of trading of the shares on the TSX for the months indicated:

Period	High (\$)	Low (\$)	Volume
April 2009	0.82	0.54	1,915,100
May 2009	0.77	0.61	1,868,300
June 2009	1.28	0.79	3,154,200
July 2009	1.35	1.00	2,010,100
August 2009	1.11	0.85	587,700
September 2009	1.32	0.79	3,462,600
October 2009	1.3	0.95	2,192,600
November 2009	1.13	0.94	1,503,300
December 2009	1.06	0.52	7,214,600
January 2010	0.78	0.50	2,578,800
February 2010	0.54	0.45	639,700
March 2010	0.62	0.34	1,733,800

## ESCROWED SECURITIES

When Amorfix amalgamated with Luxor in September 2005, a total of 10,225,000 common shares were required to be deposited into escrow in accordance with the policies of the TSX-V. As of March 31, 2010, all common shares have been released from escrow.

## DIRECTORS AND OFFICERS

### Name, Occupation and Security Holding

The following table sets out the name, residence, position with Amorfix and principal occupations for the previous five years of each of the directors and executive officers of Amorfix, as well as the period during which each has been a director of Amorfix:

Name and Residence	Position Held	Principal Occupation Last Five Years	Director Since
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<b>Name and Residence</b>	<b>Position Held</b>	<b>Principal Occupation Last Five Years</b>	<b>Director Since</b>
George Adams Ontario, Canada	Director	President and Chief Executive Officer of Amorfix from April 2005 to June 2, 2010; President of Hemo-Stat Ltd., a consulting firm, from 2004 to Present; President and Chief Executive Officer of University of Toronto Innovations Foundation from 2003 to October 2004.	May 24, 2005 to June 3, 2010
Hans Black <sup>(1)(3)</sup> Quebec, Canada	Director	Chairman of Interinvest Corporation, a private client asset and fund management firm.	November 27, 2006
William Lambert <sup>(1)(3)</sup> Ontario, Canada	Director	Corporate Director from January 2010. Special Partner of Birch Hill Equity Partners, a private equity partnership to Dec 2009.	June 9, 2006
Philippe Couillard Quebec, Canada	Director	Senior Fellow of Health Law at McGill University; Partner with Persistence Capital, a private equity fund.	September 29, 2009
Aziz Mekouar <sup>(2)</sup> Bethesda, Maryland	Director	Ambassador of Morocco to the United States	January 3, 2008
Graham Strachan <sup>(1)(2)(3)</sup> Ontario, Canada	Chairman of the Board	Chairman of the Board of Amorfix since September 20, 2005; Principal of GLS Business Development Inc, a business development and consulting firm.	September 20, 2005
Michael Sonnenreich <sup>(2)(3)</sup> District of Columbia, USA	Director	President of Kikaku America International, a pharmaceutical consulting firm.	January 9, 2007
Neil Cashman British Columbia, Canada	Director, Chief Scientific Officer	Chief Scientific Officer of Amorfix since May 31, 2004; Professor, University of British Columbia (UBC) since July 1, 2005; Canada Research Chair in Neurodegeneration and Protein Misfolding Diseases (UBC) since March 1, 2005; Director, ALS Clinic Vancouver General Hospital since July 1, 2005; Professor, University of Toronto from 2003 to 2004.	June 9, 2010
Robert Gundel	Director, President, Chief Executive Officer	President and Chief Executive Officer of Amorfix since June 2010; Co-founder and consultant of Chatham Consulting Group LLC from 2007 to Present; Vice President of Research and Development of Amorfix from January 2010 to June 2010; Interim Chief Scientific and Technology Officer of Heat Biologics Inc. from 2008 to 2009; Vice President of Research and Development of Elusys Therapeutics from February to November 2008; Chief Scientific Officer of Arius Research Inc. from 2007 to 2008; Vice President of Scientific and Corporate Development of Xoma (US) LLC from 2005 to 2007.	June 9, 2010

Name and Residence	Position Held	Principal Occupation Last Five Years	Director Since
James Parsons Ontario, Canada	Chief Financial Officer	Chief Financial Officer of Amorfix since April 2005; President of a CFO services company focused on the life sciences industry from 2004 to present.	N/A

- (1) Member of the Audit Committee.
- (2) Member of the Compensation Committee.
- (3) Member of the Corporate Governance and Nominating Committee.

The term of office of each director of Amorfix expires at the annual general meeting of shareholders each year.

The directors and executive officers of Amorfix, as a group, own or exercise control and direction over 6,200,975 common shares, being 12.8% of the issued common shares on a non-diluted basis as at March 31, 2010.

### **Cease Trade Orders, Bankruptcies, Penalties or Sanctions**

To the knowledge of the Company, and except as otherwise set out herein, no director or officer, or any shareholder holding a sufficient number of securities of the Company to materially influence control of the Company: (a) is, as at June 9, 2010, or has been within the last ten years, a director or officer of a company (including Amorfix) which, while he was acting in such capacity, (i) was subject to a cease trade or similar order or was refused an exemption prescribed by securities legislation for more than 30 consecutive days, (ii) has, after the termination of duties as a director or officer, been subject to a cease trade or similar order or been denied an exemption under securities legislation for more than 30 consecutive days due to an event that took place while that person was in office, or (iii) has, while the director or executive officer held that office or within a year of ceasing to act in that capacity, become bankrupt, made a proposal under any bankruptcy or insolvency legislation, made a proposal under any legislation relating to bankruptcy or insolvency, or was subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver-manager or trustee appointed to hold his assets, or (b) within the ten preceding years, became bankrupt, made a proposal under any bankruptcy or insolvency legislation, made a proposal under any legislation relating to bankruptcy or insolvency, or became subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver-manager or trustee appointed to hold the assets of the director, officer or shareholder, or (c) has been the subject of (i) a penalty or sanction imposed by a court relating to securities legislation or by a securities regulatory authority or entered into a settlement agreement with it, or (ii) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor making an investment.

### **Conflicts of Interest**

Certain directors or officers of the Company are also directors, officers or shareholders of other companies, and conflicts of interest may arise between their duties as a director or officer of the Company and their duties as a director, officer or shareholder of other companies. All potential conflicts of interest must be disclosed in accordance with the requirements of the *Canada Business Corporations Act*, and the directors and officers in question are required to comply with their legal obligations as well as all contractual provisions binding them. To the knowledge of the Company, no conflict of interest arose during fiscal year 2010 or currently exists.

## PROMOTERS

There has been no person or company, within the three most recently completed financial years or during the current financial year, considered a promoter of Amorfix.

## LEGAL PROCEEDINGS AND REGULATORY ACTIONS

There are no legal proceedings or regulatory actions to which Amorfix is or was a party to or of which any of its property is or was the subject of during the fiscal year ended March 31, 2010.

## INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Other than the transactions described below, no (a) director or executive officer of the Company, (b) person or company that is the direct or indirect beneficial owner of, or who exercises control or direction over, more than 10% of any class or series of the Company's outstanding securities, and (c) an associate or affiliate of any of the persons or companies referred to in (a) or (b), during the three most recently completed financial years or during the current financial year, has had any material interest, direct or indirect, in any transaction which has materially affected or would materially affect the Company.

On February 1, 2006, the Company acquired an exclusive license to develop certain SOD1 technologies owned by Dr. Cashman for diagnostic and therapeutic applications for ALS disease. In consideration, the Company spent \$300,000 on the technology and is committed to pay a small royalty on commercial sales. The Company also received an option to acquire the technology for \$100,000 at any time prior to the fifth anniversary of the license agreement. The acquisition of the technology was valued at the carrying amount, which was nominal.

In April 2006, the Company acquired certain additional SOD1 technologies owned by Dr. Cashman for a nominal amount. The Company also entered into an agreement on the same date to license exclusive rights to these SOD1 technologies from Dr. Cashman's co-inventors at the University Health Network.

In February 2007, the Company entered into an agreement with the University of British Columbia (UBC) and Vancouver Coastal Health Authority, with Dr. Cashman as principal investigator, to fund research in Dr. Cashman's laboratory related to the Amorfix ALS therapeutic program in the amount of \$300,000.

In December 2008, the Company entered into an agreement with UBC, with Dr. Cashman as principal investigator, to fund research related to the Amorfix Alzheimer's disease therapeutic program in the amount of \$426,619.

In August 2009, the company entered into an agreement with the University of British Columbia (UBC) and Vancouver Coastal Health Authority, with Dr. Cashman as principal investigator, to fund a ProMIS™ research program to discover novel disease-specific epitopes on misfolded proteins in the amount of \$240,000.

In August 2009, the company entered into an assignment agreement with the University of Toronto and Dr. Neil Cashman to acquire certain technology related to its ProMIS™ research program. The company paid \$2,000 for the technology and will pay royalties on the commercial sale of any product candidates developed from the technology.

In December 2009, the company entered into an agreement with UBC and Vancouver Coastal Health Authority, with Dr. Neil Cashman as principal investigator, to fund an aggregated misfolded protein research program in the amount of \$83,130.

### **TRANSFER AGENT AND REGISTRAR**

The Company's registrar and transfer agent, respectively, are Olympia Trust Company and Olympia Transfer Services Inc., located in Calgary, Alberta and Toronto, Ontario.

### **MATERIAL CONTRACTS**

Other than contracts entered into in the ordinary course of business, as at March 31, 2010, the Company has not entered into any material contracts in the most recently completed financial year, including certain other continuing material contracts, except:

- Assignment agreement dated February 18, 2005, as amended April 1, 2005 among N. Cashman, M. Lehto, The Governing Council of University of Toronto and Amorfix pursuant to which Amorfix acquired rights to relating to its epitope protection technology, including patent applications relating to "Methods of Detecting Prion Proteins" and "Epitope Protection Assay".
- License agreement dated February 1, 2006 between N. Cashman and Amorfix pursuant to which Amorfix acquired an exclusive worldwide license to novel targets on Superoxide Dismutase-1 ("SOD1") and an option to acquire the intellectual property rights and know how outright.
- License agreement dated April 4, 2006, as amended July 13, 2006 between University Health Network and Amorfix pursuant to which Amorfix acquired exclusive worldwide rights to additional novel targets on SOD1 and an option to acquire the intellectual property and know how outright.

### **INTERESTS OF EXPERTS**

#### **Names of Experts**

The Company's auditors are PricewaterhouseCoopers LLP, Chartered Accountants, who have prepared an independent auditors' report dated June 9, 2010 in respect of the Company's financial statements as at March 31, 2010 and March 31, 2009 and for each of the years then ended. PricewaterhouseCoopers LLP has advised that they are independent with respect to the Company within the meaning of the Rules of Professional Conduct of the Institute of Chartered Accountants of Ontario.

#### **Interests of Experts**

To the knowledge of the Company, none of the persons above held, at the time of or after such person prepared the statement, report or valuation, any registered or beneficial interests, direct or indirect, in any securities or other property of the Company or of one of its associates or affiliates or is or is expected to be elected, appointed or employed as a director, officer or employee of the Company or of any associate or affiliate of the Company.

### **ADDITIONAL INFORMATION**

Additional information, including directors' and officers' remuneration and indebtedness, principal holders of Amorfix's securities and securities authorized for issuance under equity compensation plans is contained in the management information circular for Amorfix dated August 24, 2009 (the "Information Circular"). Additional financial information relating to Amorfix is included in Amorfix's audited financial statements for the years ended March 31, 2010 and March 31, 2009 and the accompanying auditor's report and management's discussion and analysis. Copies of the Information Circular, the relevant portion of any documents incorporated by reference in this annual information statement, Amorfix's most current interim financial statements and management's discussion and analysis, and additional copies of this Annual Information Form as well as additional information relating to Amorfix may be found on SEDAR at [www.sedar.com](http://www.sedar.com).

## APPENDIX A

### FORM 52-110F1 - AUDIT COMMITTEE INFORMATION REQUIRED IN AN AIF

#### The Audit Committee Charter

The Audit Committee is a committee of the Board of Directors of Amorfix Life Sciences Ltd. (the "Company"). The primary function of the Audit Committee is to assist the Board of Directors in fulfilling its financial reporting and control responsibilities to the shareholders of the Company and the investment community. The external auditors will report directly to the Audit Committee. The Audit Committee's primary duties and responsibilities are:

- overseeing the integrity of the Company's financial statements and reviewing the financial reports and other financial information provided by the Company to any governmental body or the public and other relevant documents;
- recommending the appointment and reviewing and appraising the audit efforts of the Company's external auditor, overseeing the external auditor's qualifications and independence and providing an open avenue of communication among the external auditor, financial and senior management and the Board of Directors;
- serving as an external and objective party to oversee and monitor the Company's financial reporting process and internal controls, the Company's processes to manage business and financial risk, and its compliance with legal, ethical and regulatory requirements;
- encouraging continuous improvement of, and fostering adherence to, the Company's policies, procedures and practices at all levels.

## II. COMPOSITION

The Committee shall consist of a minimum of three directors of the Company, including the Chair of the Committee, two of whom shall be "independent" directors as such term is defined in Schedule "A". All members shall, to the satisfaction of the Board of Directors, be "financially literate" as defined in Schedule "A".

The members of the Audit Committee shall be elected by the Board of Directors at the annual organizational meeting of the Board of Directors or until their successors are duly elected and qualified. The Board of Directors may remove a member of the Audit Committee at any time in its sole discretion by resolution of the Board. Unless a Chair is elected by the full Board of Directors, the members of the Audit Committee may designate a Chair by majority vote of the full membership of the Audit Committee.

The Chair's responsibilities shall include (i) providing leadership to enhance the effectiveness and focus of the Committee, (ii) calling and chairing meetings of the Committee ensuring that the Committee meets on a regular basis, at least quarterly, (iii) setting with the Chief Financial Officer the agenda for each meeting, (iv) ensuring that the Committee receives adequate and regular updates from management on all matters necessary for the Committee to discharge its responsibilities, including but not limited to matters regarding audits, financial statements, MD&A, press releases, and procedures for disclosure of financial information and disclosure controls, (v) acting as liaison between the Committee and the external auditors with respect to the annual audit and (vi) acting as liaison between the Committee and the Board including

reporting regularly to the Board on all proceedings and deliberations of the Committee. The Chair shall also appoint a Secretary of the Committee who need not be a director.

### **III. Duties and Responsibilities**

1. The Committee shall review and recommend to the Board for approval:
  - (a) The annual audited financial statements.
  - (b) Review with financial management and the external auditor the Company's financial statements, MD&A's and earnings releases to be filed with regulatory bodies such as securities commissions prior to filing or prior to the release of earnings. Review of quarterly results with the external auditor will be at the discretion of the Committee.
  - (c) Documents referencing, containing or incorporating by reference the annual audited consolidated financial statements or interim financial results (e.g., prospectuses, press releases with financial results and Annual Information Form – when applicable) prior to their release.
2. The Committee, in fulfilling its mandate, will:
  - (a) Satisfy itself that adequate internal controls and procedures are in place to allow the Chief Executive Officer and the Chief Financial Officer to certify financial statements and other disclosure documents as required under securities laws.
  - (b) Recommend to the Board of Directors the selection of the external auditor, consider the independence and effectiveness and approve the fees and other compensation to be paid to the external auditor.
  - (c) Monitor the relationship between management and the external auditor including reviewing any management letters or other reports of the external auditor, and discussing and resolving any material differences of opinion or disagreements between management and the external auditor.
  - (d) Review and discuss, on an annual basis, with the external auditor all significant relationships they have with the Company to determine their independence and report to the Board of Directors.
  - (e) Review and approve requests for any management consulting engagement to be performed by the external auditor and be advised of any other study undertaken at the request of management that is beyond the scope of the audit engagement letter and related fees.
  - (f) Review the performance of the external auditor and approve any proposed discharge and replacement of the external auditor when circumstances warrant. Consider with management the rationale for employing accounting/auditing firms other than the principal external auditor.

- (g) Periodically consult with the external auditor out of the presence of management about significant risks or exposures, internal controls and other steps that management has taken to control such risks, and the fullness and accuracy of the organization's financial statements. Particular emphasis should be given to the adequacy of internal controls to expose any payments, transactions, or procedures that might be deemed illegal or otherwise improper.
- (h) Arrange for the external auditor to be available to the Audit Committee and the full Board of Directors as needed. Ensure that the auditors report directly to the Audit Committee and are made accountable to the Board and the Audit Committee, as representatives of the shareholders to whom the auditors are ultimately responsible.
- (i) Oversee the work of the external auditors engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services.
- (j) Pre-approve any permissible non-audit engagements of the external auditors, in accordance with applicable legislation.
- (k) Review and approve hiring policies for employees or former employees of the past and present external auditors.
- (l) Review the scope of the external audit, including the fees involved.
- (m) Review the report of the external auditor on the annual audited financial statements.
- (n) Review problems found in performing the audit, such as limitations or restrictions imposed by management or situations where management seeks a second opinion on a significant accounting issue.
- (o) Review major positive and negative observations of the auditor during the course of the audit.
- (p) Review with management and the external auditor of the Company's major accounting policies, including the impact of alternative accounting policies and key management estimates and judgments that can materially affect the financial results.
- (q) Review emerging accounting issues and their potential impact on the Company's financial reporting.
- (r) Review with management, the external auditors and legal counsel, any litigation, claims or other contingency, including tax assessments, which could have a material affect upon the financial position or operating results of the Company, and whether these matters have been appropriately disclosed in the financial statements.
- (s) Review the conclusions reached in the evaluation of management's internal control systems by the external auditors, and management's responses to any identified weaknesses



- (t) Review with management their approach to controlling and securing corporate assets (including intellectual property) and information systems, the adequacy of staffing of key functions and their plans for improvements.
  - (u) Review with management their approach with respect to business ethics and corporate conduct, written codes of conduct established by management and the program used by management to monitor compliance with the code.
  - (v) Review annually the code of ethics and legal and regulatory requirements that, if breached, could have a significant impact on the Company's published financial reports or reputation.
  - (w) Review the results of annual testing performed by the external auditors on the compliance of the Company's expense policy by management of the Company.
  - (x) Review with management relationships with regulators, and the accuracy and timeliness of filing with regulatory authorities (when and if applicable).
  - (y) Review annually the business continuity plans for the Company.
  - (z) Review the annual audit plans of the external auditors of the Company.
  - (aa) Review annually general insurance coverage of the Company to ensure adequate protection of major corporate assets including but not limited to D&O and "Key Person" coverage.
  - (bb) Satisfy itself that adequate procedures are in place for the review of the Company's public disclosure of financial information (other than the documents under section 1(b) above) extracted or derived from the Company's financial statements and must periodically assess the adequacy of such procedures.
  - (cc) Perform such other duties as required by the Company's incorporating statute and applicable securities legislation and policies.
  - (dd) Establish procedures for:
    - (i) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal controls, or auditing matters; and
    - (ii) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or audit matters.
3. The Committee may engage and communicate directly and independently with outside legal and other advisors for the Committee as required and set and pay the compensation of such advisors.
  4. On a yearly basis, the Committee will review the Audit Committee Charter and where appropriate recommend changes to the Board of Directors.

#### **IV. Secretary**

The Secretary of the Committee will be appointed by the Chair.

#### **V. Meetings**

1. The Committee shall meet at such times and places as the Committee may determine, but no less than four times per year. At least annually, the Committee shall meet separately with management and with the external auditors.
2. Meetings may be conducted with members present, in person, by telephone or by video conference facilities.
3. A resolution in writing signed by all the members of the Committee is valid as if it had been passed at a meeting of the Committee.
4. Meetings of the Audit Committee shall be held from time to time as the Audit Committee or the Chairman of the Committee shall determine upon 48 hours notice to each of its members. The notice period may be waived by a quorum of the Committee.
5. The external auditors or any member of the Committee may also call a meeting of the Committee.
6. The Board shall be kept informed of the Committee's activities by a report, including copies of minutes, at the next board meeting following each Committee meeting.

#### **VI. Quorum**

Quorum for the transaction of business at any meeting of the Audit Committee shall be a majority of the number of members of the Committee.

#### **Composition of the Audit Committee**

The Audit Committee, at the present time, is comprised of Messrs. Hans Black, William Lambert and Graham Strachan. Each member is financially literate and all members of the Audit Committee are independent directors.

#### **Relevant Education and Experience**

Dr. Hans Black received a Bachelor of Science from Union College in New York, law training in France and a Doctorate in Medicine from McGill University. Dr. Black is a founder and CEO of Interinvest, a global money management firm which manages accounts for private and institutional clients. He has been widely quoted, appearing in publications such as Barron's, the International Herald Tribune, the Financial Times, Euromoney and the Wall Street Transcript and appears frequently as a special guest on The Nightly Business Report.

William Lambert is a Special Partner with Birch Hill Equity Partners where he advises on sourcing, monitoring and creating value in its investee companies. Mr. Lambert previously held the position of Managing Director of TD Capital, the private equity arm of the Toronto-Dominion Bank. He has over 12 years' experience in merchant banking and investing, and 10 years' experience in consulting. Mr.

Lambert received his undergraduate degree from Massachusetts Institute of Technology and his M.B.A. from York University. He serves on the board of directors of a number of private and public companies.

Graham Strachan has been involved in the Canadian biotechnology industry for over 25 years. He was one of the founders of Allelix Biopharmaceuticals Inc., serving as president and CEO from 1986 until 1999 when Allelix was acquired by a large US biotechnology company. He is a Chemistry graduate from the University of Glasgow, a registered Patent Agent and a Fellow Emeritus of the Intellectual Property Institute of Canada. Mr. Strachan is presently a principal of GLS Business Development Inc., providing management and business development services to biotechnology organizations. Mr. Strachan serves on the board of directors of a number of public and private companies.

Each Audit Committee member has gained financial literacy through his/her previous working and educational experience and has a significant understanding of the life sciences business which the Company engages in and has an appreciation for the relevant accounting principles for that business.

#### **Reliance on Certain Exemptions**

At no time since the commencement of the Company's most recently completed fiscal year has the Company relied on the exemptions in section 2.4 (*De Minimis Non-audit Services*), section 3.2 (*Initial Public Offerings*), section 3.4 (*Events Outside Control of Member*), section 3.5 (*Death, Disability or Resignation of Audit Committee Member*) or Part 8 (*Exemptions*).

#### **Reliance on the Exemption in Subsection 3.3(2) or Section 3.6**

At no time since the commencement of the Company's most recently completed fiscal year has the Company relied on the exemption in subsection 3.3(2) (*Controlled Companies*) or section 3.6 (*Temporary Exemption for Limited and Exceptional Circumstances*).

#### **Reliance on Section 3.8**

At no time since the commencement of the Company's most recently completed fiscal year has the Company relied on section 3.8 (*Acquisition of Financial Literacy*).

#### **Audit Committee Oversight**

At no time since the commencement of the Company's most recently completed fiscal year was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the Board of Directors.

#### **Pre-Approval Policies and Procedures**

The Audit Committee has adopted a policy requiring the pre-approval by the Committee for the engagement of non-audit services by the Company's external auditors.

#### **External Auditor Service Fees (By Category)**

<b>Fiscal Year End</b>	<b>Audit Fees<sup>(1)</sup></b>	<b>Audit Related Fees</b>	<b>Tax Fees<sup>(2)</sup></b>	<b>All Other Fees</b>
2010	\$69,000	\$-	\$1,995	\$-
2009	\$67,000	\$-	\$-	\$-

- (1) "Audit Fees" include fees necessary to perform the annual audit and a quarterly read of the Company's financial statements. Audit Fees include fees for review of tax provisions and for accounting consultations on matters reflected in the financial statements. Audit Fees also include audit or other attest services required by legislation or regulation, such as comfort letters, consents, reviews of securities filings and statutory audits.
- (2) "Tax Fees" include fees for tax compliance, tax planning and tax advice.

FORM 52-109F1  
CERTIFICATION OF ANNUAL FILINGS  
FULL CERTIFICATE

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2010 JUL 19 P 12:25

I, Robert Gundel, Chief Executive Officer of Amorfix Life Sciences Ltd., certify the following:

1. **Review:** I have reviewed the AIF, if any, annual financial statements and annual MD&A, including, for greater certainty, all documents and information that are incorporated by reference in the AIF (together, the "annual filings") of Amorfix Life Sciences Ltd., (the "issuer") for the financial year ended March 31, 2010.

2. **No misrepresentations:** Based on my knowledge, having exercised reasonable diligence, the annual filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, for the period covered by the annual filings.

3. **Fair presentation:** Based on my knowledge, having exercised reasonable diligence, the annual financial statements together with the other financial information included in the annual filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date of and for the periods presented in the annual filings.

4. **Responsibility:** The issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as those terms are defined in National Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings*, for the issuer.

5. **Design:** Subject to the limitations, if any, described in paragraphs 5.2 and 5.3, the issuer's other certifying officer and I have, as at the financial year end

(a) designed DC&P, or caused it to be designed under our supervision, to provide reasonable assurance that

(i) material information relating to the issuer is made known to us by others, particularly during the period in which the annual filings are being prepared; and

(ii) information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and

(b) designed ICFR, or caused it to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP.

5.1 **Control framework:** The control framework the issuer's other certifying officer and I used to design the issuer's ICFR is the *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

5.2 **ICFR – material weakness relating to design:** N/A

5.3 **Limitation on scope of design:** N/A

6. **Evaluation:** The issuer's other certifying officer and I have

(a) evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer's DC&P at the financial year end and the issuer has disclosed in its annual MD&A our conclusions about the effectiveness of DC&P at the financial year end based on that evaluation; and

(b) evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer's ICFR at the financial year end and the issuer has disclosed in its annual MD&A

(i) our conclusions about the effectiveness of ICFR at the financial year end based on that evaluation; and

(ii) N/A

**7. Reporting changes in ICFR:** The issuer has disclosed in its annual MD&A any change in the issuer's ICFR that occurred during the period beginning on January 1, 2010 and ended on March 31, 2010 that has materially affected, or is reasonably likely to materially affect, the issuer's ICFR.

**8. Reporting to the issuer's auditors and board of directors or audit committee:** The issuer's other certifying officer and I have disclosed, based on our most recent evaluation of ICFR, to the issuer's auditors, and the board of directors or the audit committee of the board of directors any fraud that involves management or other employees who have a significant role in the issuer's ICFR.

Date: June 11, 2010



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Robert Gundel  
Chief Executive Officer

## CERTIFICATION OF ANNUAL FILINGS

2010 JUL 19 P 12:25

## FULL CERTIFICATE

I, James Parsons, Chief Financial Officer of Amorphix Life Sciences Ltd., certify the following:

1. **Review:** I have reviewed the AIF, if any, annual financial statements and annual MD&A, including, for greater certainty, all documents and information that are incorporated by reference in the AIF (together, the "annual filings") of Amorphix Life Sciences Ltd., (the "issuer") for the financial year ended March 31, 2010.

2. **No misrepresentations:** Based on my knowledge, having exercised reasonable diligence, the annual filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, for the period covered by the annual filings.

3. **Fair presentation:** Based on my knowledge, having exercised reasonable diligence, the annual financial statements together with the other financial information included in the annual filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date of and for the periods presented in the annual filings.

4. **Responsibility:** The issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as those terms are defined in National Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings*, for the issuer.

5. **Design:** Subject to the limitations, if any, described in paragraphs 5.2 and 5.3, the issuer's other certifying officer and I have, as at the financial year end

(a) designed DC&P, or caused it to be designed under our supervision, to provide reasonable assurance that

(i) material information relating to the issuer is made known to us by others, particularly during the period in which the annual filings are being prepared; and

(ii) information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and

(b) designed ICFR, or caused it to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP.

5.1 **Control framework:** The control framework the issuer's other certifying officer and I used to design the issuer's ICFR is the *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

5.2 **ICFR – material weakness relating to design:** N/A

5.3 **Limitation on scope of design:** N/A

6. **Evaluation:** The issuer's other certifying officer and I have

(a) evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer's DC&P at the financial year end and the issuer has disclosed in its annual MD&A our conclusions about the effectiveness of DC&P at the financial year end based on that evaluation; and

(b) evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer's ICFR at the financial year end and the issuer has disclosed in its annual MD&A

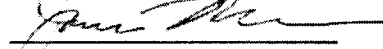
(i) our conclusions about the effectiveness of ICFR at the financial year end based on that evaluation; and

(ii) N/A

**7. Reporting changes in ICFR:** The issuer has disclosed in its annual MD&A any change in the issuer's ICFR that occurred during the period beginning on January 1, 2010 and ended on March 31, 2010 that has materially affected, or is reasonably likely to materially affect, the issuer's ICFR.

**8. Reporting to the issuer's auditors and board of directors or audit committee:** The issuer's other certifying officer and I have disclosed, based on our most recent evaluation of ICFR, to the issuer's auditors, and the board of directors or the audit committee of the board of directors any fraud that involves management or other employees who have a significant role in the issuer's ICFR.

Date: June 11, 2010



James Parsons  
Chief Financial Officer



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**FORM 51-102F3**  
**MATERIAL CHANGE REPORT**  
**UNDER NATIONAL INSTRUMENT 51-102**

**Item 1 Name and Address of Company**

Amorfix Life Sciences Ltd.  
3403 American Drive  
Mississauga, ON L4V 1T4

("Amorfix" or the "Company")

**Item 2 Date of Material Change**

May 31, 2010 and June 2, 2010

**Item 3 News Release**

A News Release was issued by the Company through Canada NewsWire on May 31, 2010 and June 2, 2010 and filed on Sedar.

**Item 4 Summary of Material Change**

Amorfix announced on May 31, 2010 an update on the development of a blood test for vCJD, one of its six product development programs. On June 2, 2010 the Company announced that Dr. George Adams was stepping down as President and Chief Executive Officer and a director of the Company, and announced the appointment of Dr. Robert Gundel as President and Chief Executive Officer.

**Item 5 Full Description of Material Change**

**5.1 Full Description of Material Change**

On May 31, 2010, Amorfix provided an update on the development of a blood test for vCJD, one of its six product development programs. The company has been successful in developing versions 2 and 3 of the test, which differ in the sample preparation steps, and both are four times more sensitive than the first version which underwent testing with vCJD patient blood in December. The company has also been successful in obtaining a rare blood sample from a person in the clinical phase of vCJD. The new versions of the EP-vCJD tests were used to test this sample and it was scored negative by both versions of the test.

The Amorfix test and those of its competitors were developed using blood samples spiked with brain prions from vCJD patients. Amorfix successfully developed the most sensitive and specific test in the world and was the first to access human samples through the UK National Institute of Biological Standards and Control process. Subsequent significant improvements to the test in the last five months did not yield positive results, and the company has reached an impasse until

scientific understanding improves or more vCJD patient blood is available. Accordingly the company will suspend the commercialization of the vCJD project allowing a more focussed effort on the development of novel therapeutics and diagnostics.

On June 2, 2010 the Board of Directors of Amorfix announced that Dr. George Adams was stepping down as President and Chief Executive Officer and a director of the Company and the appointment of Dr. Robert Gundel as President and Chief Executive Officer. Dr. Neil Cashman, scientific founder of Amorfix and an inventor and architect of the ProMIS™ platform, will be re-appointed to the Board at its next meeting on June 9, 2010. The changes are based on a strategic review related to the earlier decision to suspend commercialization of its vCJD blood test and to enable the Company to increase its focus on the priority programs. Consistent with the Company's intent to conserve cash and reduce the burn rate, five employees directly involved with the vCJD project have been released.

## **5.2 Disclosure for Restructuring Transactions**

Not applicable.

### **Item 6 Reliance on subsection 7.1(2) or (3) of National Instrument 51-102**

Not applicable.

### **Item 7 Omitted Information**

Not applicable.

### **Item 8 Executive Officer**

James Parsons  
Chief Financial Officer

Tel: (416) 847-6929

### **Item 9 Date of Report**

June 8, 2010

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**MANAGEMENT'S DISCUSSION AND ANALYSIS OF OPERATING RESULTS  
AND FINANCIAL CONDITION OF AMORFIX LIFE SCIENCES LTD.**

**FOR THE YEARS AND THREE MONTHS ENDED  
MARCH 31, 2010 AND 2009**

The following information prepared as of June 9, 2010 should be read in conjunction with Amorfix Life Sciences Ltd.'s (Amorfix or the Company) March 31, 2010 annual audited financial statements and related notes which are prepared in accordance with Canadian generally accepted accounting principles (GAAP) in Canadian dollars and the Annual Information Form dated June 9, 2010.

**Forward Looking Statements**

This Management's Discussion and Analysis contains forward-looking statements about the Company's business, financial condition, research and development and potential future products, including without limitation, the costs of research and development programs, and timing in achieving research and development and commercialization milestones. Forward-looking statements can be identified by the use of forward-looking terms such as "anticipate", "believe", "expect", "plan", "will", "can", "may," "could" or "should" or comparable terms.

The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors, including, without limitation, the need for extensive additional research and development, which is costly and time-consuming and may not produce anticipated or useful results; scientific research and development risks; intellectual property risks; partnership/strategic alliance risks; the actions of competitors; the need for regulatory approvals such as FDA approvals, which is not assured; product liability and insurance risks; the need for future human clinical testing, the occurrence and success of which is not assured; changes in business strategy or development plans; and the need for additional capital, which may not be obtained; and the fact that the Company may not produce any products or if it does, that such products may not be commercially successful.

By their nature, forward-looking statements involve numerous assumptions, inherent risks and uncertainties, both general and specific, that could cause actual results and experience to differ materially from the anticipated results or other expectations, predictions, forecasts or projections expressed in such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements and should review the "Risks and Uncertainties" below.

**The Company**

Amorfix is an emerging theranostics company focused on the diagnosis and treatment of diseases, where aggregated misfolded proteins (AMP) are prevalent. These include Transmissible Spongiform Encephalopathies (TSE), such as Bovine Spongiform Encephalopathy (BSE) and the human form variant Creutzfeldt-Jakob Disease (vCJD), as well as neurodegenerative diseases such as Alzheimer's Disease (AD) and Amyotrophic Lateral Sclerosis (ALS), and cancer.

Amorfix has developed a key expertise in the field of protein misfolding with its ability to identify regions on proteins that are unique in a diseased state and not in a normal healthy state. These unique regions are called Disease Specific Epitopes™ (DSE) and are selected by Amorfix due to their potential to provide for highly specific diagnostic assessments as well as targets for potential therapeutic drug development.

Amorfix is developing diagnostic products with the goal of detecting the presence of AMPs in tissue, blood or other biofluids. Detection of vCJD prions would improve the safety of blood transfusions and thereby avert the unintended human transmission of prion-contaminated blood. Earlier detection of people with neurodegenerative diseases or cancer has the potential to significantly change the prognosis for these patients and allow for earlier application of emerging therapies. Detection of prions in animals would enable the protection of the food supply.

Amorfix technologies are also being used to develop antibody and vaccine therapies that target Disease Specific Epitopes (DSEs) on disease-relevant proteins as an innovative approach to treat these currently incurable disorders.

Recent scientific publications in the field of neurodegenerative diseases, such as Alzheimer's Disease (AD) and Parkinson's disease, have shown that misfolded proteins can move from cell to cell in the nervous system. This opens the possibility that protein misfolding diseases can be treated, and perhaps cured, by blocking the "propagation" of protein misfolding in the space between cells. Amorfix initially developed its immunotherapeutic approach to amyotrophic lateral sclerosis (ALS) based on the idea that misfolded SOD1 propagates between cells, and can be neutralized by antibodies and thereby stop disease progression. The Company was the first to show antibodies and vaccines to DSEs on misfolded SOD1 could significantly prolong the life of ALS model mice. Building on its growing expertise in this field, the Company has recently expanded its focus to include misfolded proteins in cancer, using its proprietary ProMIS™ platform to predict protein misfolding and identify novel DSEs to develop targeted therapeutics and companion diagnostics.

### **Protecting the Blood Supply**

To date a few hundred people have been diagnosed with vCJD due to consumption of BSE-infected meat, but it is estimated that up to 23,000 people are incubating the disease in the UK alone. Four people have been infected through blood transfusions and thousands of people have received blood fractions made from vCJD-infected plasma pools. There is a general concern in the medical community that vCJD is now within the blood transfusion systems and a screening assay for blood is required to protect everyone from a secondary epidemic.

Globally, approximately 100 million units of blood are collected annually and tested for infectious agents, such as HIV-1 and hepatitis viruses at a cost of US\$4 billion. The market for a blood test for vCJD is estimated to be at least \$500 million per year based on the existing prices for blood tests for other infectious agents.

The Company believes that with its Epitope Protection (EP) platform technology it has developed the most sensitive and specific assay to detect AMPs in blood. Conventional scientific methods to date have been unable to adequately address a fundamental problem

in the detection of AMPs in blood which is the presence of the normal protein at a million-fold higher relative concentration to the misfolded protein. The Company's EP platform technology specifically addresses this issue by chemically modifying the normal proteins while protecting the misfolded aggregates. The Company's first commercial blood screening product is expected to be the EP-vCJD™ Blood Screening Assay that will detect the presence of AMPs for vCJD in human blood.

### Development History

In late 2005, the United Kingdom National vCJD Surveillance Unit and National Institute for Biological Standards and Control (NIBSC) released a series of steps that a blood test for vCJD must pass in order to be accepted. Amorfix entered into this process and from January to June 2006, increased the sensitivity of its vCJD assay using human blood samples spiked with vCJD brain prions. Amorfix and its competitors developed their assays by detecting vCJD brain prions spiked into normal human plasma rather than directly using plasma samples from people who were afflicted by the disease due to the scarcity and unavailability of these patient plasma samples. The culmination of the NIBSC process was to allow developers to gain access to some of these scarce patient plasma samples to validate their tests using clinical samples. In June 2006, Amorfix received a blinded panel from NIBSC of plasma samples containing spiked brain and spleen prions from vCJD patients, and normal controls from blood donors. Amorfix's results on the blinded panel matched internal results and demonstrated leading sensitivity over all companies or academic laboratories that had published results. This significant technical milestone provided independent validation of the Company's research program and provided rationale that an assay for detecting human vCJD prions could be developed.

From July 2006 to June 2007, Amorfix made significant progress in advancing the vCJD prion detection assay towards commercialization. The Company converted the research-based vCJD assay to a commercial 96-well high-throughput platform producing a more sensitive, specific and reproducible assay. A commercial team was hired with in vitro diagnostic device experience, critical vendors were selected and final equipment configurations were established. The Company also established a quality management system and received ISO 13485:2003 certification for its EP-vCJD™ Blood Screening Assay. During this period, the Company made advances in the NIBSC process and applied to access the vCJD patient blood samples. The Company believes that the NIBSC process was subsequently discontinued until it was determined that there would be sufficient human vCJD blood samples available to clinically validate all manufacturers' assays.

In February 2007, the UK National Health Protection Agency (HPA) issued a tender for the supply of 60,000 Research-Use-Only (RUO) tests for blood screening for vCJD prions as part of the UK's effort to understand the prevalence of vCJD in the UK blood donor population. Amorfix applied and qualified to be a potential supplier of products to the UK government. By June 1, 2007, Amorfix had produced sufficient RUO kits to test 60,000 UK blood samples. Amorfix believes that many of its competitors were unable to rapidly meet the requirements of the tender to produce 60,000 tests by June 2007 and

subsequently ceased working on development of their vCJD blood screening assays. Ultimately, the UK HPA did not proceed with this tender.

In February 2008, Amorfix reported the results of a second blinded panel of normal human blood samples spiked with human vCJD brain and spleen prions at different dilutions, and normal human controls provided by NIBSC. Amorfix demonstrated a 10-fold improved sensitivity and improved reproducibility with its commercial high-throughput assay on this 2008 blinded panel compared to its research grade assay blinded panel results from a year earlier.

In July 2007, the Company began adapting its human vCJD blood screening assay into a blood screening test for sheep scrapie to support the clinical validation of the human vCJD assay. In October 2007, the Company announced the completion of an independent blinded panel of sheep blood where the Amorfix sheep scrapie assay (EP-TSE™) was able to detect prion disease in symptomatic sheep. In April 2008, the sheep scrapie blood screening assay was successful at detecting prion disease in presymptomatic scrapie sheep.

In February 2008, the Oversight Committee of NIBSC established a new process to verify the performance of an acceptable blood test for vCJD. Amorfix received and accepted an invitation to further qualify our EP-vCJD™ Blood Screening Assay using British blood samples. NIBSC set out three steps: the first would involve the completion of a blinded panel that contains blood plasma from symptomatic diseased and normal sheep; the second step will be a large panel of normal human blood samples to assess the assay's specificity; and the third step will be a blinded panel that contains among other samples, blood from people who had contracted vCJD. In the first quarter of fiscal 2009, the Company completed a sheep scrapie blinded panel and submitted the results to NIBSC for assessment.

In the second quarter of fiscal 2009, the Company received and accepted an invitation from the British government to further qualify the specificity of its EP-vCJD™ Blood Screening Assay using UK blood donor samples to be supplied by the National Blood Service. The Company completed a blinded study of 1,000 normal and spiked fresh human plasma samples at the Prion Laboratory of NIBSC. On October 8, 2008, the Company announced the results of the study demonstrating 100% sensitivity for all spiked samples. The specificity for all samples was 99.3% on initial testing and 100% on repeat reactive testing.

NIBSC asked the Company to continue testing samples to verify the results and to determine if frozen samples can similarly be used, as all vCJD patient samples are frozen. In the third quarter of fiscal 2009, the Company completed the testing of 500 frozen blinded human plasma samples provided by NIBSC which included some samples spiked with vCJD brain prions. The EP-vCJD™ test successfully detected all (100% sensitivity) of the spiked samples down to a 1 in 100,000 dilution of 10% brain homogenate (1/1,000,000 dilution of vCJD brain).

In April 2009, the Company announced that it was advised that it is required to test additional prion-infected animal samples, supplied by NIBSC, prior to being granted access to the human vCJD blood samples.

In December 2008, the UK Spongiform Encephalopathy Advisory Committee (SEAC) announced the first clinical case of vCJD in a patient with an MV genotype (all previous vCJD clinical cases were MM genotype) and suggested that 50 to 250 further cases might arise in the UK. This was consistent with an editorial in a leading medical journal, *Lancet Neurology*, suggesting “waves” of vCJD cases could be expected. This first MV case of vCJD now shows people with MV genotypes are not resistant to vCJD, but may incubate the disease for a longer time before developing neurological symptoms.

In January 2009, the Company announced that it has initiated large-scale testing of French blood donors to demonstrate the feasibility of routine testing of blood donations for vCJD. The first 20,000 blood samples were completed by June 30, 2009 and were collected using standard procedures from routine blood donors, and anonymously tested for vCJD by staff at the EFS-Alsace Blood Transfusion Centre in Strasbourg, France. Six blood samples were repeat positive, consistent with a specificity of 99.94%, assuming the six samples were in fact negative and falsely scored positive. This specificity for the 1st-generation Amorfix test is equivalent to the specificity achieved by the current 3rd-generation blood screening tests for HIV antibodies currently in use worldwide in blood transfusion centres to assure the safety of blood. The European Union’s In Vitro Diagnostics Technical Group has recommended testing a minimum of 5,000 samples to verify specificity of at least 99.5% for a vCJD blood test. The complete Strasbourg study was presented in July 2009 at le Congrès 2009 de la Société Française de Transfusion Sanguine.

On March 18, 2009, the UK National Health Service published a framework tender under which, when awarded, the NHS may request the supply of blood test kits for a 10,000 sample assessment panel, a 50,000 sample prevalence study, and unlimited kits for routine testing. On July 17, 2009 the contract award was published on the European Tenders Electronic Daily website indicating that Amorfix and one competitor were successful.

On October 29, 2009 the Company announced it has achieved 100% specificity (no reproducible false positive results) upon testing 19,000 blood donations for variant Creutzfeldt-Jakob Disease (“vCJD”) with the EP-vCJD™ Blood Screening Assay at l’Etablissement Français du Sang de Pyrénées Méditerranée (“EFS-PM”) in Montpellier, France. The study in Montpellier included testing of fresh blood within 24 hours of collection and processing of the plasma with an automated sample handling system. This is the same process that would be used in routine blood testing. These results should give governments confidence that very few blood donors will be falsely identified as potentially having vCJD during routine blood screening. Using the settings for maximum sensitivity of 1:1,000,000 dilution of vCJD brain, as verified by testing at the NIBSC in the UK, the test in EFS-PM was 100% specific. Including these 19,000 blood samples collected and tested at EFS-PM, a total of 39,000 blood donations have now been tested at two blood transfusion centers in France. 99.90% specificity was previously reported for 20,000 samples tested at EFS-Alsace in Strasbourg. In both blood transfusion centers using two lots of kits, the EP-vCJD™ test performed better than the 99.85% specificity required by the UK Blood Transfusion Service.

On October 27, 2009, the Company announced the detection of prions in blood from non-human primates that were orally-infected with BSE and developed a primate version of

vCJD. These results are promising although from a small number of tested samples due to the limited number of these very rare primate samples that Amorfix could access. The Company made minor modifications to its EP-vCJD<sup>TM</sup> blood screening assay in order to test the primate samples.

In December 2009, the Company announced that NIBSC provided three plasma samples from three different vCJD patients which the Company tested using the first generation of the EP-vCJD<sup>TM</sup> test. The UK experts estimated based on the concentration of prions in animal blood and brain that the concentration of prions in human blood would be 1:100,000th of that in brain. Since the Amorfix test measures 1:1,000,000th, the Company was confident that the test would be able to identify human vCJD plasma samples from a blinded panel. The samples tested negative and the UK authorities have now concluded that the first generation test is not sufficiently sensitive to detect infected human blood samples.

In December 2009, the Company announced that it was attempting to obtain additional vCJD samples from other countries, and also from individuals with the disease.

During the third and fourth quarter of 2010, The Company continued development activities to improve the sensitivity of its EP-vCJD<sup>TM</sup> blood screening test. In May, 2010 the Company announced that it was successful in developing versions 2 and 3 of the test, which differ in the sample preparation steps, and both are four times more sensitive than the first version which underwent testing with vCJD patient blood in December, 2009. The Company obtained a rare blood sample from a person in the clinical phase of vCJD and used the new versions of the EP-vCJD tests to test this sample and it was scored negative by both versions of the test. Although the Company was successful in developing a 2<sup>nd</sup> and 3<sup>rd</sup> generation of the test with significantly increased sensitivity, these subsequent improvements to the test did not yield positive results in plasma from one human vCJD sample or animal models of the disease, and the Company has reached an impasse until scientific understanding improves or more vCJD patient blood is available. Accordingly, the Company has suspended the commercialization of the vCJD allowing a more focussed effort on its other research programs. Future research may prompt reevaluation of this assessment.

### **Early Diagnosis and Treatment**

Alzheimer's disease (AD), ALS and Parkinson's disease are chronic neurodegenerative illnesses which are associated with neural deposits of AMPs. Unlike the TSE diseases, these diseases are not thought to be infectious and it is believed that their AMPs result from abnormal synthesis or metabolism of the normal neural proteins. Currently, the only definitive diagnostic for these diseases is post-mortem examination of brain tissue. There are currently approximately 5 million people in North America with AD and an equal number with dementia who may be suffering from AD but an accurate diagnosis is impossible due to the lack of a blood test. A sensitive and specific diagnostic blood test could allow earlier treatment for AD patients and would lead to the development of better therapies as patients could be accurately screened into clinical drug trials. It is not known whether aggregated proteins from these diseases are present in blood as there is no test currently that could detect them. Worldwide there are 460 million people over the age of



65 who should be tested annually for AD. There are an estimated 1.6 million people in North America with Parkinson's disease and an estimated 33,000 people with ALS. The Company has the potential to develop diagnostics and therapeutics for each of these neurodegenerative diseases.

### Development History

In January 2006, the Ontario Genomics Institute (OGI) committed \$100,000 of funding through the subscription of common shares and warrants to support the initiation of an Alzheimer's disease blood diagnostic research and development program incorporating the EP platform. OGI invested \$50,000 on signing the agreement and invested a further \$50,000 in September 2006 when Amorfix established the proof of concept of its Epitope Protection technology using Abeta aggregates, the protein known to misfold and aggregate in Alzheimer's disease. This achievement was validated by an expert scientific panel convened by OGI that reviewed the Amorfix data.

On the strength of this data and the development plan, Amorfix was awarded an Industrial Research Assistance Program (IRAP) grant from the Government of Canada in December 2006. Amorfix received \$265,912 of support over the two year term of the grant under this IRAP program.

From December 2006 to March 2008, the Company initiated and progressed its AD diagnostic assay development by screening and selecting monoclonal antibodies, establishing a sample preparation protocol to enrich for the Abeta proteins, assessing several different assay formats and optimizing the assay conditions. The Company developed the assay using synthetic Abeta protein and subsequently demonstrated the ability of the assay to detect Abeta aggregates from AD brain spiked into normal plasma.

In June 2008, the AD test achieved its target sensitivity in being able to detect aggregated Abeta protein of 1 in 1,000,000 dilution of a 10% AD brain homogenate in a plasma sample. At this level of sensitivity, the Amorfix test was not able to detect aggregated Abeta in human blood plasma or cerebral spinal fluid samples.

In September 2009, the Company received a second grant from the National Research Council Canada Industrial Research Assistance Program (NRC-IRAP) of \$50,000 to continue development of an assay to measure Alzheimer's-related amyloid in blood. The sensitivity of the assay has increased and the Company will try again to detect amyloid in AD blood. The Company will first test blood from animal models which is readily available. There continues to be a need for a simple screening test for AD to identify patients, conduct clinical trials of new treatments, and to monitor disease progression.

The Company assessed other potential commercial applications for this very sensitive aggregated Abeta protein assay and identified a commercial market to assay the brain tissue of human transgenic AD mice to assist in the assessment of drug efficacy in these models. The Company's A<sup>4</sup> assay can detect Abeta amyloid in human and animal brain tissue and has been shown to detect amyloid build up in animals much earlier than conventional methods. The Company believes that the A<sup>4</sup> test will accelerate the development and evaluation of new treatments for AD.

On July 25, 2009, the Company presented validation results for the A<sup>4</sup> assay at the International Congress on AD. In October 2009, the Company promoted its A<sup>4</sup> assay service at the Society for Neuroscience meeting in Chicago, Illinois. The Company is seeking collaborations and offering the A<sup>4</sup> test as a service to drug discovery companies and academic researchers working to discover new treatments for AD.

In December 2009, the Company announced that it is conducting pilot studies with several pharmaceutical companies engaged in developing new treatments for AD and one company has publicly announced their results verifying their novel drug's ability to reduce amyloid formation in animal models of AD. The Company has recorded its first sales for this service and expects additional customers to order the test as the pilot studies are completed and the test is integrated into their standard testing protocols. The Company estimates the market for this service to be 50,000 tests per year.

In May 2010, the Company announced the A<sup>4</sup> assay could detect AD-associated aggregated Beta-amyloid in the blood from a mouse model of AD. This achievement represents the first time that aggregated ABeta has been measured in blood plasma from any animal model. The A<sup>4</sup> assay detects both oligomeric and fibrillar aggregates of ABeta, which are generally considered to be the toxic forms and major contributors to brain dysfunction in AD. The quantitative measurement of aggregated ABeta in plasma was obtained using the A<sup>4</sup> on samples from Tg2576 transgenic mice as early as 3 months of age. The Tg2576 mouse is the most commonly used transgenic model for preclinical evaluation of potential AD therapeutics. The aggregated peptide was detected in the blood from transgenic mice, but not in blood from non-transgenic age-matched control mice. This breakthrough will now allow scientists to monitor levels of aggregated Abeta in the blood of individual AD mice as they age and to detect the impact of treatments with novel AD medications. The Company has also added the detection of aggregated Abeta in plasma to its A<sup>4</sup> service offering.

The Company is continuing to develop an AD blood screening test for humans for early diagnosis and monitoring of disease progression.

### **Development of New Diagnostic Tests**

The Company believes that its expertise in the development of highly sensitive and specific diagnostic tests can be applied to the benefit of other potential biomarkers. In early fiscal 2010, the Company announced a collaboration with BioMosaics Inc, a privately-held cancer biomarker development company, to develop and commercialize a blood-based assay for the early detection of hepatocellular carcinoma (HCC) or primary liver cancer. The Company is developing an assay incorporating the existing technology for the blood test licensed to BioMosaics, plus new material from the Sunnybrook Research Institute needed to improve the test. The Company will receive royalties on commercial product sales, and an option to manufacture the assay kits and reagents for global distribution. BioMosaics is responsible for product commercialization. This project is funded by an "Intellectual Property Development and Commercialization Program" investment of \$280,000 from the Ontario Institute for Cancer Research to the

Sunnybrook Research Institute. To March 31, 2010, the Company has received funding of \$127,308 out of the \$200,000 it is eligible to receive.

HCC is the fifth most common cancer in the world, with approximately 600,000 new cases every year. It is the third most common cause of cancer-related death. Early detection could significantly improve treatment outcomes.

In December 2009, the Company announced that it has completed the development of a prototype test and will now start testing clinical samples to determine sensitivity and specificity. A key issue is the ability to differentiate between cirrhosis, hepatitis and HCC.

### **Protecting the Food Supply**

The first case of BSE in cattle emerged in the United Kingdom 17 years ago and there has been a concern about the food supply ever since. The disease has spread to 21 countries and may have crossed over to other species such as sheep and goats. Post-mortem testing of brain tissue has been the only way to accurately detect any of the TSE diseases. The Company believes its Epitope Protection (EP) technology can be used to develop assays for the ante-mortem testing of animals with TSE diseases and remove them from the food chain. The Company has applied its EP technology and developed an assay to detect sheep scrapie. During 2008, Amorfix adapted its vCJD blood screening assay to detect endogenous prions in symptomatic sheep and in the first quarter of fiscal 2009 detected endogenous prions in presymptomatic sheep. Current ante-mortem testing methods for sheep scrapie are not commercializable at scale and may not be accurate enough for broad application where a simple blood test could be adopted quickly and easily.

Scrapie-infected lambs as early as 17 months of age were detected by the Amorfix EP-TSE™ test. Sheep normally show symptoms of scrapie at 3 to 5 years of age. Detection of infected sheep 2 to 3 years prior to symptoms would allow effective removal of infected animals before they have the ability to infect other sheep in the flock. There are over 2,450 sheep ranchers in the United States who have joined the voluntary Scrapie Flock Certification Program which began in 1992 after attempts to eradicate scrapie starting in 1952 were unsuccessful. To date, approximately 500 flocks have been certified as it requires 5 years of continuous monitoring and verification of absence of disease. Similar eradication programs are ongoing in Europe with significant subsidies by the European Commission to eradicate scrapie through genetic testing and culling of susceptible sheep. Current European post-mortem testing of scrapie is labour-intensive as it requires extensive brain tissue preparation. A simple blood test could be used for surveillance as well as eradication and would lead to the identification of animals earlier.

The Company's analysis of the market opportunity for a scrapie test suggests scrapie must be recognized as a public health issue before it would be widely used to eliminate scrapie-infected sheep. Accordingly, the Company has focused its resources on projects with greater market potential at this time and will consider further development with a partner or at a time that scrapie becomes a human health concern.

## **Development of New Therapies**

ALS belongs to a family of fatal neurodegenerative diseases, which includes Alzheimer's and Parkinson's diseases, and in which AMPs are thought to be a major pathway in the progressive killing of brain cells. In ALS, also known as "Lou Gehrig's disease," muscles throughout the body weaken and atrophy, due to degeneration of motor nerve cells that supply them from the spinal cord and brain. Symptoms can start with limb weakness or muscle twitching, stiffness and muscle cramps from ages 40 to 70 years. ALS is a fatal disease in which half of affected people die within three years after diagnosis. The protein that is believed to misfold and aggregate in the central nervous system of ALS patients is called superoxide dismutase-1 (SOD1).

Amorfix's technology targets misfolded SOD1 through two approaches: a passive infusion of manufactured monoclonal antibodies and an active immunization approach designed to elicit the production of similar antibodies by the patient's own body. Amorfix's technology is based on the premise that the misfolding and aggregation of SOD1 is a principal agent in the death of neurons that occurs in brain-wasting diseases. Amorfix believes that if misfolded SOD1 can be specifically recognized and its toxic activity neutralized by antibodies, brain-wasting diseases could be effectively treated.

## **Development History**

In February and April 2006 in a series of agreements, the Company acquired certain SOD1 technologies and exclusively licensed additional SOD1 technologies owned by Dr. Neil Cashman, the Company's Chief Scientific Officer, and his co-inventors for diagnostic and therapeutic applications for ALS disease. A research plan was established to enable proof-of-concept studies to validate the Company's therapeutic approach to the treatment of ALS and potential development partners were contacted.

In August 2006, the Company signed a research and investment agreement with Biogen Idec MA (Biogen) which included an option for Biogen to license the exclusive worldwide rights to certain Amorfix technology to develop and commercialize therapeutic products directed against ALS. Over the following 28 months, Biogen contributed US\$750,000 (Cdn\$860,207) in funding support for the ALS program through subscriptions for 1,243,433 common shares of the Company in an initial investment and three additional investment transactions made on the achievement of predefined research milestones by Amorfix.

In July 2007, the Company achieved the first research milestone, the development of disease-specific antibodies to misfolded SOD1. In October 2008, the Company achieved the second research milestone; the DSE monoclonal antibody treatments demonstrated statistically significant improvement in survival over controls in a mouse model of ALS. In December 2008, the Company announced the achievement of the third research milestone with the completion of the final study report. In February 2009, Biogen allowed its option to license the SOD1 technologies for use in the treatment of ALS to lapse. The Company is seeking to partner with a biopharmaceutical company to humanize the antibodies and initiate clinical trials. As vaccines have different

development timelines and require special expertise compared to the antibodies, Amorfix is seeking other partners to develop the vaccines.

On June 3, 2010, the Company and Pan-Provincial Vaccine Enterprise Inc. (PREVENT) of Saskatoon, Saskatchewan, announced that they have entered into a licensing agreement granting PREVENT exclusive worldwide rights to Amorfix's lead amyotrophic lateral sclerosis (ALS) vaccines. The vaccines have shown efficacy in animal models of ALS and PREVENT will now, at their expense, complete the development and conduct clinical trials.

Under the agreement, PREVENT will receive the exclusive worldwide license to develop Amorfix's DSE™ vaccines for the ALS field of use. Amorfix retains all rights to develop antibodies and diagnostics for ALS. Under the license terms, PREVENT will develop vaccine formulations, finish preclinical studies for regulatory approvals and conduct clinical testing of the vaccines at their cost. Upon successful completion of Phase I clinical trials both parties have an option to lead the commercialization process under a cost-sharing and revenue-sharing arrangement which includes royalty payments.

The licensed intellectual property includes Disease Specific Epitopes (DSE™) and vaccines arising from Amorfix's discovery platform using the ProMIS™ algorithm for prediction of DSEs on misfolded proteins. This unique approach enables the discovery of antibodies that recognize and inhibit only the misfolded protein which forms in the disease, while allowing the normal protein to continue to function.

In November 2007, Amorfix announced the discovery of misfolded SOD1 protein in the brains of people with Alzheimer's Disease (AD). This breakthrough result suggests that SOD1 is a common link between the two brain-wasting diseases, Alzheimer's and ALS. SOD1 has a "Jekyll-and-Hyde" nature as it normally plays an important protective role in detoxifying free radicals in the body, but when misfolded can create lethal oxidative free radicals.

In July 2008, the Company announced a research collaboration to develop Alzheimer's treatments based upon the discovery of misfolded SOD1 protein in the brains of people with Alzheimer's disease. The research program includes preclinical efficacy studies for both antibody treatments and vaccines and is being conducted in Dr. Cashman's laboratory at the Brain Research Center at the University of British Columbia in collaboration with Amorfix scientists, and is supported by a \$227,500 grant from the Canadian Institutes for Health Research (CIHR). The Company has completed its funding of its \$540,000 cash and in-kind contribution commitment to the program. The Company expects results from the first animal series in this study this summer.

Amorfix's technology related to the role of SOD1 in ALS and Alzheimer's is covered by patent applications including one recently published entitled, "Methods and Compositions to treat and Detect Misfolded-SOD1 Mediated Diseases". The patent applications relate to the methods and two compositions for treating and detecting conditions, disease and disorders mediated by non-native SOD1. In December 2008, Amorfix received its first issued patent from the U.S. Patent and Trademark Office titled

“ALS-Specific Peptide Composition”. This patent covers one of the key disease specific epitopes in the SOD1 "Jekyll and Hyde" protein which Amorfix has shown is exposed when it misfolds and becomes toxic for nerve cells. Amorfix DSE™ antibodies bind to this region and we believe neutralize the toxic effects of SOD1 giving the longevity extension Amorfix has previously reported in animal models of ALS.

### **New Misfolded Protein Diagnostics and Therapeutics**

The Company has expanded its research program to identify novel disease-specific epitopes on misfolded proteins. The Company licensed the exclusive rights to the ProMIS™ target identification technology from the University of British Columbia, to predict novel disease specific epitopes on the molecular surface of misfolded proteins. ProMIS™ is an “in silico” rational selection approach that can be applied to any protein where the normal folding structure is at least partially known and predicts how the protein will misfold. There are 57,000 such protein structures currently available in public databases. ProMIS™ has already been used to identify potential DSE’s on three known target proteins likely to be misfolded in cancer and the development of novel immunotherapeutics and companion diagnostics for these diseases has begun.

It is well established that protein misfolding is a central pathological event in many fatal neurodegenerative diseases including Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis. Recently, intriguing evidence for a role of misfolded proteins in cancer has been identified. Studies in our laboratories and others have confirmed this role and there is a growing body of published literature on this topic providing further support for our scientific rationale. The focus on misfolded proteins represents an entirely new approach to the identification of cancer targets and may allow for the development of very selective therapeutics offering greater efficacy and less toxicity.

Cancer cells are stressed by uncontrolled growth, rapid cell division and oxidative damage which can induce protein misfolding, unfolding and partial loss of native protein structure. In some cases, the ability of cancer cells to effectively evade the immune system and continue to grow and spread throughout the body may depend on aberrant signaling by incorrectly folded proteins. It appears that misfolded proteins are tolerated more in cancer cells compared to normal cells where they are either refolded into their proper configuration or discarded. Indirect evidence for the importance of protein misfolding in cancer is derived from the demonstration of increased sensitivity of cancer cells to proteasome inhibitors suggesting the production of a larger quantity of unfolded or misfolded protein compared to normal cells. The selective targeting of cancer cells based on expression of misfolded proteins represents an entirely new avenue for therapeutic intervention.

The primary issues associated with the failure of new therapeutics in the clinic fall into three general categories:

1. The target selected for therapeutic intervention is not causal to the pathogenesis of the disease.
2. The drug being tested fails to either effectively neutralize the disease target; and
3. The drug has off target side effects that make it toxic and prevent its use at therapeutic levels.

Amorfix's strategy to identify novel DSE's on well validated targets using the ProMIS™ technology may solve these problems and provides the Company with the opportunity to produce highly selective and potent proprietary therapeutics with greater efficacy and safety while greatly reducing the risk of failure.

Recent studies with a monoclonal antibody to an undisclosed DSE site on one of the selected proteins confirmed that the misfolded protein is present on cancer cells but not on normal cells. The antibody targets a specific DSE region of the misfolded protein that is not present on the normally folded protein. This new finding indicates that the antibody has potential to be developed for both diagnostic uses and therapeutic treatments for several cancers. The Company is in the process of producing antibodies to these targets for further validation and development.

Once a protein has been identified, antibodies and vaccines can be developed and assessed for therapeutic and diagnostic use. The Company is establishing strategic alliances to expand its capabilities to develop immunotherapeutics to numerous proteins and is also exploring partnerships with other companies to accelerate the development and expand its program to other proteins of interest.

In May 2010, Amorfix entered into an agreement with Epitomics, Inc. to develop high-affinity monoclonal antibodies against a number of DSE targets for cancer predicted by Amorfix's proprietary ProMIS™ computational platform discovery technology. Epitomics, together with its partners, has successfully generated over a dozen humanized therapeutic antibody drug leads targeting immune diseases and cancers using RabMAb® technology and its proprietary Mutation Lineage Guided humanization technology.

In May 2010, Amorfix also entered into an agreement with Aragen BioScience, Inc. to develop high affinity monoclonal antibodies against a number of targets for cancer predicted by ProMIS™. Amorfix has identified several DSEs on misfolded Fas receptor which is a well characterized target on cells that, when activated, causes programmed cell death, or apoptosis. Previous attempts by others to use Fas receptor as a therapeutic target for the development of new anti-cancer therapeutics have failed because its expression and function lead to undesirable side effects on normal cells. Using our ProMIS™ technology, we believe we have identified DSEs on Fas receptor that will provide the required specificity for our mAbs to target and kill tumor cells while leaving normal cells intact.

## **Antibodies**

In October 2009, the Company announced that it has signed an agreement with Cedarlane Laboratories Limited, a leading supplier of antibodies and other research reagents, for the

sale and distribution of certain Amorfix antibodies and reagents for research purposes only.

### **Annual Results of Operations**

Since inception, the Company has incurred losses while advancing the research and development of its diagnostic and therapeutic technologies. The net loss for the year ended March 31, 2010 was \$4,857,038 compared to \$5,148,133 for the year ended March 31, 2009. The reduced net loss in the year ended March 31, 2010 resulted mainly from deferring commercialization efforts related to the vCJD program until the NIBSC process is complete, the completion of the ALS therapeutic program preclinical studies in December 2008 and due to reduced operating expenses to conserve cash, partially offset by expenditures on its ProMIS™ program.

For the year ended March 31, 2010, revenue was \$45,516 compared to \$nil for the year ended March 31, 2009. The Company recorded the first service revenue from its A<sup>4</sup> test and also recorded revenue related to a third party research agreement.

For the year ended March 31, 2010, interest revenue was \$134,063 compared to \$244,499 for the year ended March 31, 2009. The decrease was due mostly to lower market interest rates on investment and cash holdings in the current year than in last year.

Research and development expenditures for the year ended March 31, 2010 were \$3,686,663 compared to \$4,126,945 in the comparable period. Salaries and personnel-related expenses decreased by \$174,646 to \$2,536,694 for the year ended March 31, 2010 due mainly to lower stock-based compensation expense. Research and development program expenses decreased by \$228,491 to \$1,595,566 in the year ended March 31, 2010 due mainly to lower expenditures on the Company's vCJD, AD diagnostic and ALS therapeutic programs partially offset by increased expenditures related to its ProMIS™ program. Investment tax credits and federal and provincial grants recorded for the year ended March 31, 2010 were \$445,597 compared to \$408,452 for last year.

General and administration costs for the year ended March 31, 2010 were \$1,192,527 compared to \$1,040,468 in the comparable period last year. The increase for the year ended March 31, 2010 resulted mainly from higher stock-based compensation and shareholder communication expenses.

Amortization expense for the year ended March 31, 2010 was \$157,427 compared to \$225,219 in the comparable period. The decrease in amortization expense is due mainly to lower property and equipment purchases in the current year.

### **Results of Operations – Fourth Quarter 2010 and 2009**

Net loss for the quarter ended March 31, 2010 was \$1,249,460 compared to \$1,376,339 for the quarter ended March 31, 2009.

For the quarter ended March 31, 2010, interest revenue was \$27,994 as compared to \$55,915 in the same period last year. The decrease was due primarily to lower market



interest rates on investment and cash holdings in the current period than in the comparable period.

For the quarter ended March 31, 2010, research and development expenditures were \$891,991 compared to \$1,064,393 for the quarter ended March 31, 2009. Salaries and personnel-related expenses increased by \$27,804 to \$659,802 due mainly to the hiring of a Vice President of Research and Development partially offset by lower stock-based compensation expenses. Research and development program expenses decreased by \$85,505 to \$396,841 due mainly to lower external costs on its ProMIS™ program. Investment tax credits and grants were \$164,652 for the quarter ended March 31, 2010 compared to \$49,948 for the quarter ended March 31, 2009.

For the quarter ended March 31, 2010, general and administrative costs were \$347,867, which is comparable to the costs incurred in the quarter ended March 31, 2009 of \$323,108.

Amortization expense for the quarter ended March 31, 2010 was \$38,201 compared to \$44,753 for the quarter ended March 31, 2009 due mainly to lower property and equipment purchases in the current year.

### **Liquidity and Capital Resources**

Amorfix is a development stage company as it has earned minimal revenues to date and does not expect to have significant revenues until it is able to sell its product candidates after obtaining applicable regulatory approvals or it establishes collaborations that provide funding, such as licensing fees, milestone payments, royalties, research funding or otherwise. Operations have been financed since inception through the sale of equity securities and the conversion of common share purchase warrants and stock options. The Company's objectives, when managing capital, are to ensure there are sufficient funds available to carry out its research, development and commercialization programs. Once funds have been raised, the Company manages its liquidity risk by investing in highly liquid corporate and government bonds with staggered maturities to provide regular cash flow for current operations. The Company does not hold any asset-backed commercial paper and its cash and cash equivalents are not subject to any external restrictions. The Company also manages liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors reviews and approves the Company's operating and capital budgets, as well as any material transactions not in the ordinary course of business. The majority of the Company's accounts payable and accrued liabilities have maturities of less than three months.

On April 29, 2009, the Company completed a non-brokered private placement through the issuance of 5,146,300 units (Units) at a price of \$0.65 per Unit for gross proceeds of \$3,345,095 (\$3,080,411 net of cash issuance costs). Each issued Unit consisted of one common share and one-half of one common share purchase warrant (Warrant). Each whole Warrant is exercisable into one common share of Amorfix at a price of \$1.00 for a period of 24 months, subject to earlier expiry in the event (a trigger event) that the volume-weighted average price of Amorfix's common shares on the TSX for a ten-day

period exceeds \$1.20. On the occurrence of a trigger event, Amorfix may give notice to warrant holders to accelerate the expiry to a date which is not less than 30 calendar days after such notice is sent to the warrant holders.

In connection with the private placement, the Company issued 348,400 finder warrants having an aggregate fair value of \$68,356 estimated using a barrier option pricing model. Each finder warrant is exercisable into one common share of Amorfix at a price of \$0.68 for a period of 24 months, subject to earlier expiry on the occurrence of a trigger event on the same terms as applies to the Warrants.

The Company incurred a loss of \$4,857,038 for the year ended March 31, 2010 and has a deficit of \$23,758,924 as at March 31, 2010. These circumstances may cast significant doubt as to the ability of the Company to continue as a going concern. While the Company projects that its current working capital of \$4,444,749 is sufficient to fund its operations through to the end of Fiscal 2011, its ability to continue as a going concern beyond that point is dependent on its ability to generate revenues from its products or secure additional financing in order to continue its research and development activities either on its own or with partners. The Company is currently exploring various alternatives to generate positive cash flow including product out-licensing, contracts for blood screening testing for vCJD prevalence studies, and other non-dilutive sources of funding; however there is no assurance that these initiatives will be successful.

The Company measures cash burn as the net cash used in operations, which was down slightly to \$4,033,505 for the year ended March 31, 2010 compared to \$4,130,597 for the year ended March 31, 2009.

During the year ended March 31, 2010, the Company purchased \$11,595 of property and equipment compared to \$113,276 in the comparable period last year. Property and equipment is used primarily for research and development purposes.

Amorfix's working capital requirements may fluctuate in future periods depending on numerous factors, including: results of research and development activities; progress or lack of progress in our diagnostic or therapeutic research and development programs, preclinical studies or clinical testing; the ability to establish corporate collaborations and licensing agreements; the Company's ability to access research and development funding and/or equity financing; changes in the focus, direction, or costs of research and development programs; the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; competitive and technological advances; the potential need to develop, acquire or license new technologies and products; new regulatory requirements implemented by applicable regulatory authorities; the timing and outcome of the regulatory review process; or commercialization activities, if any.

### **Financial Instruments**

Financial instruments consist of cash and cash equivalents, marketable securities, amounts receivable, and accounts payable and accrued liabilities. The Company's cash and cash equivalents and marketable securities are used to fund research activities and administrative overhead. Investment decisions are made in accordance with an

investment policy that establishes guidelines for investment eligibility, credit quality, liquidity and foreign currency exposure.

The Company manages its exposure to credit loss and liquidity risk by placing its cash with major financial institutions and investing in high-quality government and corporate issuers with low credit risk. The Company invests in commercial paper with a Dominion Bond Rating Service (DBRS) rating of R-1 Low or higher, or equivalent Standard & Poor's (S&P) or Moody's Investor Service (Moody's) rating. The Company invests in government and corporate bonds with a DBRS rating of A- or higher, or equivalent S&P or Moody's rating. The Company does not hold any asset-backed commercial paper. Cash and cash equivalents held by the Company are not subject to any external restrictions.

The Company is exposed to interest rate risk arising from fluctuations in interest rates on its cash and cash equivalents and marketable securities and to foreign exchange risk on its holdings of US dollar denominated cash and cash equivalents and marketable securities. The Company manages its interest rate risk by holding its investments to maturity, where possible. The Company manages its exposure to currency fluctuations by holding cash and cash equivalents and marketable securities denominated in US dollars in amounts approximating current US dollar financial liabilities and US dollar planned expenditures. As at March 31, 2010 the Company held US dollar denominated cash and cash equivalents and marketable securities in the amount of US\$126,667.

The Company earns interest revenue from its cash, cash equivalents and marketable securities. The Company considers all cash and cash equivalents as held-for-trading. As at March 31, 2010, cash and cash equivalents consisted of cash on deposit and short-term debt instruments. The Company's marketable securities are all considered as available-for-sale and are carried at fair value with unrealized gains and losses included in other comprehensive income (OCI) until realized, when the cumulative gain or loss is recorded in the statement of operations. For the year ended March 31, 2010 the Company recorded an unrealized loss on marketable securities of \$1,250 (2009 – unrealized gain of \$16,351).

### **Critical Accounting Estimates**

#### **Equity based instruments**

The Company used the Black-Scholes and similar barrier option pricing models to value common share purchase warrants and stock options issued by the Company. These pricing models require the use of several variables involving assumptions including the price volatility of the Company's stock over a relevant timeframe, the expected life of the warrant or option, a relevant risk-free interest rate and the Company's future dividend policy. Changes in the assumptions used can have a significant impact on the values determined. Management has selected these variables and applied the valuation models on a consistent basis.

#### **Income tax valuation allowance**

The Company has a net tax benefit resulting from non-capital losses carried forward, and pools of scientific research and experimental development expenditures and investment tax credits. In view of the history of net losses incurred, management has recorded a full valuation allowance against these future income tax assets.

### **Accounting Changes and New Pronouncements**

Effective April 1, 2009 the Company adopted the Canadian Institute of Chartered Accounts (CICA) Handbook Section 3064, *Goodwill and Intangible Assets*, to replace Section 3062, *Goodwill and Other Intangible Assets* and Section 3450, *Research and Development Costs*. Section 3064 establishes standards for the recognition, measurement and disclosure of goodwill and intangible assets. The changes relating to the definition and initial recognition of intangible assets, including internally generated intangible assets, are equivalent to the corresponding provisions of International Financial Reporting Standards (IFRS). The adoption of this standard did not have an impact on the Company's financial statements.

The Company adopted a revenue recognition policy in the current period as a result of realizing its first antibody sales and service revenues. Revenue is recognized when persuasive evidence of an arrangement exists, product delivery has occurred, services have been performed, the price is fixed or determinable and collectability is reasonably assured.

In June 2009, the CICA issued amendments to Handbook Section 3862, *Financial Instruments – Disclosures*, enhancing disclosure requirements about liquidity risk and fair value measurements of financial instruments, effective no later than March 31, 2010. The enhanced disclosures are included in the March 31, 2010 annual financial statements and are not significant.

The Accounting Standards Board of Canada has announced that public companies in Canada are to adopt IFRS for fiscal years beginning on or after January 1, 2011. The Company is required to prepare its first financial statements that are compliant with IFRS for the interim period ending June 30, 2011. The Company's plan considers the impact that IFRS has on its accounting policies and implementation decisions, financial statement presentation and disclosure options available on initial changeover to IFRS, information technology and data systems, and internal control over financial reporting.

The Company's IFRS convergence project is managed by the Chief Financial Officer with assistance from one professional finance staff member. The Company has a simple corporate structure with no subsidiaries or foreign operations. The Company's compensation plans are not based on Canadian GAAP measurements. For these reasons there is not a need to have a cross functional team of human resources and information technology professionals. A consultant will be brought in to provide expert advice to the accounting team and to provide training to the CEO and the audit committee on the major

differences between Canadian GAAP and IFRS. This is expected to occur during the second quarter of fiscal 2011.

The Company has completed its assessment of the differences between its current accounting policies and IFRS for all of its significant accounting policies. The Company's plan is to have its accounting policies under IFRS finalized by September 30, 2010. The Company's plan includes monitoring changes to IFRS standards throughout the year.

An IFRS standard (IFRS1) provides companies in their first year of adopting IFRS certain optional exemptions and some mandatory exceptions from retrospective application of IFRS. The Company is currently assessing whether it will adopt any of the optional exemptions. It expects that by September 30, 2010 these choices will be finalized.

The Company is currently in the process of reviewing the impact of adopting new accounting policies on its accounting processes and financial results. The Company expects that by December 31, 2010 revisions to accounting processes to comply with any new accounting policies will be completed.

#### **Outstanding Share Data**

The authorized capital of the Company consists of an unlimited number of common shares and an unlimited number of preferred shares. No preferred shares have been issued to date.

The number of issued and outstanding common shares of Amorfix as at March 31, 2010 and to the date of this Management's Discussion and Analysis is presented below:

	<b># Shares</b>
Outstanding April 1, 2009	42,541,181
Issued in equity financing	5,146,300
Issued on exercise of stock options	355,802
Issued on exercise of warrants	474,135
Outstanding March 31, 2010 and June 9, 2010	<u>48,514,418</u>

#### **Warrants**

The following tables reflect the activity of the warrants for the year ended March 31, 2010 and to the date of this Management's Discussion and Analysis, and reflect the potential cash proceeds to the Company on exercise of these instruments:

Exercise price Expiry date	Common share Purchase Warrants \$1.95 March 8, 2010		Common share Purchase Warrants \$1.00 April 29, 2011		Common share Purchase Warrants \$0.68 April 29, 2011	
	#	\$	#	\$	#	\$
	Opening balance, April 1, 2009	4,462,521	8,701,915	-	-	-
Issued	-	-	2,573,150	2,573,150	348,400	236,912
Exercised	-	-	(270,875)	(270,875)	(200,260)	(136,176)
Expired	(4,462,521)	(8,701,915)	-	-	-	-
Closing balance, March 31 and June 9, 2010	-	-	2,302,275	2,302,275	148,140	100,736

In accordance with the accelerated maturity provisions of the \$1.00 warrants and the \$0.68 warrants, the Company shortened the expiry date of the warrants from April 29, 2011 to January 19, 2010. Effective December 4, 2009, the Company extended the expiry of the \$1.00 purchase warrants to April 29, 2011 and on February 4, 2010, the Company extended the expiry of the \$0.68 purchase warrants to April 29, 2011 and recorded an increase in other equity in the amount of \$141,000 representing the incremental value of the warrants at the dates of extension, with an offsetting charge recorded directly to the Company's deficit. These warrants continue to be subject to earlier expiry upon the occurrence of the trigger event that the volume-weighted average price of Amorfix's common shares on the TSX for a ten-day period exceeds \$1.20.

### Stock Options

The following table reflects the activity under the Company's stock option plan for the year ended March 31, 2010.

	# Options	Weighted Average Exercise Price
Outstanding April 1, 2009	4,542,375	\$ 0.96
Granted	1,076,125	\$ 0.94
Exercised	(355,802)	\$ 0.65
Expired	(64,656)	\$ 1.09
Outstanding March 31, 2010	5,198,042	\$ 0.98
Exercisable, March 31, 2010	4,258,428	\$ 0.99

### Deferred Share Unit (DSU) Plan

The following table reflects the activity under the Company's DSU plan for the year ended March 31, 2010.

	# Units
Outstanding April 1, 2009	346,092
Issued	264,000
Outstanding March 31, 2010	610,092

## Selected Annual Financial Information

Key Financial Indicators	Year ended March 31, 2010	Year ended March 31, 2009	Year ended March 31, 2008
Revenue and Interest earned	\$179,579	\$244,499	\$477,615
Research and development expenses	\$3,686,663	\$4,126,945	\$6,240,108
General and administrative expenses	\$1,192,527	\$1,040,468	\$1,259,197
Net loss	(\$4,857,038)	(\$5,148,133)	(\$7,189,981)
Net loss per common share	(\$0.10)	(\$0.12)	(\$0.17)
Working capital	\$4,444,749	\$4,458,065	\$8,119,896
Cash flow used in Operations	(\$4,033,505)	(\$4,130,597)	(\$5,562,288)
Total assets	\$5,408,724	\$5,517,184	\$9,990,282
Net cash proceeds from equity financing	\$3,719,773	\$272,622	\$160,944
Weighted average common shares outstanding	47,711,070	41,985,488	41,297,742

## Quarterly Selected Financial Information

The following tables sets out selected financial information for the Company for the preceding eight quarters. The quarterly net loss in the first quarter of fiscal 2009 reflected higher costs from development of a commercial-grade vCJD assay with associated scale-up and quality system costs, as well as the costs of new development programs for the Alzheimer's disease ante-mortem blood diagnostic test and the ALS therapeutic program initiated in 2007. The decreased net loss in last three quarters of fiscal 2009 and the four quarters of fiscal 2010 reflects the deferral of vCJD commercialization costs as the Company completes the NIBSC process, and lower R&D and general and administrative expenditures arising from general cash conservation measures taken by management.

	2010				2009			
	4th Quarter	3rd Quarter	2nd Quarter	1st Quarter	4th Quarter	3rd Quarter	2nd Quarter	1st Quarter
Revenue and interest earned	28,599	\$ 71,381	\$ 38,315	\$ 41,284	\$ 55,915	\$ 54,206	\$58,525	\$75,853
Net loss	(1,249,460)	(\$1,149,932)	(\$1,286,905)	(\$1,170,741)	(\$1,376,339)	(\$1,017,663)	(\$1,147,947)	(\$1,606,184)
Net loss per common share	(\$0.03)	(\$0.02)	(\$0.03)	(\$0.03)	(\$0.03)	(\$0.02)	(\$0.03)	(\$0.04)

The Company's year end is March 31.

## Contractual Arrangements and Commitments

In February 2009, the Company entered into an agreement with the University of British Columbia (UBC) to further the development of and to commercialize technology developed in part by Dr. Cashman that may predict DSE regions on proteins. Under the agreement, the Company is committed to make milestone payments up to \$1,400,000 per product developed using this technology based on the successful

outcomes of predefined clinical and regulatory outcomes, and to make royalty payments to UBC based on revenue earned from the licensed technology.

Under the terms of a contribution agreement with the National Research Council Canada under the Industrial Research Assistance Program (IRAP), the Company received a grant to support research on its Alzheimer's disease diagnostic test. In certain limited circumstances, including where the Company exports control of this technology out of Canada through sale or licence, the Company may be required to repay up to two times the amount of the IRAP grant received. The Company received \$265,912 in funding and has not recorded any liability for this contingent repayment as the terms for repayment have not been met.

The Company is committed to the following payments under the terms of its lease agreements for the years ending March 31,

	\$
2011	227,500
2012	229,300
2013	134,500

#### **Related Party Transactions**

During fiscal 2008 and 2009, the Company entered into three agreements with UBC, with Dr. Cashman, an officer of the Company, as principal investigator, to fund research related to the Company's research and development programs in the amount of \$749,799. During 2010, \$519,420 was paid to UBC. The Company has no remaining obligations for these three agreements.

In August 2009, the Company entered into an assignment agreement with the University of Toronto and Dr. Neil Cashman to acquire certain technology related to its ProMIS™ research program. The Company paid \$2,000 for the technology and will pay royalties on the commercial sale of any product candidates developed from the technology.

During the year ended March 31, 2010, the Company paid a consulting fee to a director of Amorfix in the amount of \$4,500.

A Company controlled by a director of Amorfix provides investment advisory services to Amorfix.

#### **Risks and Uncertainties**

Prospects for companies in the biotechnology industry generally may be regarded as uncertain given the nature of the industry and, accordingly, investments in biotechnology companies should be regarded as speculative. Biotechnology research and development involves a significant degree of risk. An investor should carefully consider the risks and uncertainties described below, as well as other information contained in this



Management's Discussion and Analysis. The risks and uncertainties described below is not an exhaustive list. Additional risks and uncertainties not presently known to the Company or that the Company believes to be immaterial may also adversely affect the Company's business. If any one or more of the following risks occur, the Company's business, financial condition and results of operations could be seriously harmed. Further, if the Company fails to meet the expectations of the public market in any given period, the market price of the Company's common shares could decline.

**Early Stage Development and Scientific Uncertainty.** Several of Amorfix's products are at an early stage of development. Significant additional investment in research and development, product validation, technology transfer to manufacturing, production scale-up, manufacturing, clinical testing, and regulatory submissions of such product candidates is required prior to commercialization. There can be no assurance that any such products will actually be developed. The development and regulatory processes may require access to rare biofluid and tissue samples from people and animals with AMP diseases which may not be available to the Company in sufficient amounts or in a timely fashion to allow Amorfix to complete the development or receive regulatory approval of any product or process. The presence of AMPs in human blood has never been measured and so may be not present or at levels so low as to be unmeasurable. A commitment of substantial time and resources is required to conduct research and clinical trials if Amorfix is to complete the development of any product. It is not known whether any of these product or process candidates will meet applicable health regulatory standards and obtain required regulatory approvals, or whether such products can be produced in commercial quantities at reasonable costs and be successfully marketed, or whether ante-mortem diagnostic tests for AMP diseases will achieve market acceptance, or if Amorfix's investment in any such products will be recovered through sales or royalties.

**Lack of Product Revenues and History of Losses.** To date, Amorfix has not recorded any revenues from the sale of biopharmaceutical products. As at March 31, 2010, Amorfix has a deficit of \$23,758,924. Amorfix expects to incur additional losses during the periods of research and development, clinical testing, and application for regulatory approval of its product candidates. Amorfix expects to incur losses unless and until such time as payments from corporate collaborations, product sales and/or royalty payments generate sufficient revenues to fund its continuing operations.

**Additional Financing Requirements and Access to Capital.** Amorfix will require substantial additional funds for further research and development, planned clinical testing, regulatory approvals, establishment of manufacturing capabilities and, if necessary, the marketing and sale of its products. Amorfix may attempt to raise additional funds for these purposes through public or private equity or debt financing, collaborations with other biopharmaceutical companies and/or from other sources. There can be no assurance that additional funding or partnerships will be available on terms acceptable to Amorfix and which would foster successful commercialization of Amorfix's products.

**Patents and Proprietary Technology.** Amorfix's success will depend in part on its ability to obtain, maintain, and enforce patent rights, maintain trade secret protection and operate without infringing the proprietary rights of third parties. There can be no assurance that pending patent applications will be allowed, that Amorfix will develop additional proprietary products that are patentable, that issued patents will provide Amorfix with any competitive advantage or will not be challenged by any third parties, or that patents of others will not have an adverse effect on the ability of Amorfix to do business. Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of Amorfix's products, or design around the products patented by Amorfix. In addition, Amorfix may be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any licenses required under such patents or proprietary rights will be available on terms acceptable to Amorfix. If Amorfix does not obtain such licenses it could encounter delays in introducing one or more of its products to the market, while it attempts to design around such patents, or could find that the development, manufacturing or sale of products requiring such licenses could be foreclosed. In addition, Amorfix could incur substantial costs in defending itself in suits brought against it on such patents or in suits where it attempts to enforce its own patents against other parties.

Until such time, if ever, that patent applications are filed, the ability of Amorfix to maintain the confidentiality of its technology may be crucial to its ultimate possible commercial success. While Amorfix has adopted procedures designed to protect the confidentiality of its technology, no assurance can be given that such arrangements will be effective, that third parties will not gain access to Amorfix's trade secrets or disclose the technology, or that Amorfix can meaningfully protect its rights to its trade secrets.

**Dependence on Collaborative Partners, Licensors and Others.** Amorfix's activities will require it to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, manufacturing, marketing and commercialization of its products. Amorfix intends to attract corporate partners and enter into additional research collaborations. There can be no assurance, however, that Amorfix will be able to establish such additional collaborations on favorable terms, if at all, or that its current or future collaborations will be successful. Failure to attract commercial partners for its products may result in the Company incurring substantial clinical testing, manufacturing and commercialization costs prior to realizing any revenue from product sales or result in delays or program discontinuance if funds are not available in sufficient quantities.

Should any collaborative partner fail to develop, manufacture, or commercialize successfully any product to which it has rights, or any partner's product to which Amorfix will have rights, Amorfix's business may be adversely affected. Failure of a collaborative partner to continue to participate in any particular program could delay or halt the development or commercialization of products generated from such program. In addition, there can be no assurance that the collaborative partners will not pursue other technologies or develop alternative products either alone or in collaboration with others,

including Amorfix's competitors, as a means for developing treatments for the diseases targeted by Amorfix's programs.

Furthermore, Amorfix will hold licenses for certain technologies and there can be no assurance that these licenses will not be terminated, or that they will be renewed on conditions acceptable to Amorfix. Amorfix intends to negotiate additional licenses in respect of technologies developed by other companies and academic institutions. Terms of license agreements to be negotiated may include, inter alia, a requirement to make milestone payments, which may be substantial. Amorfix will also be obligated to make royalty payments on the sales, if any, of products resulting from licensed technology and, in some instances, may be responsible for the costs of filing and prosecuting patent applications.

**Government Regulations.** Biotechnology and pharmaceutical companies operate in a high-risk regulatory environment. The manufacture and sale of animal and human diagnostic and therapeutic products is governed by numerous statutes and regulations in the United States, Canada and other countries where Amorfix intends to market its products. The subject matter of such legislation includes approval of manufacturing facilities, controlled research and testing procedures, review and approval of manufacturing, preclinical and clinical data prior to marketing approval, as well as regulation of marketing activities, notably advertising and labelling.

The process of completing clinical testing and obtaining required approvals is likely to take several years and require the expenditure of substantial resources. Furthermore, there can be no assurance that the regulators will not require modification to any submissions which may result in delays or failure to obtain regulatory approvals. Any delay or failure to obtain regulatory approvals could adversely affect the ability of Amorfix to utilize its technology, thereby adversely affecting operations. Further, there can be no assurance that Amorfix's diagnostic product candidates will achieve levels of sensitivity and specificity sufficient for regulatory approval or market acceptance, or that its therapeutic product candidates prove to be safe and effective in clinical trials, or receive the requisite regulatory approval. There is no assurance that the Company will be able to timely and profitably produce its products while complying with all the applicable regulatory requirements. Foreign markets, other than the United States and Canada, impose similar restrictions.

**Hazardous Materials and Environmental Matters.** Certain of Amorfix's research and development processes will involve the controlled use of hazardous materials. Amorfix is subject to federal, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although management of Amorfix believes that its procedures for handling and disposing of such materials comply with the standards prescribed, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, Amorfix could be held liable for damages and such liability could exceed the resources of Amorfix. Amorfix is not specifically insured with respect to this liability. Although management of Amorfix believes that Amorfix currently complies in all material respects with applicable environmental laws and regulations,

Amorfix may be required to incur significant costs to comply with environmental laws and regulations in the future. Furthermore, there can be no assurance that the operations, business or assets of Amorfix will not be materially adversely affected by current or future environmental laws or regulations.

**Rapid Technological Change.** The biotechnology and pharmaceutical industries are characterized by rapid and substantial technological change. There can be no assurance that developments by others will not render Amorfix's products or technologies non-competitive, or that Amorfix will keep pace with technological developments. Competitors have developed or are developing technologies that could be the basis for competitive products. Some of these products have an entirely different approach or means of accomplishing the desired diagnostic or therapeutic effect as compared with products to be developed by Amorfix, and could be more effective and less costly than the products to be developed by Amorfix. In addition, alternative forms of medical treatment may be competitive with Amorfix's products.

**Competition.** Technological competition from pharmaceutical companies, biopharmaceutical companies and universities is intense and is expected to increase. Potential competitors of Amorfix have or may develop product development capabilities or financial, scientific, marketing and human resources exceeding those of Amorfix. Competitors may develop products before Amorfix develops its own products, obtain regulatory approval for such products more rapidly than Amorfix, or develop products which are more effective than those which Amorfix intends to develop. Research and development by others may render Amorfix's technology or products obsolete or non-competitive or produce treatments or cures superior to any therapy developed or to be developed by Amorfix, or otherwise preferred to any therapy developed by Amorfix.

**Reliance on Key Personnel.** Amorfix is dependent on certain members of its management and scientific staff, the loss of services of one or more of whom could adversely affect Amorfix. In addition, Amorfix's ability to manage growth effectively will require it to continue to implement and improve its management systems and to recruit and train new employees. There can be no assurance that Amorfix will be able to successfully attract and retain skilled and experienced personnel.

**Status of Healthcare Reimbursement.** Amorfix's ability to successfully market certain diagnostic or therapeutic products may depend in part on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Significant uncertainty exists as to whether newly approved healthcare products will qualify for reimbursement. Furthermore, challenges to the price of medical products and services are becoming more frequent. There can be no assurance that adequate third-party coverage will be available to establish price levels, which would allow Amorfix to realize an acceptable return on its investment in product development.

**Potential Product Liability.** Pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. Product liability insurance is

costly, availability is limited and may not be available on terms which would be acceptable to Amorfix, if at all. An inability to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of Amorfix's potential products. A product liability claim brought against Amorfix, or withdrawal of a product from the market, could have a material adverse effect upon Amorfix and its financial condition.

**Volatility of Share Price, Absence of Dividends and Fluctuation of Operating Results.** Market prices for the securities of biotechnology companies, including the Company, have historically been highly volatile. Factors such as fluctuation of the Company's operating results, announcements of technological innovations, patents or new commercial products by Amorfix or competitors, results of clinical testing, regulatory actions, or public concern over the safety of biopharmaceutical products and other factors could have a significant effect on the share price or trading volumes for the common shares. The Company's common shares have been subject to significant price and volume fluctuations and may continue to be subject to significant price and volume fluctuations in the future. Amorfix has not paid dividends to date and does not expect to pay dividends in the foreseeable future.

#### **Disclosure Controls and Procedures**

The Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of the Company's disclosure controls and procedures as at the financial year ended March 31, 2010. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the design and operation of these disclosure controls and procedures were effective as at March 31, 2010 to provide reasonable assurance that material information relating to the Company, would be made known to them by others within the Company.

#### **Internal Control over Financial Reporting**

As at the financial year ended March 31, 2010, the Chief Executive Officer and Chief Financial Officer evaluated the design of the Company's internal control over financial reporting. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the design of internal control over financial reporting was effective as at March 31, 2010 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with Canadian GAAP. No material weaknesses in internal controls over financial reporting were identified. There were no changes in the Company's internal control over financial reporting that occurred during the most recent interim period that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**Additional Information**

Additional information relating to the Company, including its Annual Information Form, can also be found on SEDAR at [www.sedar.com](http://www.sedar.com).

Attention Business Editors:  
Amorfix and QED Bioscience announce agreement to develop novel  
monoclonal antibodies for cancer

TSX: AMF

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2010 JUL 19 P 12:29

TORONTO, June 24 /CNW/ - Amorfix Life Sciences and QED Bioscience announced today that they have entered into an agreement to develop high-affinity monoclonal antibodies against a number of targets for cancer. Under the agreement, QED will generate monoclonal antibodies against several disease specific epitopes (DSE's) on misfolded CD38 protein. The DSE's were identified by Amorfix using their proprietary PromIS(TM) computational platform discovery technology.

"CD38 is a well characterized target on the surface of a variety of lymphoid tumors including multiple myeloma, AIDS-related lymphomas and post-transplant lymphoproliferations and is part of a complex network producing growth and survival signals to tumor cells. As such, CD38 represents an attractive target for therapeutic intervention with a specific antibody," said Dr. Robert Gundel, Chief Executive Officer at Amorfix. "Using our PromIS(TM) technology, we have identified DSE's on misfolded CD38 that may provide the required specificity for our antibody to target and kill tumor cells expressing this protein while leaving normal cells intact. In addition, CD38 can be used as a prognostic marker which fits well into our strategy of developing companion diagnostics along with novel therapeutic antibodies. We are very pleased to be collaborating with QED Bioscience on this important and exciting project."

"We are very happy for the opportunity to add our expertise in monoclonal antibody development to the outstanding research being conducted at Amorfix" said Dr. Eileen Skaletsky, President and CEO of QED Bioscience. "Their technology is ideal for generating unique antibody targets, and we are looking forward to a rewarding and fruitful collaboration."

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting misfolded protein diseases including ALS, cancers, and Alzheimer's Disease (AD). Amorfix utilizes its computational discovery platform, PromIS(TM), to predict novel Disease Specific Epitopes ("DSE") on the molecular surface of misfolded proteins. Amorfix's lead programs include therapeutics and companion diagnostics for cancers and antibodies and vaccines to DSEs in ALS and AD. Amorfix's proprietary technology enables it to specifically identify very low levels of misfolded proteins in a normal sample. The Company's diagnostic programs include an ultrasensitive method for the detection of aggregated Beta-Amyloid in brain tissue and blood of animal models of AD, months prior to observable amyloid formation, and a blood screening test for liver cancer. For more information about Amorfix, visit [www.amorfix.com](http://www.amorfix.com).

#### About QED Bioscience

QED Bioscience is a leader in the field of custom antibody development for academic and industrial applications. With more than 20 years of experience in this field, QED Bioscience applies its proven proprietary methods to development of novel monoclonal and polyclonal antibodies from program design through small- or large-scale manufacturing. QED Bioscience's repertoire includes genetic immunization, anti-idiotypic antibody development, and a patented growth medium for rapid and economical production of monoclonal antibodies in vitro. For more information about QED Bioscience visit [www.qedbio.com](http://www.qedbio.com).

This information release may contain certain forward-looking information. Such information involves known and unknown risks, uncertainties and other

factors that may cause actual results, performance or achievements to be materially different from those implied by statements herein, and therefore these statements should not be read as guarantees of future performance or results. All forward-looking statements are based on the Company's current beliefs as well as assumptions made by and information currently available to it as well as other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Due to risks and uncertainties, including the risks and uncertainties identified by the Company in its public securities filings, actual events may differ materially from current expectations. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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/For further information: Dr. Robert Gundel, President & Chief Executive Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6957, Fax: (416) 847-6899, bob.gundel(at)amorfix.com; James Parsons, Chief Financial Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6929, Fax: (416) 847-6899, james.parsons(at)amorfix.com/  
(AMF.)

CO: Amorfix Life Sciences Ltd.

CNW 07:00e 24-JUN-10



News release via Canada NewsWire, Toronto, 416-863-9350

Attention Business Editors:

Amorfix announces fiscal 2010 year end results.

TSX: AMF

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2010 JUL 19 P 12:28

TORONTO, June 11 /CNW/- Amorfix Life Sciences, a company focused on the development of therapeutic monoclonal antibodies and diagnostics for the treatment of fatal neurodegenerative diseases and cancer, today announced its operational and financial results for the year ended March 31, 2010, as well as financial results for the fourth quarter.

"This is an exciting time for Amorfix as we begin fiscal 2011 with a broad pipeline of therapeutic and diagnostic programs with significant milestones planned for all programs this year," said Dr. Robert Gundel, Chief Executive Officer of Amorfix. "We have established excellent partnerships to develop novel antibody therapeutics against unique cancer targets for our PromIS(TM) program which represents a significant opportunity to quickly create value for our company as safer and more effective cancer drugs are desperately needed. Our A(4) assay service revenue is growing and the experience gained from this development program has provided us with an opportunity to develop a very sensitive Alzheimer's diagnostic for human biofluid screening that may revolutionize the way this disease is diagnosed and treated. Our partnership with PREVENT to advance our ALS vaccine program into the clinic and our ALS and Alzheimer's disease (AD) therapeutic antibody programs represent other significant opportunities for the continued strengthening of our product pipeline of novel therapeutics for the treatment of human disease."

#### Recent Corporate Highlights

In May 2010, the Company announced the A4 assay could detect AD-associated aggregated Beta-amyloid in the blood from a mouse model of AD. This achievement represents the first time that aggregated ABeta has been measured in blood plasma from any animal model.

In May 2010, the company announced that it had entered into agreements with Epitomics, Inc. and Aragen Biosciences, Inc. to develop high-affinity monoclonal antibodies against a number of Disease Specific Epitope (DSE) targets for cancer predicted by Amorfix's proprietary PromIS(TM) computational platform discovery technology.

In May 2010, the Company announced that although it has been successful in developing a significantly more sensitive test for the detection of vCJD in blood samples, the improvements to the test did not yield positive results, and the Company has reached an impasse until scientific understanding improves or more vCJD patient blood is available and accordingly the Company suspended the commercialization of the vCJD program allowing a more focussed effort on its other research programs.

In June 2010, the Company and Pan-Provincial Vaccine Enterprise Inc. (PREVENT) of Saskatoon, Saskatchewan, announced that the two groups have entered into a licensing agreement granting PREVENT exclusive worldwide rights to Amorfix's lead amyotrophic lateral sclerosis (ALS) vaccines. Under the license terms, PREVENT will develop vaccine formulations, finish preclinical studies for regulatory approvals and conduct clinical testing of the vaccines at their cost. Upon successful completion of Phase I clinical trials both parties have an option to lead the commercialization process under a cost-sharing and revenue-sharing arrangement which includes royalty payments.

#### Financial Results

For the three months ended March 31, 2010 the Company reported a net loss from operations of \$1,249,460 (\$0.03 per share) compared to net loss of \$1,376,339 (\$0.03 per share) for the three months ended March 31, 2009.

For the year ended March 31, 2010 the Company reported a net loss from operations of \$4,857,038 (\$0.10 per share) compared to a net loss of

\$5,148,133 (\$0.12 per share) for the year ended March 31, 2009.

The Company recorded service revenue from the A(4) test and also recorded revenue related to a third party research agreement totalling \$45,516.

Research and development (R&D) expenses for the three months ended March 31, 2010 were \$891,991 compared with \$1,064,393 for the three months ended March 31, 2009. The decrease was due mainly to lower external costs on its PromIS(TM) program and lower stock-based compensation expenses.

R&D expenses for the year ended March 31, 2010 were \$3,686,663 compared with \$4,126,945 for the corresponding period in 2009. The decrease was due mainly to lower expenditures on the Company's vCJD, AD diagnostic and ALS therapeutic programs and lower stock-based compensation partially offset by increased expenditures related to its PromIS(TM) program.

General and administrative expenses for the three months ended March 31, 2010 were \$347,867 which is comparable to the costs of \$323,108 that were incurred in the corresponding period in 2009.

General and administrative expenses for the year ended March 31, 2010 were \$1,192,527 compared with \$1,040,468 for the corresponding period in 2009. The increase for the year ended March 31, 2010 resulted mainly from higher stock-based compensation and shareholder communication expenses.

At March 31, 2010, the Company had working capital of \$4,444,749 and 48,514,418 common shares outstanding.

#### Outlook

The Company's Fiscal 2011 research priorities are to:

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- Advance our PromIS(TM) antibody program targeting disease specific epitopes for both therapeutics and companion diagnostics for cancer and other misfolded protein diseases to a lead compound for late-stage preclinical development;
- Advance our novel antibodies and vaccines for the treatment of ALS and AD;
- Grow the revenue from our A(4) amyloid testing service for cell culture, tissue and blood in animal models of Alzheimer's disease (AD);
- Complete development of a human Alzheimer's test adapting the A(4) test protocol to detect aggregated Abeta, the hallmark of the disease, in human plasma and cerebro-spinal fluid; and

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The Company also announced that Dr. Neil Cashman, Chief Scientific Officer and founder, and Dr. Robert Gundel, Chief Executive Officer of the company have been appointed to the Board of Directors.

Additional information about the Company, including the MD&A and financial results may be found on SEDAR at [www.sedar.com](http://www.sedar.com).

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting misfolded protein diseases including ALS, cancer, and Alzheimer's disease. Amorfix utilizes its computational discovery platform, PromIS(TM), to predict novel Disease Specific Epitopes ("DSE") on the molecular surface of misfolded proteins. Amorfix's lead therapeutic programs include antibodies and vaccines to DSEs in ALS, Alzheimer's disease and cancer. Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a normal sample. The Company's diagnostic programs include an ultrasensitive method for the detection of aggregated Beta-Amyloid in brain tissue and blood of animal models of Alzheimer's disease, months prior to observable amyloid formation, and human blood screening tests for Alzheimer's and early liver cancer detection. For more information about Amorfix, visit [www.amorfix.com](http://www.amorfix.com).

The TSX has not reviewed and does not accept responsibility for the adequacy or accuracy of this release. This information release may contain certain forward-looking information. Such information involves known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from those implied by statements herein, and therefore these statements should not be read as guarantees of future performance or results. All forward-looking statements are based on the Company's current beliefs as well as assumptions made by and information currently available to it as well as other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Due to risks and uncertainties, including the risks and uncertainties identified by the Company in its public securities filings, actual events may differ materially from current expectations. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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/For further information: Dr. Robert Gundel, President and Chief Executive Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6957, Fax: (416) 847-6899, bob.gundel(at)amorfix.com; James Parsons, Chief Financial Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6929, Fax: (416) 847-6899, james.parsons(at)amorfix.com/  
(AMF.)

CO: Amorfix Life Sciences Ltd.

CNW 07:00e 11-JUN-10

Attention Business Editors:  
Amorfix Life Sciences and PREVENT announce global licensing agreement  
for the treatment of ALS

TSX: AMF

RECEIVED  
2010 JUL 19 P 12:29

TORONTO, June 3 /CNW/ - Amorfix Life Sciences Ltd. (TSX:AMF) and Pan-Provincial Vaccine Enterprise Inc. (PREVENT) of Saskatoon, Saskatchewan, today announced that the two groups have entered into a licensing agreement granting PREVENT exclusive worldwide rights to Amorfix's lead amyotrophic lateral sclerosis (ALS) vaccines. The vaccines have shown efficacy in animal models of ALS and PREVENT will now, at their expense, complete the development and conduct clinical trials.

"We are pleased the leading organization in Canada for the commercialization of vaccines, PREVENT, has selected our vaccine technology and will take over the clinical development of our lead vaccine candidates for ALS," said Dr. Robert Gundel, President and CEO of Amorfix. "This validates the value of our PromIS(TM) discovery platform, which we are using now to develop diagnostics, antibodies and vaccines for cancers and misfolded protein diseases."

"The Amorfix ALS vaccine intellectual property, and its development program, are a great addition to the PREVENT portfolio pipeline," commented Dr. Naveen Anand, CEO of PREVENT. "The program combines the right elements of academic research, industrial involvement, novel technology and medical needs to enable a good fit with our mandate."

Under the agreement, PREVENT will receive the exclusive worldwide license to develop Amorfix's DSE(TM) vaccines for the ALS field of use. Amorfix retains all rights to develop antibodies and diagnostics for ALS. Under the license terms, PREVENT will develop vaccine formulations, finish preclinical studies for regulatory approvals and conduct clinical testing of the vaccines at their cost. Upon successful completion of Phase I clinical trials both parties have an option to lead the commercialization process under a cost-sharing and revenue-sharing arrangement which includes royalty payments.

"It is great to see a partnership between two Canadian organizations to address new treatments for ALS," said Mr. David Cameron, President to the ALS Society of Canada, "A better treatment for ALS is urgently needed."

The licensed intellectual property includes Disease Specific Epitopes (DSE(TM)) and vaccines arising from Amorfix's discovery platform using the PromIS(TM) algorithm for prediction of DSEs on misfolded proteins. This unique approach enables the discovery of antibodies that recognize and inhibit only the misfolded protein which forms in the disease, while allowing the normal protein to continue to function.

"We have only just begun to use DSEs to rationally design new treatments for many misfolded-protein illnesses" said Dr. Neil Cashman, Chief Scientific Officer of Amorfix.

Amorfix continues to discuss with potential partners alliances for the continued development of the antibodies and diagnostic applications for ALS and new projects for the PromIS(TM) discovery platform. These alliances will be announced when they are completed.

#### About PREVENT

PREVENT is a Centre of Excellence for Commercialization and Research under the Networks of Centres of Excellence program, which is an initiative of the Natural Sciences and Engineering Research Council of Canada, the Social Sciences and Humanities Research Council of Canada, the Canadian Institutes of Health Research, and Industry Canada. An incorporated not-for-profit organization, PREVENT is accelerating the development of promising early-stage vaccine candidates to address existing or potential human health issues. By partnering with Canadian stakeholders and shouldering the risk of early-stage vaccine development, PREVENT will strengthen Canada's vaccine industry, promoting growth, investment and improved global competitiveness.

## About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting misfolded protein diseases including ALS, cancer, and Alzheimer's disease. Amorfix utilizes its computational discovery platform, ProMIS(TM), to predict novel Disease Specific Epitopes ("DSE") on the molecular surface of misfolded proteins. Amorfix's lead therapeutic programs include antibodies and vaccines to DSEs in ALS, Alzheimer's disease and cancer. Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a normal sample. The Company's diagnostic programs include an ultrasensitive method for the detection of aggregated Beta-Amyloid in brain tissue and blood of animal models of Alzheimer's disease, months prior to observable amyloid formation, and human blood screening tests for Alzheimer's and early liver cancer detection. For more information about Amorfix, visit [www.amorfix.com](http://www.amorfix.com).

## Forward Looking Information

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/For further information: Dr. Robert Gundel, President & Chief Executive Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6957, Fax: (416) 847-6899, [bob.gundel@amorfix.com](mailto:bob.gundel@amorfix.com); James Parsons, Chief Financial Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6929, Fax: (416) 847-6899, [james.parsons@amorfix.com](mailto:james.parsons@amorfix.com) / (AMF.)

CO: Amorfix Life Sciences Ltd.

CNW 07:00e 03-JUN-10

Attention Business Editors:  
Amorfix announces management changes and product development plans for fiscal 2011

TSX: AMF

TORONTO, June 2 /CNW/ - The Board of Directors of Amorfix Life Sciences (TSX:AMF), a company focused on treatments and diagnostics for misfolded protein diseases, announces the following changes based on a strategic review related to the earlier decision to suspend commercialization of its vCJD blood test. These changes are designed to conserve resources and to enable the Company to increase its focus on the priority programs including:

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- Our ProMIS(TM) antibody program targeting disease specific epitopes for both therapeutics and companion diagnostics for cancer and other misfolded protein diseases;
  - The advancement of our novel antibodies and vaccines for the treatment of ALS and AD;
  - Growing the revenue from our A(4) amyloid testing service for cell culture, tissue and blood in animal models of Alzheimer's disease (AD);
  - Development of a human Alzheimer's test adapting the A(4) test protocol to detect aggregated Abeta, the hallmark of the disease, in human plasma and cerebro-spinal fluid; and
  - The contract for the development of a liver cancer early detection assay, which is nearing completion.

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To facilitate this strategic focus several personnel changes have been made:

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- Dr. George Adams, currently President & CEO will be stepping down from that role and also from the Board of Directors. Dr. Robert Gundel, formerly Vice-President R&D has been appointed President & CEO.
- Dr. Adams notes that "I personally recruited Dr. Gundel to lead the Company's therapeutic initiatives, and with his 25 years experience in drug development, particularly in the antibody space, with both big pharma and bio companies, he is eminently prepared to spearhead the Company during the next phase of its evolution".
- Dr. Neil Cashman, scientific founder of Amorfix and an inventor and architect of the ProMIS(TM) platform, who will be re-appointed to the Board at its next meeting on June 9, 2010, comments "I am particularly excited about rejoining the Board at this time as the Company refocuses on the treatment and diagnosis of protein misfolding diseases using our proprietary ProMIS(TM) platform with broad application from ALS to cancer".
- Consistent with the Company's intent to conserve cash and reduce the burn rate, five employees directly involved with the vCJD project have been released.

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Graham Strachan, Chair of Amorfix expressed the thanks of the Board to Dr. Adams for all his efforts in building the Company since its formation in 2005. "As the company's founding CEO, George has been indefatigable in leading the advancement of the diagnostic programs. Most importantly, George had the vision to ensure that the Company is endowed with a rich pipeline of

development programs and cash reserves which permits the Company to exploit several attractive opportunities."

The company has sufficient cash as well as ongoing revenue from its diagnostic services business, which will allow development activities under the new plan for approximately 18 months.

#### About Amorfix

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CO: Amorfix Life Sciences Ltd.

CNW 07:00e 02-JUN-10

Attention Business Editors:  
Corporate update on vCJD test development

TSX: AMF

TORONTO, May 31 /CNW/ - Amorfix Life Sciences (TSX:AMF), a company focused on treatments and diagnostics for misfolded protein diseases, provides an update on the development of a blood test for vCJD, one of its six product development programs.

The company has been successful in developing versions 2 and 3 of the test, which differ in the sample preparation steps, and both are four times more sensitive than the first version which underwent testing with vCJD patient blood in December. The company has also been successful in obtaining a rare blood sample from a person in the clinical phase of vCJD. The new versions of the EP-vCJD tests were used to test this sample and it was scored negative by both versions of the test.

"Although we were able to achieve unprecedented sensitivity with brain prions diluted into blood, we have been unable to detect blood prions with the latest versions of the test," said Dr. Neil Cashman, CSO of Amorfix. "At this stage, we believe our other product development programs are a better use of our resources, although future research may prompt reevaluation of this assessment."

The Amorfix test and those of its competitors were developed using blood samples spiked with brain prions from vCJD patients. Amorfix successfully developed the most sensitive and specific test in the world and was the first to access human samples through the UK National Institute of Biological Standards and Control process. Subsequent significant improvements to the test in the last five months did not yield positive results, and the company has reached an impasse until scientific understanding improves or more vCJD patient blood is available. Accordingly the company will suspend the commercialization of the vCJD project allowing a more focussed effort on the development of novel therapeutics and diagnostics which include:

<<

- Our ProMIS(TM) antibody program targeting disease specific epitopes for both therapeutics and companion diagnostics for cancer and other misfolded protein diseases;
- Growing the revenue from our A(4) amyloid testing service for cell culture, tissue and blood in animal models of Alzheimer's disease (AD);
- Development of a human Alzheimer's test adapting the A(4) test protocol to detect aggregated Abeta, the hallmark of the disease, in human plasma and cerebro-spinal fluid;
- The advancement of our novel antibodies and vaccines for the treatment of ALS and AD; and
- The contract for the development of a liver cancer early detection assay, which is nearing completion.

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#### About Amorfix

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observable amyloid formation, and a blood screening test for liver cancer. For more information about Amorfix, visit [www.amorfix.com](http://www.amorfix.com).

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(AMF.)

CO: Amorfix Life Sciences Ltd.

CNW 07:00e 31-MAY-10

Attention Business Editors:

Amorfix and Aragen Bioscience enter into agreement to develop novel monoclonal antibodies for the treatment of cancers

TSX: AMF

TORONTO, May 28 /CNW/ - Amorfix Life Sciences (TSX:AMF) and Aragen Bioscience, Inc. announced today that they have entered into an agreement to develop high-affinity monoclonal antibodies against a number of targets for cancer. Using its proprietary ProMIS(TM) computational platform discovery technology, Amorfix has identified several disease specific epitopes ("DSEs") on misfolded Fas receptor. Aragen will use those DSEs to generate highly specific monoclonal antibodies ("mAbs").

"Fas receptor is a well characterized target on cells that, when activated, causes programmed cell death, or apoptosis. Previous attempts to use Fas receptor as a therapeutic target for the development of new anti-cancer therapeutics have failed because its expression and function lead to undesirable side effects on normal cells. Using our ProMIS(TM) technology, we have identified DSEs on Fas receptor that will provide the required specificity for our mAbs to target and kill tumor cells while leaving normal cells intact," said Dr. Robert Gundel, Vice President of Research and Development at Amorfix. "We are very pleased to be collaborating with Aragen Bioscience on this important project in hopes of generating a highly effective and safe new therapeutic for the treatment of a variety of cancers."

"The ProMIS(TM) technology has identified novel and presumably rare epitopes having important potential in the treatment of several devastating diseases," commented Rick Srigley, President & CEO of Aragen Bioscience. "We are excited to be working with the Amorfix team and look forward to applying our technical skills and extensive experience to the development of novel mAbs for the treatment of cancer and other diseases."

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting misfolded protein diseases. Amorfix has utilized its computational discovery platform, ProMIS(TM), to predict novel Disease Specific Epitopes ("DSEs") on the molecular surface of misfolded proteins. Amorfix's lead therapeutic programs include antibodies and vaccines to DSEs in Amyotrophic Lateral Sclerosis ("ALS"), Alzheimer's Disease and cancer. Amorfix's proprietary Epitope Protection(TM) technology enables it to specifically identify very low levels of aggregated misfolded proteins ("AMPs") in a clinical sample. The Company's diagnostic programs include an ultrasensitive method for the detection of aggregated Beta-amyloid in brain tissue and plasma of animal models of Alzheimer's Disease months prior to the formation of observable amyloid, and a blood screening test for variant Creutzfeldt-Jakob Disease ("vCJD"). For more information about Amorfix, visit [www.amorfix.com](http://www.amorfix.com).

#### About Aragen Bioscience

Aragen Bioscience, Inc. provides high content R&D services to the biotechnology and biopharmaceutical industry. The Company's expertise in molecular and cell biology, upstream and downstream process development, immunology and animal sciences allows it to perform a wide range of routine and complex projects. Aragen's services encompass virtually all aspects of pre-clinical product development, including cell line development, cell based assays, proof of principle studies in animal models of human disease and projects that integrate its in vitro and in vivo services. For more information about Aragen and its service portfolio, visit [www.aragenbio.com](http://www.aragenbio.com).

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(AMF.)

CO: Amorfix Life Sciences Ltd.

CNW 07:00e 28-MAY-10

Attention Business Editors:

Amorfix and Epitomics enter into agreement to develop novel monoclonal antibodies against disease specific epitopes for the treatment of cancers

TSX: AMF

TORONTO, May 11 /CNW/ - Amorfix Life Sciences and Epitomics, Inc. announced today that they have entered into an agreement to develop high-affinity monoclonal antibodies against a number of targets for cancer. Amorfix has identified several disease specific epitopes (DSEs) on misfolded proteins with their proprietary PromIS(TM) computational platform discovery technology, which will be used by Epitomics to generate highly specific monoclonal antibodies (mAbs). Epitomics, together with its partners, has successfully generated over a dozen humanized therapeutic antibody drug leads targeting immune diseases and cancers using RabMab(R) technology and its proprietary Mutation Lineage Guided (MLG) humanization technology.

"Targeting misfolded proteins on cancer cells is a novel approach to developing treatments for cancers. The PromIS(TM) technology enables the identification of DSEs likely present on cancer cells and should generate proprietary mAbs with greater selectivity and safety" said Dr. Robert Gundel, Vice President of Research and Development at Amorfix. "In addition, Amorfix's vast expertise in diagnostics puts us in a great position to develop companion diagnostics for patient selection and monitoring of clinical efficacy. We are very pleased to be collaborating with Epitomics, a company with a proven track record of success in developing clinical-grade antibodies."

"Epitomics' proprietary RabMABs(R) platform is a proven approach to the generation of high affinity mAbs against peptide targets", said Weimin Zhu, Senior Vice President of Antibody Technology at Epitomics. "We are pleased that Amorfix has recognized the unique features and benefits of our RabMAB(R) platform for developing high quality and high affinity antibodies with the potential to recognize unique epitopes. We look forward to assisting Amorfix in building its product pipeline".

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting misfolded protein diseases including ALS, cancer, Alzheimer's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix utilizes its computational discovery platform, PromIS(TM), to predict novel Disease Specific Epitopes ("DSE") on the molecular surface of misfolded proteins. Amorfix's lead therapeutic programs include antibodies and vaccines to DSEs in ALS, Alzheimer's disease and cancer. Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a normal sample. The Company's diagnostic programs include an ultrasensitive method for the detection of aggregated Beta-Amyloid in brain tissue and CSF of animal models of Alzheimer's disease, months prior to observable amyloid formation, and a blood screening test for vCJD. For more information about Amorfix, visit [www.amorfix.com](http://www.amorfix.com).

#### About Epitomics

Epitomics, Inc, is a biotechnology company dedicated to developing breakthrough monoclonal antibody technology for research, diagnostic and therapeutic applications. The Company's core technology is its unique and proprietary RabMAB(R) (Rabbit Monoclonal Antibody) technology which produces antibodies with superior binding affinity and bioactivity in a wide variety of biological assays. Epitomics has also developed a proprietary method for humanizing RabMABs called Mutation Lineage Guided (MLG) humanization for generating candidate therapeutic leads. Epitomics, Inc. is headquartered in Burlingame, California, and operates a wholly owned subsidiary in Hangzhou,

the People's Republic of China. For more information about Epitomics, please visit [www.epitomics.com](http://www.epitomics.com).

#### Forward-Looking Information

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(AMF.)

CO: Amorfix Life Sciences Ltd.

CNW 07:00e 11-MAY-10

Attention Business/Health Editors:

Amorfix Life Sciences announces world's first detection of aggregated Beta-amyloid in blood using the Alzheimer's diagnostic A4 assay

TSX: AMF

TORONTO, May 4 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for misfolded protein diseases such as Alzheimer's disease (AD), announced today the detection of the AD-associated aggregated Beta-amyloid (ABeta), the hallmark of AD, in the blood from the most-frequently-used animal model of AD. The assay detects both oligomeric and fibrillar aggregates of ABeta, which are generally considered to be the toxic forms and major contributors to brain dysfunction in AD.

"This milestone achievement represents the first time that aggregated ABeta has been measured in blood plasma from any animal model. This discovery provides an important new tool for understanding AD and will significantly accelerate the evaluation of novel treatments for the disease," said Dr. Neil Cashman, Chief Scientific Officer of Amorfix. "Our detection of aggregated ABeta in blood plasma demonstrates the superior sensitivity and specificity of the A(4) test and its utility for use with tissues and biofluids".

Dr. George Adams, Chief Executive Officer of Amorfix added, "We already have a number of prestigious academic institutions and pharmaceutical companies utilizing our commercial A(4) test for ABeta in brain, so the added capability of detecting ABeta in blood plasma will further entrench Amorfix as an emerging leader in preclinical AD diagnostics."

The quantitative measurement of aggregated ABeta in blood plasma was obtained using the Amorfix A(4) on samples from Tg2576 transgenic mice as early as 3 months of age. The Tg2576 mouse is the most commonly used transgenic model for preclinical evaluation of potential AD therapeutics. The aggregated peptide was detected in the blood from transgenic mice, but not in blood from non-transgenic age-matched control mice. Amorfix developed the A(4) as an ultra-sensitive method for early detection of aggregated ABeta. The A(4) assay will allow scientists to monitor levels of aggregated Abeta in the blood of individual AD mice as they age and to detect the impact of treatments with novel AD medications.

The company is continuing to develop an AD blood screening test for humans for early diagnosis and monitoring of disease progression. There are over 400 million people in the world who would be checked regularly for AD if a screening test were available and this number is expected to double in the next 15 years. Like cancer, people should be screened to determine when AD begins to enable early treatment leading to improved outcomes. The detection of aggregated ABeta in animal models is encouraging as it suggests that aggregated ABeta may be present in the blood of AD patients.

The company continues to build its A(4) testing business with the addition of senior researchers and pharmaceutical companies as customers. Amorfix is also announcing the expansion of its A(4) testing service to include the measurement of aggregated ABeta in blood to complement the existing brain testing services. Please contact Dr. Louise Scrocchi at [louise.scrocchi@amorfix.com](mailto:louise.scrocchi@amorfix.com) for further information.

#### About A4 Assay

The Amorfix A(4) assay is an ultrasensitive method for the detection of aggregated ABeta that provides quantitative measurements of aggregates. The A(4) can detect aggregates in plasma and tissue of standard animal models of AD several months before conventional microscopic procedures thereby accelerating the preclinical screening of new drugs for AD. The A(4) is significantly more sensitive than current methods for detecting total Abeta and can be used in high-throughput applications designed to study the inhibition of amyloid formation.

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting misfolded protein diseases including ALS, cancer, Alzheimer's Disease (AD) and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix utilizes its computational discovery platform, ProMIS(TM), to predict novel Disease Specific Epitopes ("DSE") on the molecular surface of misfolded proteins. Amorfix's lead therapeutic programs include antibodies and vaccines to DSEs in ALS, AD and cancer. Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a normal sample. The Company's diagnostic programs include an ultrasensitive method for the detection of aggregated Beta-Amyloid in brain tissue and CSF of animal models of AD, months prior to observable amyloid formation, and a blood screening test for vCJD. For more information about Amorfix, visit [www.amorfix.com](http://www.amorfix.com).

#### Forward-Looking Information

This press release may contain certain forward-looking information. Such information involves known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from those implied by statements herein, and therefore these statements should not be read as guarantees of future performance or results. All forward-looking statements are based on the Company's current beliefs as well as assumptions made by and information currently available to it as well as other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Due to risks and uncertainties, including the risks and uncertainties identified by the Company in its public securities filings, actual events may differ materially from current expectations. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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(AMF.)

CO: Amorfix Life Sciences Ltd.

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FORM 13-502F1

CLASS 1 REPORTING ISSUERS -- PARTICIPATION FEE

Reporting Issuer Name: Amorfix Life Sciences Ltd

End date of last completed fiscal year: March 31, 2010

<<Market value of listed or quoted securities>>:  
Total number of securities of a class or series outstanding as at the end of the issuer's last completed fiscal year (i)  
48,514,418

Simple average of the closing price of that class or series as of the last trading day of each month in the last completed fiscal year (See clauses 2.7(a)(ii)(A) and (B) of the Rule) (ii)  
0.83

Market value of class or series (i) X (ii) = (A)  
40,266,967

(Repeat the above calculation for each other class or series of securities of the reporting issuer that was listed or quoted on a marketplace in Canada or the United States of America at the end of the last completed fiscal year) (B)  
nil

<<Market value of other securities at end of the last completed fiscal year>>:  
(See paragraph 2.7(b) of the Rule)  
(Provide details of how value was determined) (C)  
nil

(Repeat for each other class or series of securities to which paragraph 2.7(b) of the Rule applies) (D)  
nil

Capitalization for the last completed fiscal year  
(Add market value of all classes and series of securities) (A) + (B) + (C) + (D) =  
40,266,967

Participation Fee  
(From Appendix A of the Rule, select the participation fee beside the capitalization calculated above)  
1,520

Late Fee, if applicable  
(As determined under section 2.5 of the Rule)



## APPENDIX A – CORPORATE FINANCE PARTICIPATION FEES

<b>Capitalization</b>	<b>Participation Fee</b>
under \$25 million	\$700
\$25 million to under \$50 million	\$1,520
\$50 million to under \$100 million	\$3,740
\$100 million to under \$250 million	\$7,850
\$250 million to under \$500 million	\$17,200
\$500 million to under \$1 billion	\$24,000
\$1 billion to under \$5 billion	\$34,750
\$5 billion to under \$10 billion	\$44,800
\$10 billion to under \$25 billion	\$52,300
\$25 billion and over	\$58,850