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# Amorfix Life Sciences Ltd.

(a development stage company)

### Financial Statements March 31, 2009 and 2008



3-31-09 ANS

# PRICEWATERHOUSE COOPERS I

PricewaterhouseCoopers LLP Chartered Accountants Mississauga Executive Centre One Robert Speck Parkway, Suite 1100 Mississauga, Ontario Canada L4Z 3M3 Telephone +1 905 949 7400 Facsimile +1 416 814 3220

June 10, 2009

**Auditors' Report** 

To the Shareholders of Amorfix Life Sciences Ltd.

We have audited the balance sheets of **Amorfix Life Sciences Ltd.** as at March 31, 2009 and 2008 and the statements of operations and comprehensive loss, shareholders' equity and cash flows for each of 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, 2009 and 2008 and the results of its operations and its cash flows for each of the years then ended in accordance with Canadian generally accepted accounting principles.

(Signed) "PricewaterhouseCoopers LLP"

**Chartered Accountants, Licensed Public Accountants** 

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(a development stage company) Balance Sheets As at March 31

	2009 S	2008 \$
Assets		
Current assets Cash and cash equivalents Marketable securities	564,568 4,160,798	2,212,776 6,467,490
Amounts receivable Tax credits receivable (note 8) Prepaid expenses and deposits	52,663 211,082 64,963	198,026 400,082 136,855
Total current assets	5,054,074	9,415,229
Property and equipment, net (note 4)	463,110	575,053
	5,517,184	9,990,282
Liabilities		
<b>Current liabilities</b> Accounts payable and accrued liabilities (notes 9 and 11)	596,009	1,295,333
Total current liabilities	596,009	1,295,333
Shareholders' Equity		
Common shares Other equity Contributed surplus Accumulated other comprehensive income Deficit	19,467,462 3,970,704 225,297 18,598 (18,760,886)	19,194,840 2,815,838 187,777 2,247 (13,505,753)
	4,921,175	8,694,949
	5,517,184	9,990,282

Going concern (note 1) Commitments and contingencies (note 11) Subsequent event (note 15)

On behalf of the Board:

eage Alam 4 Director

George Adams

Director

Graham Strachan

### (a development stage company) Statements of Operations and Comprehensive Loss

			Period from January 23, 2004
	Year ended March 31, 2009 \$	Year ended March 31, 2008 \$	(inception) to March 31, 2009 \$
Revenue Interest earned	244,499	477,615	1,012,322
Expenses Research and development (note 7) General and administrative Amortization of property and equipment Amortization of technology rights	4,126,945 1,040,468 225,219	6,240,108 1,259,197 122,418 45,873	14,941,921 3,780,962 407,319 56,313
_	5,392,632	7,667,596	19,186,515
Loss before the undernoted	(5,148,133)	(7,189,981)	(18,174,193)
Costs related to reverse takeover			479,693
Loss for the period	(5,148,133)	(7,189,981)	(18,653,886)
Other comprehensive income Unrealized gain on available-for-sale marketable securities	16,351	52,247	
Comprehensive loss for the year	(5,131,782)	(7,137,734)	
Basic and diluted loss per common share	(0.12)	(0.17)	
Weighted average number of common shares outstanding	41,985,488	41,297,742	

Going concern (note 1)

### (a development stage company) Statement of Shareholders' Equity

		on shares is 5 and 6)	Other eq (not		Contributed surplus	Accumulated other comprehensive income (loss)	Deficit	Total
	Number	Amount S	Number	Amount S	Amount S	Amount \$	Amount \$	Amount S
Balance – March 31, 2007	40,456,749	18,028,305	8,558,047	2,404,259	4,056	•	(6,365,772)	14,070,848
Adjustment on adoption of new accounting policy	-	-	-	-	-	(50,000)	50,000	-
Balance – April 1, 2007	40,456,749	18,028,305	8,558,047	2,404,259	4,056	(50,000)	(6,315,772)	14,070,848
Issuance of common shares for cash	91,445	160,944	-	-	-	-	-	160,944
Exercise of agent options and warrants	899,186	807,855	(899,186)	(239,447)	-	-	-	568,408
Exercise of stock options	231,000	197,736	(231,000)	(82,236)	-	-	-	115,500
Expiry of warrants	-		(17,280)	(2,246)	2,246	-	-	-
Expiry of stock options	-	-	(254,875)	(181,475)	181,475	-	-	-
Issuance of stock options	-	-	1,160,125	-	-	-	-	-
Stock-based compensation	-	-	-	916,983	-	-	-	916,983
Other comprehensive income for the year	-	-	-	-	-	52,247	-	52,247
Loss for the year	-	-	-	-	-	-	(7,189,981)	(7,189,981)
Balance – March 31, 2008	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 for the year	-	-	-	-	-	16,351	-	16,351
Loss for the year	-	-		-	-	•	(5,148,133)	(5,148,133)
Balance – March 31, 2009	42,541,181	19,467,462	9,350,988	3,970,704	225,297	18,598	(18,760,886)	4,921,175

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(a development stage company) Statements of Cash Flows

Cash provided by (used in)	Year ended March 31, 2009 \$	Year ended March 31, 2008 \$	Period from January 23, 2004 (inception) to March 31, 2009 \$
Operating activities			
Loss for the period Amortization of property and equipment	(5,148,133) 225,219	(7,189,981) 122,418	(18,653,886) 407,319
Amortization of property and equipment		45,873	56,313
Stock-based compensation	1,085,386	916,983	3,013,924
Other non-cash expenses Changes in non-cash working capital (note 10)	(293,069)	542,419	235,115 176,839
	(4,130,597)	(5,562,288)	(14,764,376)
Investing activities			
Purchase of marketable securities	(6,159,771)	(1,608,840)	(27,833,681)
Maturity or sale of marketable securities	8,482,814 (113,276)	7,386,197 (492,739)	23,691,481 (870,429)
Purchase of property and equipment Purchase of technology rights	(115,270)	(15,000)	(56,313)
-	2,209,767	5,269,618	(5,068,942)
Financing activities			
Issuance of common shares, net of cash issue costs	272,622	160,944	4,655,751
Issuance of common share units, net of cash issue costs Issuance of common shares on exercise of agent options	-	-	11,973,069
and warrants	-	568,408	2,980,920
Issuance of common shares on exercise of options	-	115,500	521,368
Other financing activities	-	•	266,778
	272,622	844,852	20,397,886
Not (doownood) in analog in analog and analog			
Net (decrease) increase in cash and cash equivalents during the period	(1,648,208)	552,182	564,568
		,	
Cash and cash equivalents - Beginning of period _	2,212,776	1,660,594	
Cash and cash equivalents - End of period	564,568	2,212,776	564,568
Cash and cash equivalents are comprised of:			
Cash on deposit	297,068	775,341	
Short-term debt instruments Money market securities	267,500	-	
Money market securities		1,437,435	
_	564,568	2,212,776	

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

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

Amorfix Life Sciences Ltd. (the company or Amorfix) is an emerging theranostics company focused on the diagnosis and treatment of neurodegenerative diseases, where aggregated misfolded proteins (AMPs) are prevalent. 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 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 has incurred a loss of \$5,148,133 for the year ended March 31, 2009 and has a deficit of \$18,760,886 as at March 31, 2009. 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 \$4,458,065 together with its net proceeds from its April 2009 private placement financing (note 15) are sufficient to fund its operations through to the end of December 2010, 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 ALS therapeutic products, contracts for blood screening testing for variant Creutzfeldt-Jakob Disease prevalence studies, and sourcing other non-dilutive funding; however, there is 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 Change in accounting policies

Effective April 1, 2008, the company adopted the Canadian Institute of Chartered Accountants' (CICA) Handbook Section 3862, *Financial Instruments – Disclosure*; Section 3863, *Financial Instruments – Presentation;* Section 1535, *Capital Disclosures* and changes to Section 1400, *General Standards of Financial Statement Presentation.* These sections relate to disclosure and presentation only and do not have an impact on the company's financial results.

Section 3862 describes the required disclosure of the nature and extent of risks arising from financial instruments to which an entity is exposed and how the entity manages those risks.

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

Section 3863 establishes the standards for presentation of financial instruments and non-financial derivatives. It carries forward the existing requirements for presentation of financial instruments from Section 3861, *Financial Instruments –Presentation and Disclosure*.

Section 1535 describes the required disclosure of an entity's objectives, policies and processes for managing capital. An entity should disclose a description of what it manages as capital, the nature of externally imposed capital requirements and its compliance thereto, how it is meeting is objectives for managing capital, and summary quantitative data about what it manages as capital.

Section 1400 has been amended to change the guidance related to management's responsibility to assess the ability of the entity to continue as a going concern. Disclosure is required for material uncertainties related to events or conditions that may cast doubt on the ability to continue as a going concern.

### Future accounting changes:

### Goodwill and intangible assets

In November 2007, the CICA issued 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). These standards are effective for the company beginning on April 1, 2009. The company is currently assessing the impact that these standards will have on its financial statements.

### 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. The company is in the process of assessing the effects of the standards on its financial statements.

### 3 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

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

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. 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, 2009, no impairment of long-lived assets was determined.

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

### **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, 2009 were \$408,000 (2008 - \$380,000).

### **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 over the vesting period and for non-employees is expensed as the services are received. 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 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.

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

### 4 Property and equipment

			2009
	Cost \$	Accumulated amortization \$	Net \$
Laboratory and office equipment Computer equipment Leasehold improvements	536,846 114,258 187,432	245,422 85,476 44,528	291,424 28,782 142,904
	838,536	375,426	463,110
			2008
	Cost \$	Accumulated amortization \$	Net \$
Laboratory and office equipment Computer equipment Leasehold improvements	469,775 108,278 179,100	131,591 44,795 5,714	338,184 63,483 173,386
	757,153	182,100	575,053

### 5 Share capital

The company has authorized an unlimited number of common shares and preferred shares and has issued 42,541,181 common shares and no preferred shares as at March 31, 2009.

In July 2007, on the achievement of the first research milestone under a 2006 research and investment agreement, Biogen Idec MA (Biogen) subscribed for 91,445 common shares at \$1.76 per share for gross proceeds to Amorfix of \$160,944 (US\$150,000).

In November 2008, on the achievement of the second research milestone under this agreement, Biogen subscribed for 608,250 common shares at \$0.31 per share for gross proceeds to Amorfix of \$187,485 (US\$150,000). Proceeds net of share issue costs were \$185,195.

In December 2008, on the achievement of the third research milestone under this agreement, Biogen subscribed for 254,551 common shares at \$0.35 per share for gross proceeds to Amorfix of \$89,565 (US\$75,000). Proceeds net of share issue costs were \$87,427.

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

### 6 Warrants and options

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

a) As at March 31, 2009, the following warrants were outstanding:

	Exercise price \$	Number outstanding	Expiry date
Common share purchase warrants	1.95	4,462,521	March 8, 2010

Effective March 8, 2009, the company extended the expiry of all outstanding 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. 25,000 warrants that were extended are held by an insider of the company and this extension is still subject to shareholder approval. All warrants are subject to an earlier expiry in the event that the volume-weighted average price of the company's common shares on the Toronto Stock Exchange over a period of 10 consecutive trading days exceeds \$2.50, in which case 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. All outstanding warrants are exercisable.

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.

The following table reflects the activity under the stock option plan for the years ended March 31, 2009 and 2008 and the stock options outstanding:

	2009		200	8
	Number of stock options	Weighted average exercise price \$	Number of stock options	Weighted average exercise price \$
Outstanding - Beginning of year	3,829,500	1.03	3,155,250	1.00
Granted	799,750	0.65	1,160,125	1.00
Exercised	-	-	(231,000)	0.50
Expired	(86,875)	0.99	(254,875)	1.12
Outstanding - End of year	4,542,375	0.96	3,829,500	1.03
Exercisable – End of year	3,271,335	0.98	2,004,750	0.99

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

The following table reflects the stock options outstanding as at March 31, 2009:

		Stock	options outstandin	g	Stock options	exercisable
	Range of exercise prices \$	Number outstanding	Weighted average remaining contractual life (years)	Weighted average exercise price \$	Number exercisable	Weighted average exercise price \$
	0.50 - 0.68	1,767,250	5.26	0.58	1,168,875	0.54
	0.83 - 0.93	1,273,125	7.31	0.92	873,127	0.91
	1.14 - 1.14	40,000	2.36	1.14	40,000	1.14
<del>.</del>	1.40 - 1.78	1,462,000	_ 2.79 _	1.46	1,189,333	1.46
_	0.50 -1.78	4,542,375	5.02	0.96	3,271,335	0.98

c) During the year ended March 31, 2009, the company issued stock options with a fair value of \$408,672 (2008 - \$843,768) and recorded stock-based compensation expense of \$894,026 (2008 - \$916,983). The weighted average grant-date fair value of the stock options granted during the year ended March 31, 2009 was \$0.51 (2008 - \$0.73). The fair value of the stock options granted was estimated using the Black-Scholes option pricing model with the following assumptions:

	2009	2008
Risk-free interest rate	3.0%	3.5 - 3.9%
Dividend yield	0%	0%
Expected volatility	73%	62 - 66%
Expected life of options (years)	10	5-10

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, 2009, the company issued 346,092 Units with an average grant date fair value of \$0.55 and recorded a stock-based compensation expense of \$191,360 (2008 - \$nil).

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

### 7 Research and development

Amorfix is developing a pipeline of diagnostic and therapeutic products for the detection and treatment of neurodegenerative diseases, where aggregated misfolded proteins are prevalent. The diagnostic products are based on the company's epitope protection platform and include the development of blood screening tests for variant Creutzfeldt-Jakob Disease, Alzheimer's disease and sheep scrapie. Amorfix's therapeutics products are immunotherapies for the treatment of amyotrophic lateral sclerosis (ALS) and Alzheimer's disease.

Research and development expenditures were as follows:

	Year ended March 31, 2009 S	Year ended March 31, 2008 \$	Period from January 23, 2004 (inception) to March 31, 2009 \$
Diagnostic AMP programs Therapeutic AMP programs	3,329,459 797,486	5,080,997 1,159,111	12,566,312 2,375,609
	4,126,945	6,240,108	14,941,921

### 8 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:

	2009	2008
	\$	\$
Future income tax assets		
Non-capital losses carried forward	1,422,000	1,119,000
Research and development expenditures	3,080,000	2,264,000
Investment tax credits	1,758,000	1,189,000
Carrying value of technology rights and property and	. ,	, ,
equipment in excess of accounting basis	188,000	113,000
Ontario harmonization tax credit and other	188,000	190,000
Share issue costs	173,000	283,000
Total future income tax assets	6,809,000	5,158,000
Valuation allowance	(6,809,000)	(5,158,000)
Net future income tax assets	-	-

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

- b) As at March 31, 2009, the company has available research and development expenditures for income tax purposes of approximately \$10,676,000, which may be carried forward indefinitely to reduce future years' taxable income.
- c) As at March 31, 2009, the company had non-capital income tax loss carry-forwards of approximately \$4,913,000 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, 2009, the company had approximately \$2,352,000 of non-refundable investment tax credits available to offset future income taxes.
- 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:

	2009 \$	2008 \$
Statutory income tax rate	33.3%	35.4%
Income tax recovery based on statutory rate	(1,713,000)	(2,542,000)
Permanent differences	362,000	332,000
Net investment tax credits not recognized	(519,000)	(728,000)
Share issue costs recorded, net of equity	(1,000)	-
Change in future tax rates	181,000	592,000
Other	39,000	64,000
Change in valuation allowance	1,651,000	2,282,000
Income tax recovery		

### 9 Related party transactions

- a) Certain members of management who are also shareholders were under contract to provide employment services to the company. During 2009, the company incurred \$145,541 (2008 \$328,841) of expenses for two contracts, with \$8,058 (2008 \$83,672) payable as at March 31, 2009. These transactions occurred in the normal course of operations and were measured at the exchange amount, which is the amount of consideration established and agreed by the related parties.
- b) In February 2007, the company entered into an agreement with the University of British Columbia (UBC) and Vancouver Coastal Health Authority, with Dr. Neil Cashman who is an officer and shareholder of the company, as principal investigator, to fund research related to the Amorfix ALS therapeutic program in the amount of \$300,000. During 2009, \$45,000 (2008 \$135,000) was paid to UBC and, as at March 31, 2009, \$nil (2008 \$45,000) was included in accounts payable and accrued liabilities.
- c) A company controlled by a director of Amorfix provides investment advisory services to Amorfix.

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

### 10 Supplementary cash flow information

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

	Year ended March 31, 2009 \$	Year ended March 31, 2008 \$	Period from January 23, 2004 (inception) to March 31, 2009 S
Amounts receivable Tax credits receivable	145,363 189,000	31,666 (116,555)	(45,616) (211,082)
Prepaid expenses and deposits Accounts payable and accrued liabilities	71,892 (699,324)	(4,543) 631,851	(64,963) 498,500
	(293,069)	542,419	176,839
Supplemental cash flow information Common share purchase warrants issued as agents' compensation		_	349,204

No income tax or interest was paid by the company.

### 11 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:
  - i) fees comprising amounts due initially on entering into the agreements and additional amounts due either on specified timelines or defined services to be provided;
  - ii) milestone payments that are dependent on products developed under the agreements proceeding toward specified plans of clinical trials and commercial development; and
  - iii) 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.

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

- b) 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. During 2009, \$142,619 was paid to UBC and, as at March 31, 2009, \$71,000 was included in accounts payable and accrued liabilities.
- c) 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 royalty payments to UBC based on revenue earned from the licensed technology. The company has committed to invest \$500,000 over two years to further the development of the licensed technology, of which \$121,800 has been incurred and paid as at March 31, 2009.
- d) 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.
- e) The company is committed to the following payments under the terms of its lease agreements for the years ending March 31,

	\$
2010	243,200
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.

### 12 Financial instruments

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, 2009, 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 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.

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

Marketable securities holdings at March 31, 2009 consist primarily of high credit quality corporate debt instruments with maturities staggered over the next 14 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, 2009 was 4.7%.

### 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 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, 2009 the company held US dollar cash and cash equivalents and marketable securities in the amount of US\$329,223.

### 13 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

(a development stage company) Notes to Financial Statements March 31, 2009 and 2008

stock options. The company also sources non-dilutive funding by accessing grants, government assistance and 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.

### 14 Segmented information

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

### 15 Subsequent event

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. 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, following the expiry of the four month hold period, the volume-weighted average price of Amorfix's common shares on the TSX over a period of ten consecutive trading days 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, Amorfix paid \$232,460 cash in finder fees and issued 348,400 finder warrants. 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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### **ANNUAL INFORMATION FORM**

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

Telephone: (416) 847-6898 Facsimile: (416) 847-6899 E-mail: info@amorfix.com Web: www.amorfix.com

Unless otherwise indicated all information in this Annual Information Form is presented as at and for the year ended March 31, 2009

June 10, 2009

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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 <u>www.sedar.com</u>.

The management information circular of the Company dated August 6, 2008 and filed on SEDAR on October 10, 2008 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.

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**

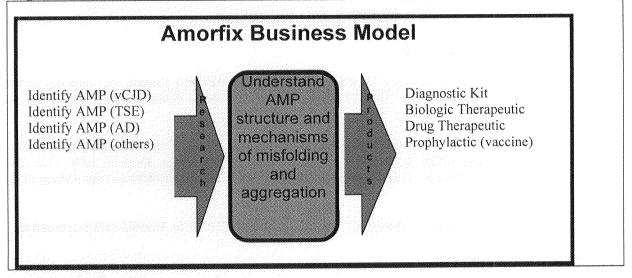
#### Three Year History

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

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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.

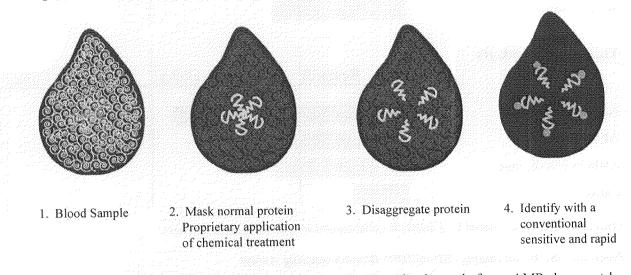
Amorfix has developed as a diagnostic platform to find and confirm the presence of these misfolded protein aggregates in living, functioning and cognitive humans and animals. The Amorfix diagnostic technology called "Epitope Protection" (EP) is designed to detect misfolded protein molecules by discovering 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
EP-vCJD <sup>™</sup> blood screening assay			Prevalence study F2010
A <sup>4</sup> Abeta assay			Launch F2010
Liver cancer screening assay*			n Magazart () - 15, anna (1)
Sheep scrapie			
Therapeutic Products	Research	Preclinical	Clinical
ALS - antibodies			
ALS - vaccines			
Alzheimer's disease			
Cancer			
			erenet entiti t

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

### Protecting the Blood Supply (EP-vCJD<sup>™</sup> 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 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\$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 product is expected to be a blood diagnostic test (EP-vCJD<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup>) 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<sup>TM</sup> Blood Screening Assay using British blood samples. NIBSC set out three steps:

the first will 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<sup>TM</sup> 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. The UK authorities have put forward to the European Community 99.9% specificity as an acceptable performance for a vCJD test on blood donor samples. The Company believes that these first results suggest that it can meet or exceed this requirement.

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<sup>TM</sup> 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 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 is consistent with a recent 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 10,000 blood samples 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 initial markets sought by the Amorfix vCJD technology for diagnostic use are in Europe due to the higher prevalence of BSE positive cattle and the resultant higher prevalence of people who have died from vCJD. A blood screening test for vCJD is currently not regulated, however, a process was established in late 2007 under the direction of the European Commission's IVD Technical Group to establish regulatory guidelines and a Common Technical Specification (CTS) for such tests. Amorfix joined the European Diagnostic Manufacturers Association (EDMA) in order to participate directly in the process for writing regulation for vCJD blood screening assays. A CTS would establish minimum standards for sensitivity and specificity that a vCJD blood screening assay must achieve to receive a CE mark registration. A CE mark registration would allow the product to be marketed and sold in Europe, subject to individual member state regulations.

The Company's vCJD assay development program is currently focused on continuing the France feasibility study and the completion of steps set out by the NIBSC expert committee prior to completing the remaining activities to scale up and commercialize the test. The Company is not in control of the timing of receiving any of the panels or receiving the results thereon from NIBSC, and significant process delays have previously occurred with the UK government agencies. There can be no certainty that Amorfix will be successful at completing the NIBSC process or commercializing its assay on its expected timelines or at all.

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.

Subsequent to year end, 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.

The Company's initial target markets for its EP-vCJD<sup>TM</sup> human blood screening assay are those countries that had the highest incidences of BSE-positive cattle. The blood transfusion market in Europe is estimated to be 20 million donations per year with half of this in the three largest countries of United Kingdom, France and Germany combined. Final commercial product sales and distribution of this assay is expected to require contracts and a regulatory-like approval process with individual country government health agencies.

### Early Diagnosis and Treatment for Alzheimer's Patients (EP-AD<sup>TM</sup> Test / A4 Amyloid Assay)

Alzheimer's disease (AD), Amyotrophic Lateral Sclerosis (ALS) and Parkinson's diseases (PD) are chronic neurodegenerative illnesses which are associated with neural deposits of AMPs made up of misfolded normally-present protein. 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 protein. Once again the only definitive diagnostic for these diseases is post-mortem examination of brain tissue. There are currently 5 million people in North America with AD and an equal number with dementia which may be suffering from AD but it is impossible to diagnose due to a lack of a blood test. Worldwide there are 460 million people over the age of 65 who should be tested annually for AD now that effective therapies are available. The worldwide market would be more than US\$1B annually.

Amorfix's assay for the sensitive and specific detection of aggregated Abeta (A $\beta$ ) in human blood or other biofluid is called EP-AD<sup>TM</sup>. 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. The Company demonstrated the use of monoclonal antibodies that recognize epitopes on A $\beta$  protein that are masked with EP treatment.

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 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 EP-AD<sup>TM</sup> test has not been able to detect aggregated Abeta in human blood plasma or cerebral spinal fluid samples. The Company has discontinued further research on the human AD blood test at this time.

The Company is assessing other potential commercial applications for this very sensitive aggregated Abeta protein assay and has identified a potential market to assay the brain tissue of human transgenic AD mice to assist in the assessment of drug efficacy in these models. The Company modified its EP- $AD^{TM}$  test to create the A<sup>4</sup> assay that 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.

Validation results for the  $A^4$  test will be presented at the International Congress on AD in July 2009 and the Company plans to offer the  $A^4$  test as a service to drug discovery companies and academic researchers working to discover new treatments for AD.

### 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. Subsequent to year end, 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 will develop 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.

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.

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

The first case of BSE in cattle emerged in the United Kingdom over 20 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 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 have been detected by the Amorfix EP-TSE<sup>™</sup> 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.

Amorfix began the development of its blood screening assay for sheep scrapie as a consequence of supporting the regulatory pathway for its  $EP-vCJD^{TM}$  test. Amorfix does not currently plan to advance the development of a live animal TSE test without external funding from a commercial partner for this product. 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 brain 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.

In calendar 2006 in a series of agreements, the Company acquired certain SOD1 technologies and exclusively licensed additional SOD1 technologies owned by Dr. Cashman 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 (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 now seeking to partner with a biopharmaceutical company to humanize the antibodies, develop the vaccines 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 this 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 will fund approximately \$540,000 in cash and in-kind contributions to the program.

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 (DSE) 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 is expanding its research program to identifying novel disease-specific epitopes (DSE) on misfolded proteins. The Company 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 as previously shown. The Company is establishing strategic alliances to expand its capabilities to develop immunotherapeutics to numerous proteins.

### **Significant Acquisitions**

Amorfix made no significant acquisitions during fiscal year 2009 and 2008 for which disclosure is required under Part 8 of National Instrument 51-102.

#### **DESCRIPTION OF BUSINESS**

#### **Business of 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<sup>TM</sup> (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 (DSE) on disease-relevant proteins as an innovative approach to treat these currently incurable disorders.

### **Operations**

Amorfix intends to outsource the physical manufacturing of its diagnostic and therapeutic products where practical to ensure the lowest possible cost with the highest quality. This outsourcing of manufacturing is expected to allow Amorfix to minimize costs and focus on continued innovation and development while utilizing other manufacturers' existing production infrastructure and expertise. Amorfix achieved ISO 13485:2003 Medical Device certification in June 2007 which qualifies its quality management system to support the design, development, feasibility, validation and commercialization of its products.

All Amorfix products will be required to be manufactured under applicable regulatory guidelines including ISO quality management system or GMP guidelines. Amorfix qualifies all suppliers under its quality management system to ensure they meet the established criteria for supply. Certain components or raw materials used in the EP-vCJD<sup>TM</sup> test kit are sourced and available only from a single supplier. The Company has negotiated draft commercial supply or license agreements for these components and intends to have final agreements in place prior to commercial product sales. All other components and the kit assembly operation have more than one available source of 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

The markets for the Amorfix technology can be organized based upon ultimate target recipient, namely human markets and animal markets. Within each of these broad markets are certain diseases which the Amorfix technology seeks to diagnose, to detect and then ultimately treat through later research and development activities. In the human markets, the Amorfix technology seeks to detect AMPs in diseases such as vCJD, AD, ALS, PD and cancer. Within the animal market, the Amorfix technology is targeted at Scrapie, BSE and Chronic Wasting Disease.

### Human Markets

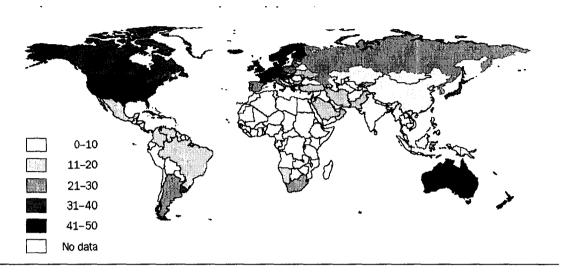
The Amorfix EP-CJD<sup>™</sup> Blood Screening Assay for screening for prions in blood is a significant opportunity. There is a general concern that vCJD is now within the blood transfusion systems and a screening assay for blood is urgently required to protect everyone from a secondary (after oral infection 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>1</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>2</sup>, less than 40 per cent are collected in the developing world where 82 per cent of the planet's population lives (Figure 4). 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. The potential development of prion-detecting products through the application of the Amorfix technology in stored blood inventories is potentially significant.

<sup>&</sup>lt;sup>1</sup> <u>http://www.who.int/bloodsafety/global\_database/en/SumRep\_English.pdf</u>

<sup>&</sup>lt;sup>2</sup> http://www.ifrc.org/docs/news/04/04040601/



### Figure 4: Number of Blood Donations per 1000 Population in 1998-99

(Reference: <u>http://www.who.int/bloodsafety/global\_database/en/SumRep\_English.pdf</u>)

The global market for blood products is large and growing. Over 40 million units of whole blood are collected each year in the U.S., Europe and Japan, yielding over 40 million units of red blood cells for transfusion.<sup>3</sup> Worldwide, approximately US\$4 billion is spent each year on red blood cells<sup>4</sup> Over one-third of all transfusions occur in the U.S. where it is estimated that one out of every three Americans will receive a transfusion at some point during his or her lifetime. Driven by an aging population susceptible to illness, increased prevalence of new disease and a rise in the number of major surgeries performed, blood use in the U.S. grew more than ten percent between 1999 and 2002. Blood use, particularly units of red blood cells, is expected to continue to increase as aggressive therapeutic treatments requiring chronic transfusions become more routine.

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 to hospitals for storage and transfusion: red blood cells, plasma and platelets.

The demand for blood products is ultimately driven by hospital-based physicians, particularly surgeons, in the acute care setting. Hematologists and oncologists also prescribe most of the blood used to treat chronic diseases such as cancer. 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.

<sup>&</sup>lt;sup>3</sup> The World Health Report; The World Health Organization; 2003.

<sup>&</sup>lt;sup>4</sup> Annual Report to the Securities and Exchange Commission on Form-10-K for Calendar Year 2002 for VI. Technologies, Inc.

In the United States and Canada, prior to transfusion, blood is tested for:

- 1. ABO Typing provides determination of Blood type: A, B, O, or AB
- 2. Rh Factor Determination indicates positive or negative Blood type
- 3. Blood Group Antibodies indicates unexpected antibodies that may be a result of prior transfusion, pregnancy or other factors
- 4. Hepatitis B Surface Antigen indicates a present infection (hepatitis) or carrier state of hepatitis B virus
- 5. Antibody to Hepatitis B Core additional test that detects a present or past infection with the hepatitis B virus
- 6. Antibody to Hepatitis C Virus indicates antibody to a virus that causes hepatitis C (responsible for non-A non-B hepatitis.) The mean incubation time is six to eight weeks
- 7. Alanine Aminotransferase (ALT) identifies a liver enzyme that, when increased, may indicate undetectable forms of hepatitis
- 8. Antibody to HTLV 1 and 2 indicates the antibody to a virus that causes adult T-cell leukemia, among other things
- 9. Antibody to HIV 1 and 2 indicates an infection with Human Immune Deficiency Virus
- 10. Syphilis screens for this dangerous venereal disease
- 11. West Nile disease seasonally.

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 cytomeglavirus.
- 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.

Data from 2002 indicates it costs US\$40-\$50 to test each blood donation<sup>5</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>6</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 1).

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

 Table 1: Blood Screening Market (If a screening test was available)

Adoption of the test 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. Amorfix has developed relationships with several blood transfusion services who have indicated a desire to have such a test when available.

# AMP Neurodegenerative Diseases

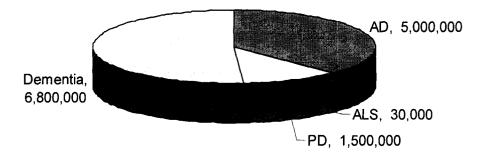
Three significant human AMP diseases are Alzheimer's Disease (AD), Parkinson's Disease (PD) and Amyotrophic Lateral Sclerosis (ALS). Estimates of the world market for these diseases are given in

<sup>&</sup>lt;sup>5</sup> http://www.priondata.org/data/A\_mktblood.html

<sup>&</sup>lt;sup>6</sup> http://www.chiron.com/investors/shareholder/index.html

Table 2. 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>7</sup> One in 10 persons over 65 and nearly half of those over 85 have Alzheimer's Disease,<sup>8</sup> the most common form of dementia, accounting for over 60% of cases.<sup>9</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 5)<sup>10</sup>.

Figure 5: 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 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>11</sup>

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

 Table 2: Diagnostic Markets (If a screening test was available)

<sup>7</sup> U.S. Bureau Census. Current Population Reports, Special Studies, P23-190. April 1996.

<sup>&</sup>lt;sup>8</sup> Alzheimer's Association – Statistics Available.

<sup>&</sup>lt;sup>9</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>&</sup>lt;sup>10</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.

<sup>&</sup>lt;sup>11</sup> The World Health Report; The World Health Organization; 1998.

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>12</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>13</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>14</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>15</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.

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 Amorfix 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 has not been able to detect aggregated Abeta in human blood plasma or cerebral spinal fluid samples. The Company has discontinued further research on the human AD blood test at this time.

<sup>&</sup>lt;sup>12</sup> US Neurodegenerative Disease Treatment Market, March, 2003.

<sup>&</sup>lt;sup>13</sup> Healthcare Review: CNS. Datamonitor. September, 2002.

<sup>&</sup>lt;sup>14</sup> Alzheimer's Treatment Alternative Set to Expand Lucrative Market. Datamonitor. May 9, 2002.

<sup>&</sup>lt;sup>15</sup> Alzheimer's Treatment Alternative Set to Expand Lucrative Market. Datamonitor. May 9, 2002.

The Company is assessing other potential commercial applications for this very sensitive aggregated Abeta protein assay and has identified a potential 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 A4 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 A4 test will accelerate the development and evaluation of new treatments for AD.

The Company estimates that there are approximately 200,000 mice used annually in Azheimer 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 expects that its assay could also be sold in this price range as it complements the existing IHC test, provides quantitative measurement data and could be used to detect aggregated Abeta significantly earlier providing significant advantage in shortening the time course of preclinical studies.

## 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.

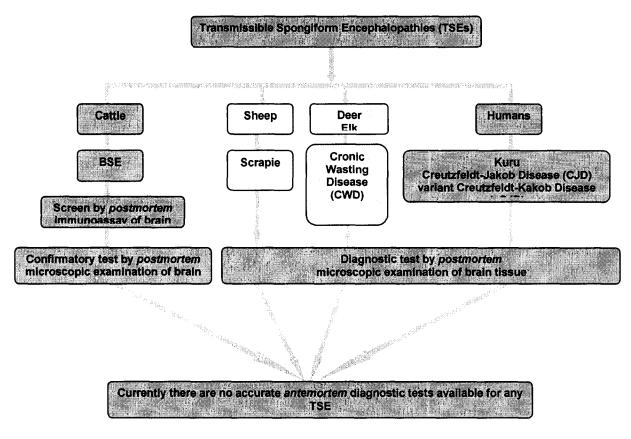
The market for an ALS diagnostic test is small even if you assumed 10 times more people would be tested than actually have the disease. This would be 60,000 tests per year and at US\$100 per test would only be a US\$6,000,000 market size. The test may also be useful in monitoring therapy where the market is estimated at 70,000 patients worldwide.

## 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.



## Figure 6: Transmissible Spongiform Encephalopathies (TSEs)

#### 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>16</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>17</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

<sup>&</sup>lt;sup>16</sup> Scrapie Prevention and Awareness on U.S. Sheep Operations (January 2004). USDA Web site.

<sup>&</sup>lt;sup>17</sup> Scrapie Program. USDA Web site.

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>18</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>19</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>20</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.

#### 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<sup>TM</sup> test or EP-TSE<sup>TM</sup> 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. Other than its blood screening test for vCJD, Amorfix intends to out-

<sup>&</sup>lt;sup>18</sup> Bovine Spongiform Encephalopathy (February 2002). USDA Web site.

<sup>&</sup>lt;sup>19</sup> Bovine Spongiform Encephalopathy (BSE). USDA Web site.

<sup>&</sup>lt;sup>20</sup> USDA News Release No. 0432.03. USDA Makes Preliminary Diagnosis of BSE. USDA Web site.

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. Complete the NIBSC process to validate the performance of the EP-vCJD<sup>™</sup> Blood Screening Assay using human patient samples and to manufacture and supply diagnostic kits for prevalence studies;
- 2. Continue to generate assay performance data in France for the vCJD assay in a blood transfusion center;
- 3. Form collaborations to expand the utility and further validate the benefits of the  $A^4$  assay;
- 4. Complete development of screening test for liver cancer in collaboration with BioMosaics;
- 5. Complete proof-of-concept preclinical studies for Alzheimer's Disease targeting misfolded SOD1 using passive and active immunization targeting the misfolded SOD1 protein;
- 6. Identify and develop new DSEs on misfolded protein targets for both diagnostic and therapeutic applications.

## **Regulatory** Approval and Certification

- 7. Maintain ISO 13485 Certification for Company for first product EP-vCJD<sup>TM</sup>.
- 8. Obtain CE Mark (or alternatively self-declared CE Mark if current process is delayed) for EPvCJD<sup>TM</sup> Blood Screening Assay to allow sales and marketing of the product in Europe, subject to individual country regulations.

## Marketing and Sales

- 9. Sell EP-vCJD<sup>TM</sup> Blood Screening Assay for research-use-only prevalence studies and follow with the commercial introduction of human diagnostics for blood screening for prions.
- 10. Engage partners for the ALS vaccine and antibody DSE programs.
- 11. Launch a service business using the  $A^4$  assay to test preclinical samples;
- 12. Engage partners in the therapeutic development of novel DSE targets on misfolded proteins.

#### **Manufacturing**

13. Establish manufacturing for the EP-vCJD<sup>TM</sup> Blood Screening Assay, and warehouse and quality control facilities in Europe through partnerships for commercial supply.

## General and Administrative

14. 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 sought by the Amorfix vCJD technology for diagnostic use are in Europe due to the higher prevalence of BSE positive cattle and the resultant higher prevalence of people who have died from vCJD. A blood screening test for vCJD is currently not regulated, however, a process was established in late 2007 under the direction of the European Commission's IVD Technical Group to establish regulatory guidelines and a Common Technical Specification (CTS) for an in vitro diagnostic test for vCJD. Amorfix joined the European Diagnostic Manufacturers Association (EDMA) in order to participate directly in this regulatory process for establishing an in vitro diagnostic (IVD) test for vCJD. A CTS would establish standards of measurement that a vCJD blood screening assay must achieve to receive a CE mark registration. A CE mark registration would allow the product to be marketed and sold in Europe, subject to individual EU country regulations.

The initial markets for Amorfix's other 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

## Europe

In-vitro diagnostic medical devices are regulated in Europe by the In Vitro Diagnostic Medical Device Directive (IVDD) 98/79/EC of the European Parliament on *in vitro* diagnostic medical devices. The principles of the IVDD have to be transformed into national law in each member state of the European Union. In vitro diagnostics can only be put on the EU market if they carry the CE mark. The IVDD describes the provisions how to achieve the CE mark according to the type of device; those listed in List A under Annex II, those listed in List B under Annex II and those that are not regulated by Annex II. List A includes high-risk devices for blood screening such as HIV, HTLV and hepatitis tests, and these devices are required to meet the requirements defined in a Common Technical Specification (CTS).

Currently, an in vitro diagnostic blood test for vCJD blood screening is not a regulated test under the IVDD, however, the process to determine if and how a test should be regulated in Europe has been initiated at the request of a member state. A draft CTS for a vCJD test has been developed. It is expected that this draft will be finalized early 2010 followed by inclusion of vCJD into the IVDD Annex II List A. The first placing on the market and/or the clinical investigation of a medical device must be registered with the appropriate competent authorities.

## 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<sup>TM</sup> 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<sup>TM</sup> 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 pre-clinical 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>21</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**

Amorfix's vCJD blood screening assay will be sold to the national blood collection services of the various countries that implement the test. The pricing will be established by negotiation between the parties and will typically result in a minimum three year contract award.

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

<sup>&</sup>lt;sup>21</sup> The EFSA Journal (2007) 540, 1-12

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 plans to market and sell the vCJD blood screening assay direct to the national blood collection agencies of each country that determines it needs to implement the test. This can be accomplished by a company of Amorfix's size due to the limited number of blood agencies in each country. Amorfix does not intend to market other 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 human and animal diagnostic and therapeutic healthcare markets. Amorfix is pursuing this objective with the strategies below.

#### Generate Product Revenues

Amorfix's revenues, if any, in the future are expected to be first derived from sales of its vCJD blood screening assay to blood collection agencies in jurisdictions concerned about the potential transmission of blood infectivity from prions. Further product revenues 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, milestone payments, 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 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

Whenever practical, Amorfix will seek to 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 who have demonstrated their capabilities at other device and drug development companies. Amorfix will need to continue to recruit additional talent from the human and animal pharmaceutical industry to strengthen its operations, while also seeking to retain current personnel.

## Competitive Conditions

Amorfix faces competition from large biotechnology and pharmaceutical companies in blood safety, food 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 and veterinary needs. Each of these markets will be discussed below.

# **Protecting the Blood Supply**

The Amorfix technology application for blood supply will compete with current approaches to enhance blood safety, as well as with future products under development by others, including larger medical technology, biotechnology, pharmaceutical and hospital supply companies, national and regional blood centers, governmental organizations and agencies, academic institutions and other agencies. Many companies and organizations may be competitors to Amorfix and have substantially greater financial and other resources and may have greater experience in conducting field studies and clinical trials as well as obtaining regulatory approvals for these products. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended safety purposes of the Amorfix products, or that might render the Amorfix technology and products relatively obsolete. A number of companies have been and are attempting to develop such a vCJD blood screening test (Table 3) and to date, to the knowledge of Amorfix, they have not been successful.

able 5: Companies working on a riton rest for blood					
Apparent start of prion work	Still working in prion field?	Commercial Post-Mortem Assay?	Working on blood prion test?		
1998	Probably	No	Unknown		
1999	Yes	Yes	Unknown		
2003	Yes	No	No		
1998	Yes	No	Unknown		
2003	Yes	No	Unknown		
Unknown	Yes	No	No		
Unknown	Yes	No	Yes		
Pre-2001	Yes	Yes	Unknown		
1997	Yes	No	No		
2003	Yes	No	Unknown		
2002	With Roche	No	Unknown		
2001	Yes	No	Unknown		
1999	Yes	Yes	No		
1996	Yes	Yes	Yes		
1980	Yes	Yes	No		
2000	Yes	Yes	Unknown		
	Apparent start of prion work 1998 1999 2003 1998 2003 Unknown Unknown Dre-2001 1997 2003 2002 2001 1999 1996 1996	Apparent start of prion workStill working in prion field?1998Probably1999Yes2003Yes1998Yes2003Yes2003YesUnknownYesYesYes1997Yes1997Yes2003Yes1997Yes2003Yes1997Yes1997Yes2003Yes2003Yes1997Yes2003Yes2003Yes2004Yes2005Yes1999Yes1996Yes1980Yes	Apparent start of prion workStill working probablyCommercial post-Mortem postave?1998ProbablyNo1999YesNo2003YesNo1998YesNo2003YesNo2003YesNo1998YesNo2003YesNo1997YesNo1997YesNo2003YesNo2003YesNo1997YesNo2003YesNo2004YesNo2005YesNo2006YesNo2007YesNo2001YesNo2001YesNo1999YesYes1996YesYes1996YesYes		

Table 3: Companies Working on a Prion Test	t for Blo	)od <sup>22</sup>
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Of these competitors, the ones known to be working on a blood prion test have presented various forms of data at international conferences. Chiron and Microsens are the only companies other than Amorfix to present independent data from a NIBSC blinded panel and this information was incomplete.

Amorfix believes that application of its technology in developing diagnostic detectors of the presence of prions in stored blood could significantly improve the safety of the world's blood supply which currently is offered without any meaningful prion testing to date. The reality of the risk of infection through donated blood has recently been demonstrated clinically as four people have been infected through direct blood transfusions and several thousand people received blood fractions made from a vCJD-infected plasma pool. There is a general concern that vCJD is now within the blood transfusion systems and a screening assay for blood is urgently required to protect everyone from the next epidemic.

# **Protecting the Food Supply Market**

To date, nearly 90 institutions, companies, or research laboratories have experimented in the area of prion detection. The worldwide market for detecting prions was galvanized with the awarding of the Nobel

<sup>&</sup>lt;sup>22</sup> Table extracted from <u>http://www.priondata.org/</u> and modified to the best of the Company's knowledge

Prize in Medicine in 1997 to Dr. Stanley Prusiner, a researcher connected with the University of California at San Francisco who made the initial discovery that the existence of prions in animals and humans may cause neurodegenerative disease predisposition in these species.

Subsequent to this finding, many researchers have focused upon analyzing the presence of prions in the biofluids, particularly in the central nervous system where such prions tend to aggregate. The difficulty confronting researchers is that the extraction of biofluids from living organisms is a problematic and challenging endeavour, particularly when attempting to extract fluids from the brain or the spinal column of the studied species. Therefore, research until recently has been relegated to focusing upon measuring and attempting to detect prions in tissues from post-mortem autopsies of humans or animals.

The European Food Safety Authority published a report comparing seven rapid post-mortem tests for  $BSE^{23}$ . The Idexx Laboratories Inc, test was the most sensitive but many of the others performed well enough to be approved for use. To date, no ante-mortem test has been published. Once again those companies working on a blood screening test for vCJD (see Table 3) are likely also working on a blood test for BSE in cattle and other animals, but no one has validated such a test.

Amorfix is developing an ante-mortem vCJD blood test with the highest specificity and sensitivity reported to date (TSE Conference, Berlin, June 2007) using vCJD brain prions spiked into human plasma. Others have investigated this ante-mortem blood testing venue but with little success. Those entities investigating in this ante-mortem prion field have been comparatively categorized according to the following table:

	Specific	Sensitive	<b>Blood-Based</b>	Scalable	Protectable
Surrogate Marker Technologies	No	Yes	Yes	Yes	Yes
Protease Resistance Technologies	Yes	No	No	No	No
Affinity Reagent Technologies	No	Yes	No	Yes	Yes
Conformation Dependent Immunoassay Technologies	Yes	Yes	No	No	Yes
Amorfix Technology Applications	Yes	Yes	Yes	Yes	Yes

## Table 4: Antemortem Blood Testing Technology Comparison

As can be seen from the foregoing table, competitive surrogate marker technologies, while sensitive and accessible in blood, lack specificity in determining the presence of misfolded proteins or prions. Those tests involving protease resistance, while specific, are not as scientifically sensitive as the Amorfix test and therefore, cannot be scalable. Affinity reagent tests are not specific and cannot be utilized in premortem testing. Finally, conformational dependent immunoassays, while somewhat specific and sensitive, are neither scalable nor can be applied in the ante-mortem prion testing context. Conversely, the Amorfix technology is specific, highly sensitive, available for use in ante-mortem context, is scalable and has definite proprietary protection.

<sup>&</sup>lt;sup>23</sup> http://www.efsa.eu.int/science/tse\_assessments/bse\_tse/694\_de.html

There is currently one company marketing a test for CWD to deer hunters, who must cut out a defined piece of tissue and mail it to a central facility and wait prior to eating the meat. This market is small and will not be addressed unless market conditions demand a diagnostic test.

### 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>24</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

<sup>&</sup>lt;sup>24</sup> http://www.predictivediagnostics.com/041905.html

companies have significant programs to develop drugs for the treatment of neurodegenerative disease. 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. The EP technology may have the potential to validate or refute these claims as well as to discover AMPs in many other disorders. Amorfix will look for partners to take a proteomics approach to achieving these discoveries.

## **Proprietary Protection**

Amorfix has acquired the rights to certain proprietary discovery platforms for the identification of proteins involved in misfolding diseases embodied in various patent applications, including but not limited to "Methods of Detecting Prion Proteins" defined in Canadian Patent Application 2,437,675 and "Epitope Protection Assay" defined in U.S. Provisional Patent Application 60,497,362. Amorfix has also filed an international patent applications related to SOD1-based immunotherapy to further protect its intellectual property rights related to its therapeutic programs. 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, 2009, Amorfix has a deficit of \$18,760,886. 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 partnership 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 favourable terms, if at all, or that its current or future collaborations will be successful. Failure to attract 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 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, 2009, 42,541,181 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, 2007and 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 2008	0.93	0.76	469,200
May 2008	0.93	0.78	526,300
June 2008	0.90	0.67	663,400
July 2008	0.72	0.50	263,900
August 2008	0.63	0.51	108,800
September 2008	0.63	0.27	1,223,200
October 2008	0.48	0.20	1,211,700
November 2008	0.44	0.24	1,260,100
December 2008	0.69	0.20	970,000
January 2009	0.81	0.58	1,016,700
February 2009	0.95	0.42	1,479,200
March 2009	0.70	0.52	403,000

## **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, 2009, 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
George Adams Ontario, Canada	President, Chief Executive Officer and Director	President and Chief Executive Officer of Amorfix since April 2005; 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
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	Special Partner of Birch Hill Equity Partners, a private equity partnership.	June 9, 2006
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	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.	N/A
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 6,226,400 common shares, being 14.6% of the issued common shares on a non-diluted basis as at March 31, 2009.

### 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 10, 2009, 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, became 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 2009 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, 2009.

## 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.

## 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, 2009, 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 10, 2009 in respect of the Company's financial statements as at March 31, 2009 and March 31, 2008 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 6, 2008 (the "Information Circular"). Additional financial information relating to Amorfix is included in Amorfix's audited financial statements for the years ended March 31, 2009 and March 31, 2008 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.

## **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 Board including 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.

Fiscal Year End	Audit Fees <sup>(1)</sup>	Audit Related Fees	Tax Fees <sup>(2)</sup>	All Other Fees
2009	\$67,000	\$-	\$-	\$-
2008	\$64,210	\$-	\$450	\$-

## External Auditor Service Fees (By Category)

(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**

I, George Adams, President & 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, 2009.

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(s) 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 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, 2009 and ended on March 31, 2009 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 10, 2009

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George Adams President & Chief Executive Officer

### FORM 52-109F1

#### **CERTIFICATION OF ANNUAL FILINGS**

### FULL CERTIFICATE

I, James Parsons, Chief Financial 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, 2009.

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(s) 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 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, 2009 and ended on March 31, 2009 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 10, 2009

James Parsons Chief Financial Officer

# FORM 52-109F2

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# **Certification of Interim Filings**

I, George Adams, President & Chief Executive Officer of Amorfix Life Sciences Ltd., certify that:

- 1. I have reviewed the interim financial statements and interim MD&A (together, the "interim filings") of Amorfix Life Sciences Ltd. (the "issuer") for the interim period ended December 31, 2008.
- 2. Based on my knowledge, having exercised reasonable diligence, the interim 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, with respect to the period covered by the interim filings.
- 3. Based on my knowledge, having exercised reasonable diligence, the interim financial statements together with the other financial information included in the interim filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date and for the periods presented in the interim filings.
- 4. 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) for the issuer, as those terms are defined in National Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings*, for the issuer.
- 5. 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 end of the period covered by the interim filings
  - (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 interim 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 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 N/A
- 5.3 N/A
- 6. The issuer has disclosed in its interim MD&A any change in the issuer's ICFR that occurred during the period beginning on October 1, 2008 and ended on December 31, 2008 that has materially affected, or is reasonably likely to materially affect, the issuer's ICFR.

Date: February 11, 2009

Geage Adam

George Adams President & Chief Executive Officer

# FORM 52-109F2

# **Certification of Interim Filings**

I, James Parsons, Chief Financial Officer of Amorfix Life Sciences Ltd., certify that:

- 1. I have reviewed the interim financial statements and interim MD&A (together, the "interim filings") of Amorfix Life Sciences Ltd. (the "issuer") for the interim period ended December 31, 2008.
- 2. Based on my knowledge, having exercised reasonable diligence, the interim 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, with respect to the period covered by the interim filings.
- 3. Based on my knowledge, having exercised reasonable diligence, the interim financial statements together with the other financial information included in the interim filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date and for the periods presented in the interim filings.
- 4. 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) for the issuer, as those terms are defined in National Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings*, for the issuer.
- 5. 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 end of the period covered by the interim filings
  - (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 interim 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 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 N/A
- 5.3 N/A
- 6. The issuer has disclosed in its interim MD&A any change in the issuer's ICFR that occurred during the period beginning on October 1, 2008 and ended on December 31, 2008 that has materially affected, or is reasonably likely to materially affect, the issuer's ICFR.

Date: February 11, 2009

James Parsons Chief Financial Officer

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# ANNUAL INFORMATION FORM

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

Telephone: (416) 847-6898 Facsimile: (416) 847-6899 E-mail: info@amorfix.com Web: www.amorfix.com

Unless otherwise indicated all information in this Annual Information Form is presented as at and for the year ended March 31, 2008

June 11, 2008

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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 <u>www.sedar.com</u>.

The management information circular of the Company dated August 9, 2007 and filed on SEDAR on August 24, 2007 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.

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**

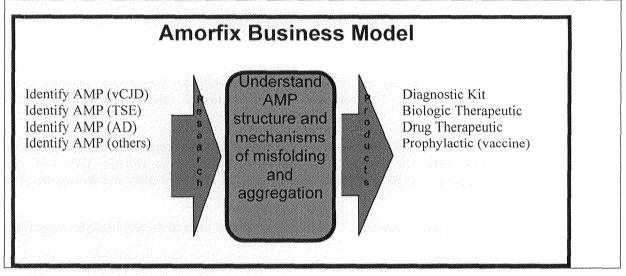
#### Three Year History

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).





- 6 -

#### AMP Detection Technology

 $(1,1) \in \{1,2,2,\dots,n\}$ 

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.

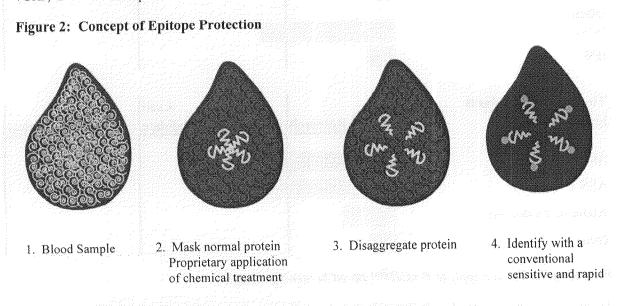
There are no definitive diagnostic tests for AMP diseases prior to death. Current diagnostic testing is limited because the species being tested require invasion into the central nervous system by means of the spinal column. Detecting the presence of AMPs in living organisms becomes risky, expensive 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 has 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.



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 a 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 entry of the products will depend upon regulatory approval processes which vary from country to country and depend upon the product's use for agriculture or human applications.

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 Antibastica Pitali 2004 (Antibastica Pitali 2004)

<b>Diagnostic Products</b> Blood screening assays	Research	Validation Pre-commercial	Regulatory
<u>Human</u> vCJD			Launch 2009
Alzheimer's disease		na sana na nana na na na na na na na na na n	
<u>Animal</u> Scrapie			
Animal			

# **Figure 3: Product Development Pipeline**

BSE

**Therapeutic Products** Human Candidate Research Preclinical ALS - antibodies ALS - vaccines Alzheimer's disease Other

Lead

# **Protecting the Blood Supply (EP-vCJD<sup>TM</sup> Blood Screening Assay)**

To date approximately two hundred people have been diagnosed with vCJD due to consumption of BSEinfected meat, but it is estimated that many people are incubating the disease. To date, four people have been infected through direct blood transfusions and several thousand people received blood fractions made from a vCJD-infected plasma pool. There is a general concern that vCJD is now within the blood transfusion systems and a screening assay for blood is urgently required to protect everyone from the next epidemic. 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.

The Company believes that its Epitope Protection (EP) platform technology will allow it to develop 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 product is expected to be a blood diagnostic test (EP-vCJD<sup>TM</sup> Blood Screening Assay) that will detect the presence of AMPs for vCJD in human blood.

In late 2005, the United Kingdom National vCJD Surveillance Unit and National Institute for Biological Standards and Controls (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. 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 support 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<sup>TM</sup> Blood Screening Assay. During this period, the Company applied to access human vCJD blood samples as part of the process that had been established by NIBSC. 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 manufacturer's 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. The UK HPA subsequently slowed down the tender process.

In February 2008, Amorfix reported the results of a second blinded panel of spiked 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 highthroughput assay on this 2007 blinded panel compared to its research grade assay blinded panel results from a year earlier.

From July 2007 to present, the Company focused on 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<sup>TM</sup>) was able to detect prion disease in symptomatic sheep. Subsequent to year end, in April 2008, the sheep scrapie blood screening assay was successful at detecting prion disease in presymptomatic scrapie sheep. Amorfix continues to develop the EP-TSE<sup>TM</sup> assay to improve the robustness and sensitivity of the assay and is assessing the potential market opportunity for the development of a commercial version of the test for the veterinary market.

In February 2008, the Expert Advisory Group 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 the EP-vCJD<sup>TM</sup> Blood Screening Assay using British blood samples. The Company believes this process will have three steps: the first will involve the completion of a blinded sheep 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 variant CJD disease. The Company believes that it will have to successfully pass each step in order to progress to the next step. Subsequent to year-end, the Company completed the sheep scrapie blinded panel and submitted the results to NIBSC for assessment.

As the NHS has not yet awarded the tender contract to supply blood screening tests for a prevalence study of vCJD using 60,000 British blood samples, the Company believes that the tender may not be awarded until the Company and any potential competitors complete the NIBSC process.

A blood screening test for vCJD is currently not regulated, however, the process to determine if and how a test should be regulated in Europe has been initiated at the request of the UK. On October 26, 2007 Amorfix attended the workshop for vCJD diagnostic assays sponsored by the Medical Device branch of the Enterprise and Industry Directorate-General of the European Commission. The Company was the only attendee to present a blood diagnostic test for vCJD that was in the process of being commercialized. Amorfix will support and assist the regulatory process and has joined the European Diagnostic Manufacturers Association (EDMA) as one way to participate in this process. Amorfix will attend a regulatory meeting in Brussels in June 2008 through EDMA. The European Commission has a current projected target date of the end of calendar 2008 to complete the development of a Common Technical Specification (CTS) which will establish standards of measurement that a vCJD blood screening assay must achieve to receive a CE mark registration. A CE mark registration would allow the product to be marketed and sold in Europe, subject to individual EU country regulations.

The Company's vCJD assay development is currently focused on completion of the steps set out by the NIBSC expert committee prior to completing the remaining activities to scale up and commercialize the test. The Company is not in control of the timing of receiving any of the panels or receiving the results thereon from NIBSC, and significant process delays have previously occurred with the UK government agencies. There can be no certainty that Amorfix will be successful at completing the NIBSC three-step process or commercializing its assay on its expected timelines or at all.

The Company's initial target markets for its EP-vCJD<sup>TM</sup> human blood screening assay are those countries that had the highest incidences of BSE-positive cattle. The blood transfusion market in Europe is estimated to be 20 million donations per year with half of this in the three largest countries of United Kingdom, France and Germany combined. Final commercial product sales and distribution of this assay is expected to require contracts and a regulatory-like approval process with individual country government health agencies.

Given the need for an ante-mortem test to protect the blood supply, it is anticipated regulatory approvals will not be unduly delayed. Amorfix launched its test for sale "for research use only" purposes in June 2007. Amorfix's initial strategy is to market this test for investigational use by the national health services of various countries as a tool to gain information on the prevalence of vCJD in their country's population, while the Company completes the validation of the commercial test. This will familiarize the national blood screening centres with Amorfix's assay and provide information to assist the various countries in assessing their need to adopt a blood screening test for vCJD.

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

The first case of BSE in cattle emerged in the United Kingdom over 20 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 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 fiscal 2008, Amorfix adapted its vCJD blood screening assay to detect endogenous prions in symptomatic sheep and subsequent to year end 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 have been detected by the Amorfix EP-TSE<sup>™</sup> 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.

Amorfix's assay for the sensitive and specific detection of BSE in bovine blood is called EP-BSE<sup>TM</sup>. In January 2006, the Company completed the proof of concept for developing a test for BSE by identifying two epitopes (or binding sites) on bovine prion protein which are blocked by Epitope Protection. Future development of EP-BSE<sup>TM</sup> will involve the testing of blood using a suitable animal model (bovinized mice), optimization of the assay with bovine blood and analysis using ante-mortem blood samples from cows which have BSE. Although the number of cases has declined significantly, the United Kingdom continues to report new cases of BSE each year. Amorfix has made contact with the UK authorities and has access to blood samples from BSE-positive cattle. Amorfix does not currently plan to advance the development of a live animal BSE test without external funding from a commercial partner for this product.

Amorfix began the development of its blood screening assay for sheep scrapie as a consequence of supporting the regulatory pathway for its  $EP-vCJD^{TM}$  test. While the human vCJD blood screening test will be sold to a limited number of customers by Amorfix, the blood transfusion agencies in each country that adopts the test, the marketing and sale of TSE blood screening tests will require an established sales and marketing partner. Amorfix is seeking partners who would support the commercial development of its animal TSE assays.

#### Early Diagnosis and Treatment for Alzheimer's Patients (EP-AD<sup>™</sup> Test)

Alzheimer's disease (AD), Amyotrophic Lateral Sclerosis and Parkinson's diseases are chronic neurodegenerative illnesses which are associated with neural deposits of AMPs made up of misfolded normally-present protein. 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 protein. Once again the only definitive diagnostic for these diseases is post-mortem examination of brain tissue. There are currently 5 million people in North America with AD and an equal number with dementia which may be suffering from AD but it is impossible to diagnose due to a lack of a blood test. Worldwide there are 460 million people over the age of 65 who should be tested annually for AD now that effective therapies are available. The worldwide market would be more than US\$1B annually.

Amorfix's assay for the sensitive and specific detection of aggregated Abeta (A $\beta$ ) in human blood or other biofluid is called EP-AD<sup>TM</sup>. 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. The Company demonstrated the use of monoclonal antibodies that recognize epitopes on A $\beta$  protein that are masked with EP treatment.

On the strength of these data and the development plan, Amorfix was awarded an Industrial Research Assistance Program (IRAP) grant from the Government of Canada in the amount of \$322,000 that supports a portion of the salaries of the research staff for this project.

From December 2006 to March 2008, the Company initiated and progressed its AD diagnostic assay development by screening and selecting monoclonal antibodies, established a sample preparation protocol to enrich for the Abeta proteins, assessed several different assay formats and began to optimize 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. The Company plans to test human AD patient blood samples for the detection of aggregated Abeta based on the current sensitivity of the assay. The Company has identified a source for these samples and believes it will be able to access sufficient numbers of samples for testing and validation. If unsuccessful at detecting aggregated Abeta in AD patient blood, the Company will make a decision to continue to optimize the assay for greater sensitivity and repeat human AD patient blood sample testing or abandon the project.

Once the assay has been validated with AD blood samples, Amorfix may be in a position to commercialize the product. The EP-AD<sup>TM</sup> test will then be optimized for high-speed platforms with a partner with significant market share in the human diagnostics field. Amorfix expects to establish manufacturing under ISO and GMP guidelines with a third party. A beta-test site will be established at a large clinical laboratory and normal and AD patient blood samples will be screened to determine the value and ease of use of the EP-AD<sup>TM</sup> test. These data will be used to apply for regulatory approval for the test. It is estimated that the regulatory submission could be made in 2009 with approval and product launch in 2010. Given the need for a diagnostic test for early detection of AD, it is anticipated regulatory approvals will not be unduly delayed.

#### **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 brain of ALS patients is called Superoxide dismutase-1 (SOD1).

In calendar 2006 in a series of agreements, the Company acquired certain SOD1 technologies and exclusively licensed additional SOD1 technologies owned by Dr. Cashman 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 (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. Biogen subscribed for 289,187 common shares of the company at \$1.46 per share for gross proceeds to Amorfix of \$422,213. On July 23, 2007, the Company announced the achievement of the first research milestone, the development of disease-specific antibodies to misfolded SOD1, and an additional Biogen investment of US\$150,000 in Amorfix to retain their option to license Amorfix's technology. Consequently, Biogen subscribed for 91,445 common shares of Amorfix at a price of \$1.76 per share for gross proceeds to Amorfix of \$160,944 (US\$150,000). During the remaining term of the option, Biogen may subscribe for up to an additional US\$225,000 of additional common shares of Amorfix based on the achievement of two further predefined research goals. If Biogen exercises its option, over the term of the license agreement Amorfix will be eligible to receive milestone payments in excess of US\$25 million plus royalties on sales. Biogen will be responsible for all development and commercialization costs.

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. During 2007, Amorfix established the proof-of-concept of both of these approaches in pilot studies with mouse models of ALS disease. The next Biogen research milestone involves demonstrating a therapeutic benefit in an animal model of ALS using the candidate antibodies. Amorfix has now initiated larger ALS animal model studies and expects results in the second half of calendar 2008.

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, also known as Lou Gehrig's Disease. 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. Amorfix is currently assessing potential mouse models of AD that could be used to test candidate antibodies and vaccines that target misfolded SOD1.

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 application relates to the methods and two compositions for treating and detecting conditions, disease and disorders mediated by non-native SOD1.

#### Significant Acquisitions

Amorfix made no significant acquisitions during fiscal year 2008 for which disclosure is required under Part 8 of National Instrument 51-102.

#### **DESCRIPTION OF BUSINESS**

#### **Business of the Company**

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

Amorfix was formed in January 2004 to commercialize the discoveries of the epitope protection (EP) technologies at the University of Toronto discovered by Dr. Neil Cashman and Dr. Marty Lehto. Amorfix acquired the rights to the technology including patent applications relating to "Methods of Detecting Prion Proteins" and "Epitope Protection Assay", pursuant to an assignment agreement dated February 18, 2005, as amended April 1, 2005, among Amorfix, Dr. Cashman, Dr. Lehto and the University of Toronto.

Since the acquisition of this founding technology in 2005, Amorfix has built a portfolio of diagnostic and therapeutic product opportunities, validated each of these research and development programs with independent third parties, established strong research and operating teams to develop and commercialize our first diagnostic tests, and acquired the financial resources necessary to support this product development.

Amorfix's theranostic strategy involves the development of products which can detect the presence of AMPs in blood or other biofluids. Detection of prions in infected animals has the potential to enhance the protection of the food supply. Detection of vCJD prions has the potential to improve the safety of blood transfusions and thereby avert the unintended human transfusions of prion-contaminated blood. Earlier detection of people with neurodegenerative diseases has the potential to significantly change the prognosis for these patients and allow for earlier application of emerging therapies and the potential for monitoring of disease progression and effectiveness of therapeutic treatment using this diagnostic test. Finally, with the knowledge gained from developing the diagnostic tests and through gaining an understanding of the structure of misfolded proteins and their mechanism of misfolding, Amorfix plans to develop therapies to treat these diseases.

# **Operations**

Amorfix intends to outsource the physical manufacturing of its diagnostic and therapeutic products where practical to ensure the lowest possible cost with the highest quality. This outsourcing of manufacturing is expected to allow Amorfix to minimize costs and focus on continued innovation and development while utilizing other manufacturers' existing production infrastructure and expertise. Amorfix achieved ISO 13485:2003 Medical Device certification in June 2007 which qualifies its quality management system to support the design, development, feasibility, validation and commercialization of its products.

All Amorfix products will be required to be manufactured under applicable regulatory guidelines including ISO quality management system or GMP guidelines. Amorfix qualifies all suppliers under its quality management system to ensure they meet the established criteria for supply. Certain components or raw materials used in the EP-vCJD<sup>TM</sup> test kit are sourced and available only from a single supplier. The company has negotiated draft commercial supply or license agreements for these components and intends to have final agreements in place prior to commercial product sales. All other components and the kit assembly operation have more than one available source of supply.

The company is currently testing the parameters of various steps of the EP-vCJD<sup>TM</sup> assay to determine the limits for establishing quality control ranges. The finished prion diagnostic kits would undergo final product validation testing before product release including verification that all quality control testing and manufacturing processes have been completed, documented and have met all performance specifications.

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

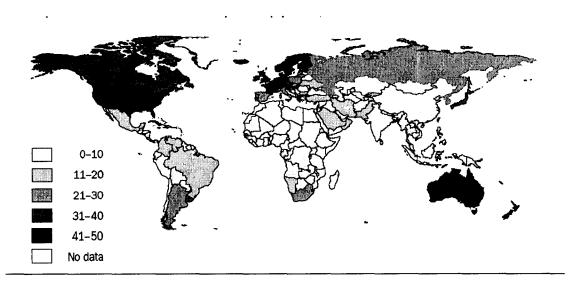
The markets for the Amorfix technology can be organized based upon ultimate target recipient, namely human markets and animal markets. Within each of these broad markets are certain diseases which the Amorfix technology seeks to diagnose, to detect and then ultimately treat through later research and development activities. In the human markets, the Amorfix technology seeks to detect AMPs in diseases such as vCJD, AD, ALS, and PD. Within the animal market, the Amorfix technology is targeted at Scrapie, BSE and CWD.

#### Human Markets

The Amorfix EP-CJD<sup>™</sup> test for screening for prions in blood is a significant opportunity. There is a general concern that vCJD is now within the blood transfusion systems and a screening assay for 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>1</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>2</sup>, less than 40 per cent are collected in the developing world where 82 per cent of the planet's population lives (Figure 4). 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. The potential development of prion-detecting products through the application of the Amorfix technology in stored blood inventories is potentially significant.



### Figure 4: Number of Blood Donations per 1000 Population in 1998-99

(Reference: http://www.who.int/bloodsafety/global\_database/en/SumRep\_English.pdf)

<sup>&</sup>lt;sup>1</sup> http://www.who.int/bloodsafety/global\_database/en/SumRep\_English.pdf

<sup>&</sup>lt;sup>2</sup> http://www.ifrc.org/docs/news/04/04040601/

The global market for blood products is large and growing. Over 40 million units of whole blood are collected each year in the U.S., Europe and Japan, yielding over 40 million units of red blood cells for transfusion.<sup>3</sup> Worldwide, approximately US\$4 billion is spent each year on red blood cells<sup>4</sup> Over one-third of all transfusions occur in the U.S. where it is estimated that one out of every three Americans will receive a transfusion at some point during his or her lifetime. Driven by an aging population susceptible to illness, increased prevalence of new disease and a rise in the number of major surgeries performed, blood use in the U.S. grew more than ten percent between 1999 and 2002. Blood use, particularly units of red blood cells, is expected to continue to increase as aggressive therapeutic treatments requiring chronic transfusions become more routine.

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 to hospitals for storage and transfusion: red blood cells, plasma and platelets.

The demand for blood products is ultimately driven by hospital-based physicians, particularly surgeons, in the acute care setting. Hematologists and oncologists also prescribe most of the blood used to treat chronic diseases such as cancer. 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 the United States and Canada, prior to transfusion, blood is tested for:

- 1. ABO Typing provides determination of Blood type: A, B, O, or AB
- 2. Rh Factor Determination indicates positive or negative Blood type
- 3. Blood Group Antibodies indicates unexpected antibodies that may be a result of prior transfusion, pregnancy or other factors
- 4. Hepatitis B Surface Antigen indicates a present infection (hepatitis) or carrier state of hepatitis B virus
- 5. Antibody to Hepatitis B Core additional test that detects a present or past infection with the hepatitis B virus
- 6. Antibody to Hepatitis C Virus indicates antibody to a virus that causes hepatitis C (responsible for non-A non-B hepatitis.) The mean incubation time is six to eight weeks
- 7. Alanine Aminotransferase (ALT) identifies a liver enzyme that, when increased, may indicate undetectable forms of hepatitis

<sup>&</sup>lt;sup>3</sup> The World Health Report; The World Health Organization; 2003.

<sup>&</sup>lt;sup>4</sup> Annual Report to the Securities and Exchange Commission on Form-10-K for Calendar Year 2002 for VI. Technologies, Inc.

- 8. Antibody to HTLV 1 and 2 indicates the antibody to a virus that causes adult T-cell leukemia, among other things
- 9. Antibody to HIV 1 and 2 indicates an infection with Human Immune Deficiency Virus
- 10. Syphilis screens for this dangerous venereal disease
- 11. West Nile disease seasonally.

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 cytomeglavirus.
- 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.

Currently (2002), it costs US\$40-\$50 to test each blood donation<sup>5</sup>. Chiron, Inc. has 80% of the market share in North America and does US\$500 million/yr in sales for HIV, HBV and HCV testing only in 2004<sup>6</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 1).

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

 Table 1: Blood Screening Market (If a screening test was available)

Adoption of the test 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. Amorfix has contacted several blood transfusion services who have indicated a desire to have such a test when available.

#### **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 3. 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>7</sup> One in 10 persons over 65 and nearly half of those over 85 have Alzheimer's Disease,<sup>8</sup> the most common form of dementia, accounting for over 60% of cases.<sup>9</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 5)<sup>10</sup>.

<sup>&</sup>lt;sup>5</sup> <u>http://www.priondata.org/data/A\_mktblood.html</u>

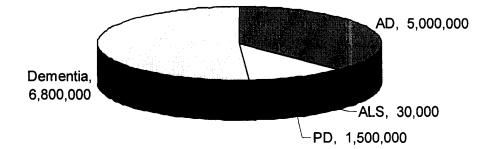
<sup>&</sup>lt;sup>6</sup> http://www.chiron.com/investors/shareholder/index.html

<sup>&</sup>lt;sup>7</sup> U.S. Bureau Census. Current Population Reports, Special Studies, P23-190. April 1996.

<sup>&</sup>lt;sup>8</sup> Alzheimer's Association – Statistics Available.

<sup>&</sup>lt;sup>9</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>&</sup>lt;sup>10</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.



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 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>11</sup>

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 If a screening test was available	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

Table 2: Diagnostic Markets (	(If a screening test was available)
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Figure 5: Distribution of Neurodegenerative Diseases

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

<sup>&</sup>lt;sup>11</sup> The World Health Report; The World Health Organization; 1998.

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>12</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>13</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>14</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>15</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.

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.

An AD diagnostic assay has potential application initially to elderly patients with memory problems visiting a physician. Much like a PSA assay (used for detection of prostate cancer) or cholesterol measure (arteriosclerosis), an AD diagnostic assay could rapidly become a routine diagnostic test that would not only be used by physicians to assess the vast majority of elderly patients, but also a test that is demanded by patients themselves. Co-marketing strategies for, perhaps novel, therapeutics that could be used in conjunction with a reliable diagnostic assay could greatly increase the potential market opportunity for a diagnostic test.

# 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 the 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

<sup>&</sup>lt;sup>12</sup> US Neurodegenerative Disease Treatment Market, March, 2003.

<sup>&</sup>lt;sup>13</sup> Healthcare Review: CNS. Datamonitor. September, 2002.

<sup>&</sup>lt;sup>14</sup> Alzheimer's Treatment Alternative Set to Expand Lucrative Market. Datamonitor. May 9, 2002.

<sup>&</sup>lt;sup>15</sup> Alzheimer's Treatment Alternative Set to Expand Lucrative Market. Datamonitor. May 9, 2002.

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.

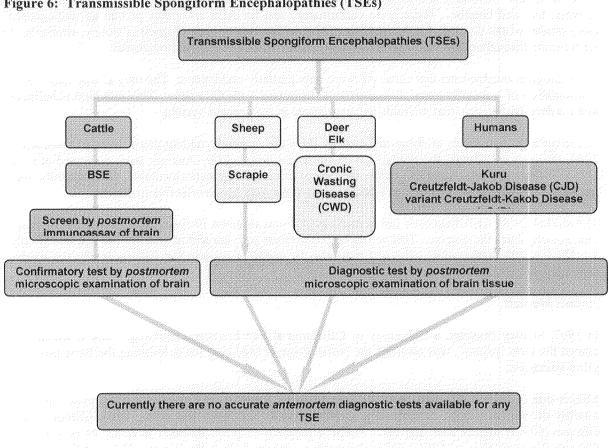
Approximately two thirds of those afflicted by ALS are currently undergoing a form of treatment. In 2002, the sales of Rilutek, the principal ALS treatment drug sold by Aventis, were estimated at roughly US\$35 million in North America. Given the lack of effective treatments available, the therapeutic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

The market for an ALS diagnostic test is small even if you assumed 10 times more people would be tested than actually have the disease. This would be 60,000 tests per year and at US\$100 per test would only be a US\$6,000,000 market size. The test may also be useful in monitoring therapy where the market is estimated at 70,000 patients worldwide.

#### 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.



#### Figure 6: Transmissible Spongiform Encephalopathies (TSEs)

## 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>16</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>17</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 scrapic 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.

<sup>&</sup>lt;sup>16</sup> Scrapie Prevention and Awareness on U.S. Sheep Operations (January 2004). USDA Web site.

<sup>&</sup>lt;sup>17</sup> Scrapie Program. USDA Web site.

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 recently 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.

Amorfix is developing a blood screening test for sheep scrapie and is seeking a partnership with an established animal diagnostics company to support commercial development, sales and marketing of the test.

#### 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.<sup>18</sup> The disease was first diagnosed in 1986 in Great Britain.<sup>19</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>20</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>21</sup>

On December 23, 2002, the US Department of Agriculture ("USDA") announced that a Holstein cow in the state of Washington had tested presumptively positive for BSE.<sup>22</sup> On December 25, 2003, the diagnosis was confirmed by an international reference laboratory in England.<sup>23</sup> On September 21, 2004, the Japanese Ministry of Health also confirmed the diagnosis of BSE in livestock in northern Japan. However, according to the USDA, the American beef supply is currently safe and there appears to be an extremely low risk to human health due to consumption of BSE-contaminated beef in the U.S. But the presence of Mad Cow Disease in the U.S. raises a host of medical, regulatory, and safety questions, including whether BSE screening of cattle should be increased, research funding is adequate, and facilities exist.

Because of the BSE outbreak in the United Kingdom, the rest of the European market banned the import of British beef from 1996 until 2006. In addition, findings of cattle with BSE over the last few years in the U.S. and Canada has had a similar impact on beef exports where export borders have been periodically closed pending assessment of the extent of the BSE outbreak. The financial consequence of this to the United Kingdom exceeded US\$2.5 billion per year. In Canada the economic loss after the discovery of the second cow with BSE was estimated at \$2.5 million per day.

Amorfix has demonstrated the proof of concept of using its Epitope Protection technology for the development of an ante-mortem blood test for BSE. To date, there now have been sixteen confirmed cases of BSE in North America. The possibility that BSE has entered the livestock industry worldwide is a growing concern. BSE has been diagnosed in native-born cattle in Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Switzerland, and the United

<sup>&</sup>lt;sup>18</sup> Consumer Questions and Answers About BSE (May 2003). Food and Drug Administration Web site.

<sup>&</sup>lt;sup>19</sup> Bovine Spongiform Encephalopathy (February 2002). USDA Web site.

<sup>&</sup>lt;sup>20</sup> Bovine Spongiform Encephalopathy (BSE). USDA Web site.

<sup>&</sup>lt;sup>21</sup> USDA News Release No. 0432.03. USDA Makes Preliminary Diagnosis of BSE. USDA Web site.

<sup>&</sup>lt;sup>22</sup> BSE and CJD Information and Resources. CDC Web site.

<sup>&</sup>lt;sup>23</sup> Regalado A. U.S. research into prion diseases is limited. Wall Street Journal. January 2, 2004.

Kingdom. More than 95% of cases identified have developed in the United Kingdom. In early 2005, BSE was confirmed as developing in a single goat that was slaughtered in 2002 in France.<sup>24</sup>

The industry has banned feeding ruminant parts to ruminants in the Western world, but still allows their use in feed to pigs, chickens and other livestock depending on the jurisdiction. Amorfix believes it is only a matter of time before BSE is shown to exist in cattle in North America and other animals worldwide. Although the number of detected BSE-positive cattle in Europe has declined from 2170 animals in 2001 to 323 in 2006, the continued existence of BSE is concerning given that feed bans have yet to be effective in eradicating the disease.<sup>25</sup> There currently is no practical test available that can accurately diagnose BSE in livestock. Confirmed diagnoses must be made post-mortem by examining brain tissue through a microscope or by using other test methods that can identify the abnormal form of prion AMP.

Amorfix is in the early stages of research and development towards an ante-mortem blood-based diagnostic for BSE in cattle. Prions have been shown to accumulate in lymphoid organs in rodent models of BSE. However, to date researchers have not shown that there are circulating prions in the blood of BSE-infected cattle. Further development of this BSE test by Amorfix will be made in conjunction with a commercial partner.

#### **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. Other than its blood screening test for vCJD, Amorfix intends to outlicense 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**

- Complete the validation and commercial development of the EP-vCJD<sup>TM</sup> blood screening test. 1.
- 2. Complete technology development, validation and commercial development of sheep scrapie blood screening test with a commercial partner.
- 3. Complete technology development of Alzheimer's blood screening test and validate test using human samples.
- Achieve next two research milestones under the Biogen agreement relative to the ALS drug 4. development program including demonstrating efficacy in an ALS model of the disease.

http://www.avma.org/pubhlth/bse/bse\_bgnd.pdf
 USDA Foreign Agricultural Service GAIN Report 3/1/2007

# **Regulatory Approval and Certification**

- 6. Maintain ISO 13485 Certification for Company for first product EP-vCJD<sup>TM</sup>.
- 7. Participate in the establishment of a common technical specification for a European CE Mark for an in vitro diagnostic test for the detection of variant CJD prions in blood.
- Obtain CE Mark (or alternatively self-declared CE Mark if current process is delayed) for EPvCJD<sup>TM</sup> Blood Screening Assay to allow sales and marketing of the product in Europe, subject to individual country regulations.
- 9. Make application and obtain approval for EP-TSE<sup>TM</sup> sheep scrapie diagnostic test for prion disease detection.

# Marketing and Sales

- 10. Sell EP-vCJD<sup>™</sup> Blood Screening Assay for research-use-only and follow with the commercial introduction of human diagnostics for blood screening for prions.
- 11. Engage a human healthcare partner to sell and market the Alzheimer's diagnostic test.
- 12. Engage an animal healthcare partner to sell and market the sheep scrapie diagnostic test.

## Manufacturing

13. Establish manufacturing, warehouse and quality control facilities in Europe through partnerships.

#### General and Administrative

14. 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 schemes exist.

The initial markets sought by the Amorfix vCJD technology for diagnostic use are in Europe due to the higher prevalence of BSE positive cattle and the resultant higher prevalence of people who have died from vCJD. A blood screening test for vCJD is currently not a regulated test, but it is expected that a common technical specification for a vCJD test will be developed by the end of calendar 2008 with regulatory implementation to follow in 2009.

The initial markets for an Alzheimer's diagnostic and a therapy for ALS 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

#### Europe

In-vitro diagnostic medical devices are regulated in Europe by the In Vitro Diagnostic Medical Device Directive (IVMDD) 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. The principles of the IVMDD have to be transformed into national law in each member state of the European Union. In vitro diagnostics can only be put on the EU market if they carry the CE mark. The IVMDD describes the provisions how to achieve the CE mark according to the type of device; those listed in List A under Annex II, those which come under List B or Annex II and those that are not regulated by Annex II. Currently, an in vitro diagnostic blood test for vCJD blood screening is not a regulated test under the IVMDD, however, the process to determine if and how a test should be regulated in Europe has been initiated at the request of the UK. The Company believes that a common technical specification for a vCJD test will be developed by the end of calendar 2008 with regulatory implementation to follow in 2009. The Company believes that a blood screening test for vCJD will ultimately be included in List A which covers higher-risk devices such as HIV and hepatitis B, C, and D tests. The first placing on the market and/ or the clinical investigation of a medical device must be registered with the appropriate competent authorities depending on the location of the company's authorized representative.

# 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<sup>™</sup> 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<sup>TM</sup> 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 pre-clinical 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>26</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**

Amorfix's vCJD blood screening assay will be sold to the national blood collection services of the various countries that implement the test. The pricing will be established by negotiation between the parties and will typically result in a minimum three year contract award.

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 the Amorfix prion 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.

<sup>&</sup>lt;sup>26</sup> The EFSA Journal (2007) 540, 1-12

# **Commercial Marketing Plans and Strategies**

Amorfix plans to market and sell the vCJD blood screening assay direct to the national blood collection agencies of each country that determines it needs to implement the test. This can be accomplished by a company of Amorfix's size due to the limited number of blood agencies in each country. Amorfix does not intend to market other 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 human and animal diagnostic and therapeutic healthcare markets. Amorfix is pursuing this objective with the strategies below.

# Generate Product Revenues

Amorfix's revenues, if any, in the future are expected to be first derived from sales of its vCJD blood screening assay to blood collection agencies in jurisdictions concerned about the potential transmission of blood infectivity from prions. Further product revenues 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, milestone payments, and royalties from partnerships to be completed by Amorfix with selected third-party, multi-national health care firms. As of the date of this application, Amorfix has not generated any 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

Whenever practical, Amorfix will seek to 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 who have demonstrated their capabilities at other device and drug development companies. Amorfix will need to continue to recruit additional talent from the human and animal pharmaceutical industry to strengthen its operations, while also seeking to retain current personnel.

# Competitive Conditions

Amorfix faces competition from large biotechnology and pharmaceutical companies in blood safety, food 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 and veterinary needs. Each of these markets will be discussed below.

# **Protecting the Blood Supply**

The Amorfix technology application for blood supply will compete with current approaches to enhance blood safety, as well as with future products under development by others, including larger medical technology, biotechnology, pharmaceutical and hospital supply companies, national and regional blood centers, governmental organizations and agencies, academic institutions and other agencies. Many companies and organizations may be competitors to Amorfix and have substantially greater financial and other resources and may have greater experience in conducting field studies and clinical trials as well as obtaining regulatory approvals for these products. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended safety purposes of the Amorfix products, or that might render the Amorfix technology and products relatively obsolete.

A number of companies have been and are attempting to develop such a vCJD blood screening test (Table 3) and to date, to the knowledge of Amorfix, they have not been successful.

# Table 3: Companies Working on a Prion Test for Blood<sup>27</sup>

Company Name	Apparent start of prion work	Still working in prion field?	Commercial Post-Mortem Assay?	Working on blood prion test?
Abbeymoy Ltd.	1998	Probably	No	Unknown
Abbott Laboratories	1999	Yes	Yes	Unknown
Adlyfe Inc.	2003	Yes	No	No
Advanced Bioconcept Ltd.	1998	Yes	No	Unknown
Beckman-Coulter, Inc.	2003	Yes	No	Unknown
bioMerieux (France)	Unknown	Yes	No	No

<sup>&</sup>lt;sup>27</sup> Table extracted from <u>http://www.priondata.org/</u> and modified to the best of the Company's knowledge

Company Name	Apparent start of prion work	Still working in prion field?	Commercial Post-Mortem Assay?	Working on blood prion test?
BioPeople (Korea)	Unknown	Yes	No	Yes
Bio-Rad Inc.	Pre-2001	Yes	Yes	Unknown
Caprion Pharmaceuticals and Ortho-Clinical Diagnostics	1997	Yes	No	No
Chiron Inc.	2003	Yes	No	Unknown
ExonHit Therapeutics	2002	With Roche	No	Unknown
Genecor plus CAMR	2001	Yes	No	Unknown
Microsens Biotechnology	1999	Yes	Yes	Yes
Prionics	1996	Yes	Yes	Yes
InPro	1980	Yes	Yes	No
Roche Ltd. (2 test systems)	2000	Yes	Yes	Unknown

Of these competitors, the ones known to be working on a blood prion test have presented various forms of data at international conferences. Chiron and Microsens are the only companies other than Amorfix to present independent data from the NIBSC blinded panel and this information was incomplete.

Amorfix believes that application of its technology in developing diagnostic detectors of the presence of prions in stored blood could significantly improve the safety of the world's blood supply which currently is offered without any meaningful prion testing to date. The reality of the risk of infection through donated blood has recently been demonstrated clinically as four people have been infected through direct blood transfusions and several thousand people received blood fractions made from a vCJD-infected plasma pool. There is a general concern that vCJD is now within the blood transfusion systems and a screening assay for blood is urgently required to protect everyone from the next epidemic.

# **Protecting the Food Supply Market**

To date, nearly 90 institutions, companies, or research laboratories have experimented in the area of prion detection. The worldwide market for detecting prions was galvanized with the awarding of the Nobel Prize in Medicine in 1997 to Dr. Stanley Prusiner, a researcher connected with the University of California at San Francisco who made the initial discovery that the existence of prions in animals and humans may cause neurodegenerative disease predisposition in these species.

Subsequent to this finding, many researchers have focused upon analyzing the presence of prions in the biofluids, particularly in the central nervous system where such prions tend to aggregate. The difficulty confronting researchers is that the extraction of biofluids from living organisms is a problematic and challenging endeavour, particularly when attempting to extract fluids from the brain or the spinal column of the studied species. Therefore, research until recently has been relegated to focusing upon measuring and attempting to detect prions in tissues from post-mortem autopsies of humans or animals.

The European Food Safety Authority published a report comparing seven rapid post-mortem tests for BSE<sup>28</sup>. The Idexx Laboratories Inc, test was the most sensitive but many of the others performed well

<sup>&</sup>lt;sup>28</sup> http://www.efsa.eu.int/science/tse assessments/bse tse/694 de.html

enough to be approved for use. To date, no ante-mortem test has been published. Once again those companies working on a blood screening test for vCJD (see table 3) are likely also working on a blood test for BSE in cattle and other animals, but no one has validated such a test.

Amorfix is developing an ante-mortem vCJD blood test with the highest specificity and sensitivity reported to date (TSE Conference, Berlin, June 2007) using vCJD brain prions spiked into human plasma. Others have investigated this ante-mortem blood testing venue but with little success. Those entities investigating in this ante-mortem prion field have been comparatively categorized according to the following table:

	Specific	Sensitive	<b>Blood-Based</b>	Scalable	Protectable
Surrogate Marker Technologies	No	Yes	Yes	Yes	Yes
Protease Resistance Technologies	Yes	No	No	No	No
Affinity Reagent Technologies	No	Yes	No	Yes	Yes
Conformation Dependent Immunoassay Technologies	Yes	Yes	No	No	Yes
Amorfix Technology Applications	Yes	Yes	Yes	Yes	Yes

Table 4: Antemortem	Blood Testing	Technology Comparison
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As can be seen from the foregoing table, competitive surrogate marker technologies, while sensitive and accessible in blood, lack specificity in determining the presence of misfolded proteins or prions. Those tests involving protease resistance, while specific, are not as scientifically sensitive as the Amorfix test and therefore, cannot be scalable. Affinity reagent tests are not specific and cannot be utilized in premortem testing. Finally, conformational dependent immunoassays, while somewhat specific and sensitive, are neither scalable nor can be applied in the ante-mortem prion testing context. Conversely, the Amorfix technology is specific, highly sensitive, available for use in ante-mortem context, is scalable and has definite proprietary protection.

There is currently one company marketing a test for CWD to deer hunters, who must cut out a defined piece of tissue and mail it to a central facility and wait prior to eating the meat. This market is small and will not be addressed unless market conditions demand a diagnostic test.

#### 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>29</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

<sup>&</sup>lt;sup>29</sup> http://www.predictivediagnostics.com/041905.html

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. The Amorfix potential competitors 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. 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. The EP technology may have the potential to validate or refute these claims as well as to discover AMPs in many other disorders. Amorfix will look for partners to take a proteomics approach to achieving these discoveries.

#### **Proprietary Protection**

Amorfix has acquired the rights to certain proprietary discovery platforms for the identification of proteins involved in misfolding diseases embodied in various patent applications, including but not limited to "Methods of Detecting Prion Proteins" defined in Canadian Patent Application 2,437,675 and "Epitope Protection Assay" defined in U.S. Provisional Patent Application 60,497,362. Amorfix has also filed an international patent application entitled "Methods and Compositions to Treat and Detect Misfolded-SOD1 Mediated Diseases" to further protect its intellectual property rights related to its ALS therapeutic program. An analysis of the patents in the field has revealed additional opportunities for patents based upon improved knowledge of AMP structure and formation. 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 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, 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 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. Since January 2004, Amorfix has accumulated net losses of \$13,505,753 (to March 31, 2008). 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 partnership 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 favourable 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 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, 2008, 41,678,380 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, 2007and 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 and TSX-V for the months indicated:

Period	High (\$)	Low (\$)	Volume
April 2007	1.98	1.49	1,253,751
May 2007	1.90	1.72	943,046
June 2007	1.90	1.50	1,103,095
July 2007	1.52	1.25	2,327,660
August 2007	1.28	0.80	1,255,775
September 2007	1.17	0.82	1,347,370
October 2007	1.30	0.89	1,112,945
November 2007	1.35	1.02	2,749,675
December 2007	1.25	0.93	1,307,193
January 2008	1.22	0.80	976,145
February 2008	1.05	0.85	1,168,180
March 2008	0.99	0.75	682,608

#### **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, 2008, a total of 8,691,250 common shares have been released from escrow. The following table sets out information with respect to the balance of the escrowed securities at March 31, 2008.

Number of Securities held in							
Designation of Class	Escrow <sup>(2)(3)</sup>	Percentage of Class <sup>(1)</sup>					
Common Shares	1,533,750	3.68%					

(1) Based on a total number of 41,678,380 common shares outstanding at March 31, 2008 (on a non-diluted basis).

(2) The remaining balance of 1,533,750 escrowed shares will be released on September 30, 2008.

(3) The escrowed shares are held by Olympia Trust Company as the escrow agent pursuant to escrow agreements dated September 20, 2005 entered into among Amorfix, the escrow agent and directors, officers and founders of Amorfix and Luxor.

#### **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	<b>Position Held</b>	Principal Occupation Last Five Years	<b>Director Since</b>
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Name and Residence	Position Held	Principal Occupation Last Five Years	Director Since
George Adams Ontario, Canada	President, Chief Executive Officer and Director	President and Chief Executive Officer of Amorfix since April 2005; President of Hemo- Stat Ltd., a consulting firm, from 2002 to Present; President and Chief Executive Officer of University of Toronto Innovations Foundation from 2003 to October 2004.	May 24, 2005
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	Special Partner of Birchill Equity Partners, a private equity partnership.	June 9, 2006
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	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.	N/A
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 2003 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 6,226,400 common shares, being 14.94% of the issued common shares on a non-diluted basis as at March 31, 2008.

#### 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 11, 2008, 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, became 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 2008 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, 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, 2008.

#### 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 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.

#### 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, 2008, 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.
- Research, investment and option agreement dated August 3, 2006 between Amorfix and Biogen Idec MA Inc. ("Biogen", an affiliate of Biogen Idec Inc.) pursuant to which Amorfix and Biogen are collaborating using Amorfix's technology to research, develop and commercialize therapeutic products directed against Amyotrophic Lateral Sclerosis ("ALS"). The agreement includes an option for Biogen to license the exclusive worldwide rights to Amorfix's technology for certain therapeutic products against ALS.

#### **INTERESTS OF EXPERTS**

#### Names of Experts

The Company's auditors are PricewaterhouseCoopers LLP, Chartered Accountants, who have prepared an independent auditors' report dated June 11, 2008 in respect of the Company's financial statements as at March 31, 2008 and March 31, 2007 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 9, 2007 (the "Information Circular"). Additional financial information relating to Amorfix is included in Amorfix's audited financial statements for the years ended March 31, 2008 and March 31, 2007 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.

#### **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.
- (1) Review the scope of the external audit, including the fees involved.
- (m) Review the report of the external auditor on the annual audited consolidated 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 internal 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. The external auditors of the Company will receive notice of every 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)**

Fiscal Year End	Audit Fees <sup>(1)</sup>	Audit Related Fees	Tax Fees <sup>(2)</sup>	All Other Fees
2008	\$64,210	\$-	\$450	\$-

Fiscal Year End	Audit Fees <sup>(1)</sup>	Audit Related Fees	Tax Fees <sup>(2)</sup>	All Other Fees
2007	\$49,570	\$-	\$2,000	\$-

(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.

(a development stage company)

Financial Statements March 31, 2008 and 2007

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PricewaterhouseCoopers LLP Chartered Accountants PO Box 82 Royal Trust Tower, Suite 3000 Toronto Dominion Centre Toronto, Ontario Canada M5K 1G8 Telephone +1 416 863 1133 Facsimile +1 416 365 8215

June 11, 2008

**Auditors' Report** 

To the Shareholders of Amorfix Life Sciences Ltd.

We have audited the balance sheets of **Amorfix Life Sciences Ltd.** as at March 31, 2008 and 2007 and the statements of operations and comprehensive loss, shareholders' equity and cash flows for the each of 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, 2008 and 2007 and the results of its operations and its cash flows for each of the years then ended in accordance with Canadian generally accepted accounting principles.

Pricewaterhouse Coopers LLP

**Chartered Accountants, Licensed Public Accountants** 

(a development stage company) **Balance Sheets** As at March 31

	2008 \$	2007 \$
Assets		
Current assets Cash and cash equivalents Marketable securities Amounts receivable Tax credits receivable (note 8) Prepaid expenses and deposits	2,212,776 6,467,490 198,026 400,082 136,855	1,660,594 12,192,600 229,692 283,527 132,312
Total current assets	9,415,229	14,498,725
Property and equipment, net (note 4) Technology rights, net	575,053	204,732 30,873
	9,990,282	14,734,330
Liabilities		
<b>Current liabilities</b> Accounts payable and accrued liabilities (note 9)	1,295,333	663,482
Total current liabilities	1,295,333	663,482
Shareholders' Equity		
Common shares Warrants and options Contributed surplus Accumulated other comprehensive income Deficit	19,194,840 2,815,838 187,777 2,247 (13,505,753)	18,028,305 2,404,259 4,056 (6,365,772)
	8,694,949	14,070,848
	9,990,282	14,734,330

# Going concern (note 1) Commitments and contingencies (note 11)

On behalf of the Board:

Jeage Adam Director

George Adams

Director

Graham Strachan

	Year ended March 31, 2008 \$	Year ended March 31, 2007 \$	Period from January 23, 2004 (inception) to March 31, 2008 \$
Revenue Interest earned	477,615	253,701	767,823
		233,701	101,025
<b>Expenses</b> Research and development (note 7) General and administrative Amortization of property and equipment Amortization of technology rights	6,240,108 1,259,197 122,418 45,873	3,407,098 1,021,478 48,439 10,440	10,814,976 2,740,494 182,100 56,313
	7,667,596	4,487,455	13,793,883
Loss before the undernoted	(7,189,981)	(4,233,754)	(13,026,060)
Costs related to reverse takeover		<u> </u>	479,693
Loss for the period	(7,189,981)	(4,233,754)	(13,505,753)
Other comprehensive income Unrealized gain on available-for-sale marketable securities Comprehensive loss for the period	<u> </u>		
Basic and diluted loss per common share	(0.17)	(0.13)	
Weighted average number of common shares outstanding .	41,297,742	31,757,381	

Going concern (note 1)

#### (a development stage company) Statement of Shareholders' Equity

	+	on shares note 5)	Warrants and (not		Contributed surplus	Accumulated other comprehensive income (loss) (note 2)	Deficit	Total
	Number	Amount S	Number	Amount \$	Amount \$	Amount \$	Amount \$	Amount S
Balance – March 31, 2006	28,891,073	6,692,671	5,756,336	738,874	-	-	(2,132,018)	5,299,527
Issuance of common shares for cash at \$1.46 per share	289,187	422,213	-	-	-	-	-	422,213
Issuance of common share units for cash at \$1.05 per unit, net of cash issue costs	47,619	41,338	23,810	8,662	-	-	-	50,000
Issuance of common share units for cash at \$1.30 per unit, net of cash issue costs	7,694,000	8,156,577	3,847,001	1,022,307	-	-	-	9,178,884
Common share purchase warrants issued as agents' compensation	-	(153,151)	615,520	153,151	-	-	-	-
Exercise of stock options	75,000	64,200	(75,000)	(26,700)	-	-	-	37,500
Exercise of agent options and warrants	3,459,870	2,804,457	(3,459,870)	(350,565)	-	-	-	2,453,892
Expiry of warrants	-	-	(45,000)	(4,056)	4,056	-	-	-
Issuance of stock options	-	-	1,895,250	-	-	-	-	-
Stock-based compensation	-	-	-	862,586	-	-	-	862,586
Loss for the period				-		-	(4,233,754)	(4,233,754)
Balance – March 31, 2007	40,456,749	18,028,305	8,558,047	2,404,259	4,056	-	(6,365,772)	14,070,848
Adjustment on adoption of new accounting policy (note 2)	-	-	-		-	(50,000)	50,000	
Balance – April 1, 2007	40,456,749	18,028,305	8,558,047	2,404,259	4,056	(50,000)	(6,315,772)	14,070,848
Issuance of common shares for cash at \$1.76 per share	91,445	160,944	-	-	-	-	-	160,944
Exercise of agent options and warrants	899,186	807,855	(899,186)	(239,447)	-	-	-	568,408
Exercise of stock options	231,000	197,736	(231,000)	(82,236)	-	-	-	115,500
Expiry of warrants	-		(17,280)	(2,246)	2,246	-	-	-
Expiry of stock options	-	-	(254,875)	(181,475)	181,475	-	-	-
Issuance of stock options	-	-	1,160,125	-	-	-	-	-
Stock-based compensation	-	-	-	916,983	-	-	-	916,983
Other comprehensive income for the period	-	-	-	-	-	52,247	-	52,247
Loss for the period	-	-	-	-	-	-	(7,189,981)	(7,189,981)
Balance – March 31, 2008	41,678,380	19,194,840	8,315,831	2,815,838	187,777	2,247	(13,505,753)	8,694,949

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(a development stage company) Statements of Cash Flows

Cash provided by (used in)	Year ended March 31, 2008 \$	Year ended March 31, 2007 \$	Period from January 23, 2004 (inception) to March 31, 2008 \$
<b>Operating activities</b> Loss for the period Amortization of property and equipment Amortization of technology rights Stock-based compensation Other non-cash expenses Changes in non-cash working capital (note 10)	(7,189,981) 122,418 45,873 916,983 542,419	(4,233,754) 48,439 10,440 862,586 50,000 (133,340)	(13,505,753) 182,100 56,313 1,928,538 235,115 469,908
	(5,562,288)	(3,395,629)	(10,633,779)
Investing activities Purchase of marketable securities Sale of marketable securities Purchase of property and equipment Purchase of technology rights	(1,608,840) 7,386,197 (492,739) (15,000)	(13,715,070) 6,724,405 (168,082) (41,313)	(21,673,910) 15,208,667 (757,153) (56,313)
-	5,269,618	(7,200,060)	(7,278,709)
Financing activities Issuance of common shares, net of cash issue costs Issuance of common share units, net of cash issue costs Issuance of common shares on exercise of agent options	160,944 -	422,213 9,228,884	4,383,129 11,973,069
and warrants Issuance of common shares on exercise of options Other financing activities	568,408 115,500	2,126,524 364,868	2,980,920 521,368 266,778
_	844,852	12,142,489	20,125,264
Net increase in cash and cash equivalents during the period	552,182	1,546,800	2,212,776
Cash and cash equivalents - Beginning of period _	1,660,594	113,794	
Cash and cash equivalents - End of period	2,212,776	1,660,594	2,212,776
<b>Cash and cash equivalents are comprised of:</b> Cash on deposit Money market securities	775,341 1,437,435	146,560 1,514,034	
_	2,212,776	1,660,594	

(a development stage company) Notes to Financial Statements March 31, 2008 and 2007

#### 1 Nature of operations and going concern

Amorfix Life Sciences Ltd. (the company or Amorfix) is an emerging theranostics company focused on the diagnosis and treatment of neurodegenerative diseases, where aggregated misfolded proteins (AMPs) are prevalent. 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 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 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 has incurred a loss of \$7,189,981 for the year ended March 31, 2008 and has a deficit of \$13,505,753 as at March 31, 2008. 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 \$8,119,896 is sufficient to fund its operations through to the end of June 2009, 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 for cash flow generation including product out-licensing, contracts for blood screening testing for variant Creutzfeldt-Jakob Disease prevalence studies, and other non-dilutive sources of funding; however, there is 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 Change in accounting policies

Effective April 1, 2007, Amorfix adopted The Canadian Institute of Chartered Accountants' (CICA) Handbook Section 1530, *Comprehensive Income*; Section 3251, *Equity*; Section 3855, *Financial Instruments – Recognition and Measurement*; Section 3861, *Financial Instruments – Disclosure and Presentation*; Section 3865, *Hedges*; and Section 1506, *Accounting Changes*. The prospective adoption of these new standards resulted in changes in the accounting and presentation for financial instruments.

On adoption of the new standards, Amorfix began accounting for marketable securities on an available-for-sale basis. Under this method, unrealized gains or losses on marketable securities are accumulated in the equity section of the balance sheet under the caption "accumulated other comprehensive income or loss" (AOCI). Previously, unrealized losses were recorded in income. The aggregate unrealized loss on marketable securities on the company's balance sheet as at March 31, 2007 was \$50,000. As a transitional provision to the new standards, this \$50,000 unrealized loss, which was recognized in the statement of operations for the year ended

(a development stage company) Notes to Financial Statements March 31, 2008 and 2007

March 31, 2007, has been reclassified on April 1, 2007 as the opening balance of AOCI, with a corresponding reduction in the opening deficit. For the year ended March 31, 2008, the Company recorded an unrealized gain on marketable securities of \$52,247 which was recorded to the AOCI with a corresponding increase in the carrying value of marketable securities. The following summarizes the revised CICA Handbook sections noted above.

#### Section 1530, Comprehensive Income

Section 1530 introduces comprehensive income, which consists of net income and other comprehensive income (OCI). OCI is a new requirement to temporarily present certain gains and losses from changes in fair value outside of net income. It includes unrealized gains and losses, such as gains and losses on holding available-for-sale marketable securities. Comprehensive income or loss is presented in the statement of shareholders' equity.

#### Section 3251, Equity

Section 3251 describes disclosure requirements for equity and changes in equity as a result of the new requirements of Section 1530, including the changes in equity arising from OCI. Accumulated changes in OCI are included in AOCI, presented in the statement of shareholders' equity as a separate component of shareholders' equity.

# Section 3855, Financial Instruments – Recognition and Measurement / Section 3861, Financial Instruments – Disclosure and Presentation

Under the new standards, financial assets and financial liabilities are initially recognized at fair values and their subsequent measurement is dependent on their classification, as described below. Their classification depends on the purpose for which the financial instruments were acquired or issued, their characteristics and Amorfix's designation of such instruments.

The standards require that all financial assets be classified either as held-for-trading, available-for-sale, heldto-maturity or loans and receivables. The standards require that all financial assets, including all derivatives, be measured at fair value with the exception of loans and receivables, debt securities classified as held-tomaturity and available-for-sale financial assets that do not have quoted market prices in an active market. Settlement date accounting continues to be used for all financial assets, except changes in fair value between the trade date and settlement date are reflected in the statement of operations for held-for-trading financial assets, while changes in fair value between the trade date and settlement date are reflected in OCI for available-for-sale financial assets.

Financial liabilities can be classified as either held-for-trading or other liabilities. After initial recognition, an entity should measure all financial liabilities at amortized cost using the effective interest method, except for financial liabilities that are classified as held-for-trading, including derivatives, which should be measured at their fair values.

#### Held-for-trading

Held-for-trading assets and liabilities are measured at fair value at the balance sheet date. Interest earned, interest accrued, gains and losses realized on disposal and unrealized gains and losses from market

(a development stage company) Notes to Financial Statements March 31, 2008 and 2007

> fluctuations are included in interest income or expense. Speculative financial assets and liabilities, other than loans or receivables, and derivative instruments are accounted for as held-for-trading financial assets or liabilities unless the derivative is linked to, and must be settled with equity instruments of another entity whose fair value cannot be reliably measured. In addition, if the fair value of a non-derivative instrument is reliably measurable, Amorfix may elect to designate it as held-for-trading at the time of its initial recognition. The designation for this instrument is irrevocable. Amorfix has classified its cash and cash equivalents as held-for-trading.

> Financial liabilities designated at fair value are those non-derivative financial liabilities that Amorfix elects to designate on initial recognition as instruments that it will measure at fair value in the statement of operations and comprehensive loss. These are accounted for in the same manner as held-for-trading financial assets. Amorfix has not designated any non-derivative financial liabilities as fair valued financial liabilities.

#### Available-for-sale

Available-for-sale financial assets are those non-derivative financial assets that are designated as availablefor-sale, or that are not classified as loans and receivables, held-to-maturity investments or held-for-trading. Available-for-sale financial assets are carried at fair value with unrealized gains and losses included in OCI until realized, when the cumulative gain or loss is recorded in the statement of operations and comprehensive loss. Amorfix has classified its marketable securities as available-for-sale.

#### Held-to-maturity

Held-to-maturity financial assets are non-derivative financial assets with fixed or determinable payments and a fixed maturity, other than loans and receivables, that an entity has the positive intention and ability to hold to maturity. After initial recognition at fair value, these financial assets are measured at amortized cost. Amorfix has not designated any financial assets as held-to-maturity.

#### Loans and receivables

Loans and receivables are non-derivative financial assets that are initially recognized at fair value and, thereafter, are accounted for at cost or amortized cost. Amorfix has designated certain amounts receivable as loans and receivables.

#### Other liabilities

Other liabilities are non-derivative financial liabilities that are initially recognized at fair value and, thereafter, are recorded at amortized cost and include all liabilities, other than derivatives or liabilities to which the fair value designation has been applied. Accounts payable and accrued liabilities are classified as other liabilities.

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#### Derivatives

Derivatives are carried at fair value and are reported as assets when they have a positive fair value and as liabilities when they have a negative fair value. The change in fair value during the period is recognized in the statement of operations and comprehensive loss. Amorfix had no outstanding derivatives at March 31, 2008.

#### Embedded derivatives

Derivatives embedded in other financial instruments or contracts are separated from their host contracts and accounted for as derivatives when their economic characteristics and risks are not closely related to those of the host contract; the terms of the embedded derivative are the same as those of a free-standing derivative; and the combined instrument or contract is not measured at fair value, with changes in fair value recognized in the statement of operations. These embedded derivatives are measured at fair value with changes therein recognized in the statement of operations and comprehensive loss. The elected transition date for the purpose of identifying embedded derivatives was January 23, 2004, the date of inception.

#### Determination of fair value

The fair value of a financial instrument is the amount of consideration that would be agreed upon in an arm's length transaction between knowledgeable, willing parties who are under no compulsion to act. The fair value of a financial instrument on initial recognition is the transaction price, which is the fair value of the consideration given or received. Subsequent to initial recognition, the fair values of financial instruments that are quoted in active markets are based on bid prices for financial assets held and offer prices for financial liabilities. When independent prices are not available, fair values are determined by using valuation techniques that refer to observable market data. These include comparisons with similar instruments where market observable prices exist, discounted cash flow analysis, option pricing models and other valuation techniques using non-observable market data or transaction prices.

#### Section 3865, Hedges

Section 3865 specifies the criteria that must be satisfied in order for hedge accounting to be applied and the accounting for each of the permitted hedging strategies: fair value hedges and cash flow hedges. Hedge accounting is discontinued prospectively when the derivative no longer qualifies as an effective hedge or the derivative is terminated or sold, or on the sale or early termination of the hedged item. Since the company does not currently have any hedging programs in place, the adoption of this standard did not have any impact on the company's financial statements.

#### Section 1506, Accounting Changes

The Accounting Standards Board issued a replacement of the CICA Handbook Section 1506, which sets the standard for accounting for changes in accounting policies, changes in accounting estimates and corrections of prior period errors. The new standard allows voluntary changes to accounting policies only when they result in more reliable and relevant information, requires that changes be applied retrospectively unless not practical, requires errors in prior periods to be adjusted retrospectively and requires enhanced disclosure regarding the effects of changes in accounting policies, changes in estimates, or errors on the financial statements. The adoption of this policy has no impact on these financial statements.

(a development stage company) Notes to Financial Statements March 31, 2008 and 2007

#### **Recent Accounting Pronouncements:**

Effective April 1, 2008, Amorfix will adopt the following new accounting pronouncements from the CICA Handbook: Section 3862, *Financial Instruments – Disclosures*; Section 3863, *Financial Instruments – Presentation*; Section 1535, *Capital Disclosures*, and changes to Section 1400, *General Standards of Financial Statement Presentation*. These sections relate to disclosure and presentation only and will not have an impact on the company's financial results.

Section 3862 describes the required disclosure of the nature and extent of risks arising from financial instruments to which an entity is exposed and how the entity manages those risks.

Section 3863 establishes the standards for presentation of financial instruments and non-financial derivatives. It carries forward the existing requirements for presentation of financial instruments from Section 3861, *Financial Instruments – Presentation and Disclosure.* 

Section 1535 describes the required disclosure of an entity's objectives, policies and processes for managing capital. An entity should disclose a description of what it manages as capital, the nature of externally imposed capital requirements and its compliance thereto, how it is meeting its objectives for managing capital, and summary quantitative data about what it manages as capital.

Section 1400 has been amended to change the guidance related to management's responsibility to assess the ability of the entity to continue as a going concern. Disclosure is required for material uncertainties related to events or conditions that may cast doubt on the ability to continue as a going concern.

#### Future accounting changes:

#### Goodwill and intangible assets

In November 2007, the CICA issued 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. These standards are effective for the company for its interim financial statements beginning on October 1, 2008. The company is currently assessing the impact that these standards will have on its financial statements.

#### 3 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

(a development stage company) Notes to Financial Statements March 31, 2008 and 2007

tax credits receivable, the valuation allowance for future income tax assets, and the fair values used to account 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**

Amorfix invests primarily in high credit quality corporate debt instruments with maturities staggered over the next 14 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. Accordingly, all marketable securities are classified as current assets in the accompanying balance sheets. The weighted average yield of the debt instruments held at March 31, 2008 was 4.6%.

#### **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

#### **Technology** rights

The company has determined that the technology rights have finite lives and, accordingly, they are being amortized on a straight-line basis over their estimated useful lives. As at March 31, 2008, the technology rights were fully amortized.

#### 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, 2008, no impairment of long-lived assets was determined.

#### **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.

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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, 2008 were \$380,000 (2007 - \$410,000).

#### **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 at the grant date. The fair value of stock options awarded to employees is expensed over the vesting period and for non-employees is expensed as the services are received.

#### 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 Canadian dollars at the period-end exchange rate. All gains and losses are included in the statement of operations and comprehensive loss.

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#### 4 Property and equipment

			2008
	Cost \$	Accumulated amortization \$	Net \$
Laboratory and office equipment Computer equipment Leasehold improvements	469,775 108,278 179,100	131,591 44,795 5,714	338,184 63,483 173,386
	757,153	182,100	575,053
			2007
	Cost \$	Accumulated amortization \$	Net \$
Laboratory and office equipment Computer equipment	220,980 43,434	41,438 18,244	179,542 25,190
	264,414	59,682	204,732

#### 5 Share capital

The company has authorized an unlimited number of common shares and preferred shares and has issued 41,678,380 common shares and no preferred shares as at March 31, 2008.

#### a) Biogen investment

- 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 the neurodegenerative disease amyotrophic lateral sclerosis (ALS). Biogen subscribed for 289,187 common shares of the company at \$1.46 per share for gross proceeds to Amorfix of \$422,213.
- ii) On the achievement of the first research milestone under this agreement in July 2007, Biogen subscribed for an additional 91,445 common shares of the company at \$1.76 per share for gross proceeds to Amorfix of \$160,944 (US\$150,000). During the term of the option, Biogen may subscribe for up to US\$225,000 of additional common shares of Amorfix based on the achievement of predefined research goals. If Biogen exercises its option, over the term of the license agreement

(a development stage company) Notes to Financial Statements March 31, 2008 and 2007

Amorfix will be eligible to receive milestone payments in excess of US\$25 million plus royalties on sales. Biogen will be responsible for all development and commercialization costs.

#### b) Private placements - common share units

 In September 2006, the Ontario Genomics Institute (OGI) subscribed for 47,619 common share units at \$1.05 per unit for gross proceeds of \$50,000. Each common share unit consisted of one common share and one-half common share purchase warrant. Each full common share purchase warrant entitles OGI to acquire one common share at \$1.05 until September 11, 2008.

The allocation of the \$1.05 common share 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 the Black-Scholes option pricing model. The common shares were allocated a price of \$0.87 per share and the one-half common share purchase warrants were allocated a price of \$0.18 per share. There were no costs on the issue. Assumptions used to determine the value of the common share purchase warrants were: dividend yield 0%; risk-free interest rate 4.2%; expected volatility 73%; and average expected life of 24 months.

ii) On March 8, 2007, the company completed a private placement of 7,694,000 common share units at a price per unit of \$1.30 for gross proceeds of \$10,002,000 (\$9,178,884, net of cash issuance costs). Each common share unit consisted of one common share and one-half common share purchase warrant. In connection with the financing, the company issued 615,520 agents' compensation warrants having an aggregate fair value of \$172,346 (\$153,151 after allocation of non-cash issue costs) estimated using the Black-Scholes option pricing model. Each whole common share purchase warrant and each agents' compensation warrant entitles the warrant holder to acquire one common share at an exercise price of \$1.95 per share prior to expiry on March 8, 2009.

The allocation of the \$1.30 common share 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 these warrants was determined using the Black-Scholes option pricing model. The common shares were allocated a price of \$1.16 per share and the one-half common share purchase warrants were allocated a price of \$0.14 per share. The costs of the issue were allocated on a pro rata basis to the common shares and one-half common share purchase warrants. Accordingly, \$8,003,426 was allocated to common shares and \$1,003,112 to common share purchase warrants and the agents' compensation warrants were: dividend yield 0%; risk-free interest rate 3.9%; expected volatility 69%; and average expected life of 24 months.

#### c) Escrow

As at March 31, 2008, a total of 1,533,750 common shares of the company remain in escrow related to a 2005 amalgamation agreement. These shares will be released from escrow on September 30, 2008.

(a development stage company) Notes to Financial Statements **March 31, 2008 and 2007** 

#### 6 Warrants and options

a) The company has issued warrants and options for the purchase of common shares. All outstanding warrants are exercisable. As at March 31, 2008, the following warrants and options (other than stock options) were outstanding:

	Exercise price \$	Number outstanding	Expiry date
OGI common share purchase warrants			
(note $5(b)(i)$ )	1.05	23,810	September 11, 2008
Common share purchase warrants			•
(note $\hat{5}(b)(ii)$ )	1.95	3,847,001	March 8, 2009
Agent compensation warrants			
(note 5(b)(ii))	1.95	615,520	March 8, 2009
		4,486,331	

b) On September 20, 2007, the company's shareholders approved the 2007 Stock Option Plan, which replaced the 2005 Stock Option Plan. Under the company's 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.

The following table reflects the activity under the stock option plan for the years ended March 31, 2008 and 2007 and the stock options outstanding:

	2008		2007	
	Number of stock options	Weighted average exercise price \$	Number of stock options	Weighted average exercise price \$
Outstanding – Beginning of year	3,155,250	1.00	1,335,000	0.51
Granted	1,160,125	1.00	1,895,250	1.33
Exercised	(231,000)	0.50	(75,000)	0.50
Expired	(254,875)	1.12	-	-
Outstanding – End of year	3,829,500	1.03	3,155,250	1.00
Exercisable – End of year	2,004,750	0.99	1,228,500	0.78

(a development stage company) Notes to Financial Statements March 31, 2008 and 2007

The following table reflects the stock options outstanding as at March 31, 2008:

	Stock	Stock options outstanding		Stock options	Stock options exercisable	
Range of exercise prices \$	Number outstanding	Weighted average remaining contractual life (years)	Weighted average exercise price \$	Number exercisable	Weighted average exercise price \$	
0.50 - 0.68	969,000	2.53	0.52	808,500	0.51	
0.83 - 0.93	1,333,500	8.38	0.92	226,250	0.86	
1.14 - 1.15	65,000	3.28	1.14	65,000	1.14	
1.40 - 1.78	1,462,000		1.46	905,000	1.44	
0.50 -1.78	3,829,500	5.06	1.03	2,004,750	0.99	

c) During the year ended March 31, 2008, the company issued stock options with a fair value of \$843,768 (2007 - \$1,876,188) and recorded a stock-based compensation expense of \$916,983 (2007 - \$862,586). The weighted average grant-date fair value of the stock options granted during the year ended March 31, 2008 was \$0.73 (2007 - \$0.94). The fair value of the stock options granted was estimated using the Black-Scholes option pricing model with the following assumptions:

	2008	2007
Risk-free interest rate	3.5 - 3.9%	3.8 - 4.3%
Dividend yield	0%	0%
Expected volatility	62 - 66%	69 - 106%
Expected life of options (years)	5-10	5

#### 7 Research and development

Amorfix is developing a pipeline of diagnostic and therapeutic products for the detection and treatment of neurodegenerative diseases, where aggregated misfolded proteins are prevalent. The diagnostic products are based on the company's epitope protection platform and include the development of blood screening tests for variant Creutzfeldt-Jakob Disease, Alzheimer's disease and sheep scrapie. Amorfix's therapeutics products are immunotherapies for the treatment of amyotrophic lateral sclerosis (ALS) and Alzheimer's disease.

(a development stage company) Notes to Financial Statements March 31, 2008 and 2007

Research and development expenditures were as follows:

	Year ended March 31, 2008 \$	Year ended March 31, 2007 \$	Period from January 23, 2004 (inception) to March 31, 2008 \$
Diagnostic AMP programs Therapeutic AMP programs	5,080,997 1,159,111	2,988,086 419,012	9,236,853 1,578,123
	6,240,108	3,407,098	10,814,976

#### 8 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:

	2008 \$	2007 \$
Future income tax assets		
Non-capital losses carried forward	1,119,000	653,000
Research and development expenditures	2,264,000	1,107,000
Investment tax credits	1,189,000	514,000
Carrying value of technology rights and property and		
equipment in excess of accounting basis	113,000	150,000
Ontario harmonization tax credit and other	190,000	-
Share issue costs	283,000	452,000
Total future income tax assets	5,158,000	2,876,000
Valuation allowance	(5,158,000)	(2,876,000)
Net future income tax assets		

(a development stage company) Notes to Financial Statements March 31, 2008 and 2007

- b) As at March 31, 2008, the company has available research and development expenditures for income tax purposes of approximately \$7,845,000, which may be carried forward indefinitely to reduce future years' taxable income.
- c) As at March 31, 2008, the company had non-capital income tax loss carry-forwards of approximately \$3,876,000 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, 2008, the company had approximately \$1,624,000 of non-refundable investment tax credits available to offset future income taxes.
- 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:

	2008 \$	2007 \$
Statutory income tax rate	35.4%	36.1%
Income tax recovery based on statutory rate	(2,542,000)	(1,528,000)
Permanent differences	332,000	323,000
Net investment tax credits not recognized	(728,000)	(384,000)
Share issue costs recorded, net of equity	-	(327,000)
Change in future tax rates	592,000	208,000
Other	64,000	26,000
Change in valuation allowance	2,282,000	1,682,000
Income tax recovery		

#### 9 Related party transactions

- a) Certain members of management who are also shareholders were under contract to provide employment services to the company. During 2008, the company incurred \$489,305 (2007 \$380,630) of expenses for three contracts, with \$108,163 (2007 \$32,028) payable as at March 31, 2008. These transactions occurred in the normal course of operations and were measured at the exchange amount, which is the amount of consideration established and agreed by the related parties.
- b) On February 1, 2006, the company acquired an exclusive licence to develop certain SOD1 technologies owned by Dr. Neil Cashman, an officer and shareholder of the company, for diagnostic and therapeutic applications for ALS. In consideration, the company funded \$300,000 of research on the technology and committed to pay a royalty on commercial sales. The company also received an option to acquire the technology on payment of \$100,000 in cash or common shares at any time prior to the fifth anniversary of the licence agreement. The acquisition of the licence was valued at the carrying amount, which was nominal.

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- c) On April 4, 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 (UHN). As consideration for the licence, the company paid \$5,000 in cash, assumed a liability for \$4,400 in patent costs, agreed to fund \$260,000 of SOD1 research at UHN, and committed to pay commercial royalties and make milestone payments as follows:
  - i) Diagnostics \$15,000 in pre-commercial milestones and \$100,000 on first product approval; and
  - ii) Therapeutics \$300,000 in clinical milestones and \$200,000 on first product approval.

The company also received a buyout option from UHN to allow the company to acquire the technologies prior to commercialization. During 2008, \$97,500 (2007 - \$97,500) was paid to UHN and as at March 31, 2008 \$65,000 (2007 - \$nil) was included in accounts payable and accrued liabilities.

d) 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. During 2008, \$135,000 (2007 - \$120,000) was paid to UBC and, as at March 31, 2008, \$45,000 (2007-\$nil) was included in accounts payable and accrued liabilities.

#### 10 Supplementary cash flow information

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

	Year ended March 31, 2008 \$	Year ended March 31, 2007 \$	Period from January 23, 2004 (inception) to March 31, 2008 \$
Amounts receivable Tax credits receivable Prepaid expenses and deposits Accounts payable and accrued liabilities	31,666 (116,555) (4,543) 631,851	(149,306) (283,527) (116,111) 415,604	(190,979) (400,082) (136,855) 1,197,824
	542,419	(133,340)	469,908
Supplemental cash flow information Common share purchase warrants issued as agents' compensation		172,346	349,204

No income tax or interest was paid by the company.

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#### 11 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:
  - i) fees comprising amounts due initially on entering into the agreements and additional amounts due either on specified timelines or defined services to be provided;
  - ii) milestone payments that are dependent on products developed under the agreements proceeding toward specified plans of clinical trials and commercial development; and
  - iii) royalty payments calculated as a percentage of net sales, commencing on commercial sale of any product candidates developed from the technologies.

As at March 31, 2008, the company had commitments under contracts with vendors for research and development in the amount of \$51,000 over the next 12 months.

- b) 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.
- c) Under the terms of a contribution agreement with the National Research Council Canada under the Industrial Research Assistance Program (IRAP), the company was granted up to \$322,000 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. To date, the company has received \$158,570 in funding and has not recorded any liability for this contingent repayment.
- d) The company is committed to the following payments under the terms of its lease agreements for the years ending March 31,

	\$
2009	294,100
2010	272,700
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

(a development stage company) Notes to Financial Statements March 31, 2008 and 2007

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.

#### 12 Financial instruments

a) Fair value of financial instruments

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, 2008, there was no significant difference between the carrying values of these amounts and their estimated fair values due to their short-term nature.

b) Concentration of credit risk

Financial instruments that potentially subject the company to a significant concentration of credit risk consist primarily of cash and cash equivalents and marketable securities. The company mitigates 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.

c) Concentration of foreign currency risk and interest rate risk

The company holds cash and cash equivalents and marketable securities denominated in US dollars in amounts approximating current US dollar financial liabilities.

The company is exposed to interest rate risk arising from fluctuations in interest rates on its cash and cash equivalents and marketable securities. The company seeks to mitigate this risk by holding investments to their maturity.

#### 13 Segmented information

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

#### Certification of Annual Filings

I, George Adams, President & Chief Executive Officer of Amorfix Life Sciences Ltd., certify that:

- I have reviewed the annual filings (as this term is defined in Multilateral Instrument 52-109 Certification of Disclosure in Issuers' Annual and Interim Filings) of Amorfix Life Sciences Ltd. (the issuer) for the period ending March 31, 2008;
- 2. Based on my knowledge, 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, with respect to the period covered by the annual filings;
- 3. Based on my knowledge, 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 and for the periods presented in the annual filings;
- 4. The issuer's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures and internal control over financial reporting for the issuer, and we have:
- (a) designed such disclosure controls and procedures, or caused them to be designed under our supervision, to provide reasonable assurance that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the annual filings are being prepared;
- (b) designed such internal control over financial reporting, 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; and
- evaluated the effectiveness of the issuer's disclosure controls and procedures as of the end of the period covered by the annual filings and have caused the issuer to disclose in the annual MD&A our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by the annual filings based on such evaluation; and
- 5. I have caused the issuer to disclose in the annual MD&A any change in the issuer's internal control over financial reporting that occurred during the issuer's most recent interim period that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

Date: June 11, 2008

Signed "George Adams" George Adams President & Chief Executive Officer

#### **Certification of Annual Filings**

I, James Parsons, Chief Financial Officer of Amorfix Life Sciences Ltd., certify that:

- 1. I have reviewed the annual filings (as this term is defined in Multilateral Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings*) of Amorfix Life Sciences Ltd. (the issuer) for the period ending March 31, 2008;
- 2. Based on my knowledge, 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, with respect to the period covered by the annual filings;
- 3. Based on my knowledge, 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 and for the periods presented in the annual filings;
- 4. The issuer's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures and internal control over financial reporting for the issuer, and we have:
  - (a) designed such disclosure controls and procedures, or caused them to be designed under our supervision, to provide reasonable assurance that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the annual filings are being prepared;
  - (b) designed such internal control over financial reporting, 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; and
  - (c) evaluated the effectiveness of the issuer's disclosure controls and procedures as of the end of the period covered by the annual filings and have caused the issuer to disclose in the annual MD&A our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by the annual filings based on such evaluation; and
- 5. I have caused the issuer to disclose in the annual MD&A any change in the issuer's internal control over financial reporting that occurred during the issuer's most recent interim period that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

Date: June 11, 2008

Signed "James Parsons" James Parsons Chief Financial Officer

#### **Certification of Interim Filings**

I, George Adams, President & Chief Executive Officer of Amorfix Life Sciences Ltd., certify that:

- 1. I have reviewed the interim filings (as this term is defined in Multilateral Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings*) of Amorfix Life Sciences Ltd. (the issuer) for the interim period ending September 30, 2008;
- 2. Based on my knowledge, the interim 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, with respect to the period covered by the interim filings;
- 3. Based on my knowledge, the interim financial statements together with the other financial information included in the interim filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date and for the periods presented in the interim filings;
- 4. The issuer's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures and internal control over financial reporting for the issuer, and we have:
  - (a) designed such disclosure controls and procedures, or caused them to be designed under our supervision, to provide reasonable assurance that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the interim filings are being prepared; and
  - (b) designed such internal control over financial reporting, 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; and
- 5. I have caused the issuer to disclose in the interim MD&A any change in the issuer's internal control over financial reporting that occurred during the issuer's most recent interim period that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

Date: November 5, 2008

Signed *"George Adams"* George Adams President & Chief Executive Officer 

#### **Certification of Interim Filings**

I, George Adams, President & Chief Executive Officer of Amorfix Life Sciences Ltd., certify that:

- 1. I have reviewed the interim filings (as this term is defined in Multilateral Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings*) of Amorfix Life Sciences Ltd. (the issuer) for the interim period ending June 30, 2008;
- 2. Based on my knowledge, the interim 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, with respect to the period covered by the interim filings;
- 3. Based on my knowledge, the interim financial statements together with the other financial information included in the interim filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date and for the periods presented in the interim filings;
- 4. The issuer's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures and internal control over financial reporting for the issuer, and we have:
  - (a) designed such disclosure controls and procedures, or caused them to be designed under our supervision, to provide reasonable assurance that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the interim filings are being prepared; and
  - (b) designed such internal control over financial reporting, 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; and
- 5. I have caused the issuer to disclose in the interim MD&A any change in the issuer's internal control over financial reporting that occurred during the issuer's most recent interim period that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

Date: August 6, 2008

Signed "George Adams" George Adams President & Chief Executive Officer

#### **Certification of Interim Filings**

I, James Parsons, Chief Financial Officer of Amorfix Life Sciences Ltd., certify that:

- 1. I have reviewed the interim filings (as this term is defined in Multilateral Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings*) of Amorfix Life Sciences Ltd. (the issuer) for the interim period ending September 30, 2008;
- 2. Based on my knowledge, the interim 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, with respect to the period covered by the interim filings;
- 3. Based on my knowledge, the interim financial statements together with the other financial information included in the interim filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date and for the periods presented in the interim filings;
- 4. The issuer's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures and internal control over financial reporting for the issuer, and we have:
  - (a) designed such disclosure controls and procedures, or caused them to be designed under our supervision, to provide reasonable assurance that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the interim filings are being prepared; and
  - (b) designed such internal control over financial reporting, 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; and
- 5. I have caused the issuer to disclose in the interim MD&A any change in the issuer's internal control over financial reporting that occurred during the issuer's most recent interim period that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

Date: November 5, 2008

Signed "James Parsons"

James Parsons Chief Financial Officer

#### **Certification of Interim Filings**

I, James Parsons, Chief Financial Officer of Amorfix Life Sciences Ltd., certify that:

- 1. I have reviewed the interim filings (as this term is defined in Multilateral Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings*) of Amorfix Life Sciences Ltd. (the issuer) for the interim period ending June 30, 2008;
- 2. Based on my knowledge, the interim 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, with respect to the period covered by the interim filings;
- 3. Based on my knowledge, the interim financial statements together with the other financial information included in the interim filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date and for the periods presented in the interim filings;
- 4. The issuer's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures and internal control over financial reporting for the issuer, and we have:
  - (a) designed such disclosure controls and procedures, or caused them to be designed under our supervision, to provide reasonable assurance that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which the interim filings are being prepared; and
  - (b) designed such internal control over financial reporting, 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; and

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5. I have caused the issuer to disclose in the interim MD&A any change in the issuer's internal control over financial reporting that occurred during the issuer's most recent interim period that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

Date: August 6, 2008

Signed "James Parsons"

James Parsons Chief Financial Officer

#### AMORFIX LIFE SCIENCES LTD.

#### PROXY

#### FOR HOLDERS OF COMMON SHARES

#### THIS PROXY IS SOLICITED BY THE MANAGEMENT OF AMORFIX LIFE SCIENCES LTD. FOR THE ANNUAL MEETING OF SHAREHOLDERS TO BE HELD ON NOVEMBER 5, 2008.

The undersigned holder of common shares of Amorfix Life Sciences Ltd. ("Amorfix") hereby appoints Dr. George Adams, President & CEO of Amorfix or failing him, James Parsons, CFO of Amorfix with full power of substitution, or instead of either of them, \_\_\_\_\_\_\_, as proxy holder for and on behalf of the undersigned, to attend, act, and vote all of the common shares of Amorfix in respect of all matters, including any variations or amendments thereto, that may properly come before the annual meeting of common shareholders of Amorfix (the "Meeting") to be held on Wednesday, November 5, 2008, and at any adjournment thereof, with all the powers which the undersigned could exercise if personally present. A common shareholder has the right to appoint a person to attend and act on his behalf at the Meeting other than any of the persons designated in this form of proxy. This right may be exercised by inserting such other person's name in the blank space provided for that purpose above or by completing another proper form of proxy.

Without limiting the general powers conferred by this form of proxy, the undersigned hereby revokes any proxy previously given and directs the person named above as proxy holder to vote at the Meeting and at any adjournment thereof, the common shares represented by this proxy as follows (for full details of each item, please see the enclosed Information Circular):

		For	Against	Withhold
1.	Appoint PricewaterhouseCoopers, Chartered Accountants, as auditor of the Corporation and authorize the Directors to fix the auditor's remuneration		N/A	
2.	Elect as Director, George Adams		N/A	
3.	Elect as Director, Hans Black		N/A	
4.	Elect as Director, William Lambert		N/A	
5.	Elect as Director, Aziz Mekouar		N/A	
6.	Elect as Director, Graham Strachan		N/A	
7.	Elect as Director, Michael Sonnenreich		N/A	
8.	Approve the adoption of a Deferred Share Unit plan			N/A
9.	Approve an allocation of shares reserved for issuance under the Corporation's Deferred Share Unit plan			N/A

Dated this \_\_\_\_\_day of \_\_\_\_\_\_, 2008.

(Signature of Shareholder) (Please sign exactly as shares are registered)

(Name of Shareholder, Please Print)

(Numbers of Shares Voted)

IMPORTANT - SEE REVERSE SIDE

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# PLEASE MARK, DATE AND SIGN THIS INSTRUMENT OF PROXY AND PROMPLY RETURN IT USING THE ENCLOSED ENVELOPE.

Notes:

- 1. In order for this proxy to be effective, this proxy must be executed by the holder of common shares or attorney of such person authorized in writing or, if the holder of common shares is a corporation, under its corporate seal or by an officer or attorney thereof duly authorized and must be forwarded in the enclosed self-addressed envelope or otherwise delivered to Olympia Trust Company, 120 Adelaide Street West, Suite 920, Toronto, Ontario, M5H 1T1, to reach the addressee no later than 48 hours, excluding Saturday, Sundays and holidays, prior to the date of the Meeting, or any adjournment thereof. If the date is not inserted in the blank space provided above, this proxy shall be deemed to be dated on the day on which it is mailed by Amorfix with the Management Proxy Circular.
- 2. The signature of the holder of common shares should be exactly the same as the name in which such securities are registered.
- 3. Persons signing as executors, administrators, trustees, etc. should so indicate. If the holder of common shares is a corporation, its corporate seal must be affixed or this proxy must be signed by an officer or attorney thereof duly authorized.
- 4. The securities represented by this Instrument of Proxy will be voted or withheld from voting in accordance with the instructions of the holder on any ballot of a resolution that may be called for and, if the holder specifies a choice with respect to any matter to be acted upon, the securities will be voted accordingly. If a holder has submitted an Instrument of Proxy, the holder may still attend the Meeting and may vote in person. To do so, the holder must record his/her attendance with the scrutineers before the commencement of the Meeting and revoke, in writing, the prior votes.

(a development stage company)

Financial Statements

### Third Quarter Ended December 31, 2008 Fiscal 2009

These unaudited interim financial statements were not reviewed by external auditors.

Trading symbol: TSX: AMF

For more information please contact: James Parsons, Chief Financial Officer Email: james.parsons@amorfix.com

www.amorfix.com

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(a development stage company) **Balance Sheets** 

	December 31, 2008 \$ (unaudited)	March 31, 2008 \$
Assets		
Current assets Cash and cash equivalents Marketable securities Amounts receivable Tax credits receivable Prepaid expenses and deposits	1,300,4774,010,49378,239620,00069,360	2,212,776 6,467,490 198,026 400,082 136,855
Total current assets	6,078,569	9,415,229
Property and equipment, net	505,526	575,053
	6,584,095	9,990,282
Liabilities		
Current liabilities Accounts payable and accrued liabilities	725,478	1,295,333
Total current liabilities	725,478	1,295,333
Shareholders' equity		
Common shares Other equity Contributed surplus Accumulated other comprehensive (loss) income Deficit	19,467,462 3,445,047 224,311 (656) (17,277,547) 5,858,617 6,584,095	19,194,840 2,815,838 187,777 2,247 (13,505,753) 8,694,949 9,990,282
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Going concern (note 1)

(a development stage company)

### Statements of Operations and Comprehensive Loss

(Unaudited)

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	Three mor Decem 2008		Nine months ended December 31, 2008 2007		Period from January 23, 2004 (inception) to December 31, 2008	
	\$	S	<b>2</b> 008 S	\$	_000 \$	
Revenues						
Interest earned	54,206	111,820	188,584	371,742	956,407	
Expenses						
Research and development	804,871	1,358,132	3,062,552	4,559,654	13,877,528	
General and administrative	199,922	190,064	717,360	975,762	3,457,854	
Amortization of property and equipment	67,076	28,168	180,466	72,709	362,566	
Amortization of technology rights	-	12,720	0	33,159	56,313	
	1,071,869	1,589,084	3,960,378	5,641,284	17,754,261	
Loss before the undernoted	(1,017,663)	(1,477,264)	(3,771,794)	(5,269,542)	(16,797,854)	
Costs related to reverse takeover			-		479,693	
Loss for the period	(1,017,663)	(1,477,264)	(3,771,794)	(5,269,542)	(17,277,547)	
Other comprehensive income (loss)						
Unrealized gain (loss) on available-for-sale marketable securities	(2,986)	26,470	(2,903)	16,391		
Comprehensive loss for the period	(1,020,649)	(1,450,794)	(3,774,697)	(5,253,151)		
Basic and diluted loss per common share	(0.02)	(0.04)	(0.09)	(0.13)		
Weighted average number of common shares outstanding	42,052,754	41,508,217	41,803,625	41,183,744		

(a development stage company) Statements of Shareholders' Equity (Unaudited)

	Common	shares	Other (No	equity te 5)	Contributed surplus	Accumulated other comprehensive income (loss)	Deficit	Total
	Number	Amount \$	Number	Amount S	Amount \$	Amount S	Amount \$	Amount S
Balance - March 31, 2007	40,456,749	18,028,305	8,558,047	2,404,259	4,056	-	(6,365,772)	14,070,848
Adjustment on adoption of new accounting policy	-	-			-	(50,000)	50,000	-
Balance – April 1, 2007	40,456,749	18,028,305	8,558,047	2,404,259	4,056	(50,000)	(6,315,772)	14,070,848
Exercise of stock options	36,000	30,816	(36,000)	(12,816)	-	-	-	18,000
Exercise of agent options and warrants	559,898	448,637	(559,898)	(115,124)	-	-	-	333,513
Expiry of warrants	-		(17,280)	(2,246)	2,246	-	-	-
Issuance of stock options	-	-	120,000	-	-	-	-	-
Stock-based compensation	-	-	-	307,983	-	-	-	307,983
Other comprehensive loss for the period	-	-	-	-	-	(33,657)	-	(33,657)
Loss for the period	-	-	-	-	-	-	(1,784,856)	(1,784,856)
Balance - June 30, 2007	41,052,647	18,507,758	8,064,869	2,582,056	6,302	(83,657)	(8,100,628)	12,911,831
Issuance of common shares for cash	91,445	160,944	-	_,,	-	-	(0,100,020)	160,944
Exercise of agent options and warrants	289,288	307,106	(289,288)	(117,211)	-	-	_	189,895
Expiry of stock options	-	-	(66,750)	(585)	585	-	-	107,075
Stock-based compensation	-	-	-	297,595	-	-	-	297,595
Other comprehensive income for the period	-	-	-	-	-	23,578	-	23,578
Loss for the period	-		-	-	-		(2,007,422)	(2,007,422)
Balance – September 30, 2007	41,433,380	18,975,808	7,708,831	2,761,855	6,887	(60,079)	(10,108,050)	11,576,421
Exercise of stock options	195,000	166,920	(195,000)	(69,420)	- ,	-	-	97,500
Expiry of stock options	-	-	(159,000)	(156,040)	156,040	-	-	-
Stock-based compensation	-	-		126,706	<i>_</i>	_		126,706
Other comprehensive income for the period	-	-	-	-	-	26,470	-	26,470
Loss for the period	-	-	-	-	-	20,470	(1,477,264)	(1,477,264)
Balance – December 31, 2007	41,628,380	19,142,728	7,354,831	2,663,101	162,927	(33,609)	(11,585,314)	10,349,833
Exercise of agent options and warrants	50,000	52,112	(50,000)	(7,112)	-	-	-	45,000
Issuance of stock options	-	-	1,040,125	-	-	-	-	-
Expiry of stock options	-	-	(29,125)	(24,850)	24,850	-	-	-
Stock-based compensation – options	-	-	-	184,699	-	-	-	184,699
Other comprehensive income for the period	-	-	-	-	-	35,856	-	35,856
Loss for the period	-	-	-	-	-	-	(1,920,439)	(1,920,439)
Balance, March 31, 2008	41,678,380	19,194,840	8,315,831	2,815,838	187,777	2,247	(13,505,753)	8,694,949

#### (a development stage company) Statement of Shareholders' Equity (Unaudited)

	Common shares				Contributed surplus	Accumulated other comprehensive income (loss)	Deficit	Total
	Number	Amount S	Number	Amount S	Amount \$	Amount S	Amount S	Amount \$
Balance – April 1, 2008	41,678,380	19,194,840	8,315,831	2,815,838	187,777	2,247	(13,505,753)	8,694,949
Expiry of stock options	-	-	(30,750)	(24,850)	24,850	· _	-	-
Stock-based compensation	-	-	-	221,087	-	-	-	221,087
Other comprehensive loss for the period	-	-	•		-	(6,626)	-	(6,626)
Loss for the period		<u> </u>	•				(1,606,184)	(1,606,184)
Balance – June 30, 2008	41,678,380	19,194,840	8,285,081	3,012,075	212,627	(4,379)	(15,111,937)	7,303,226
Expiry of stock options	-	-	(44,938)	(175)	175	-	-	-
Stock-based compensation	-	-	-	219,339	-	-	-	219,339
Expiry of warrants	-	-	(23,810)	(8,662)	8,662	-	-	-
Other comprehensive income for the period	-	-	-	-	-	6,709	-	6,709
Loss for the period	-	-				-	(1,147,947)	(1,147,947)
Balance – September 30, 2008	41,678,380	19,194,840	8,216,333	3,222,577	221,464	2,330	(16,259,884)	6,381,327
Issuance of common shares for cash	862,801	272,622	-	-	-	-	-	272,622
Issuance of deferred share units	-	-	160,000	70,400	-	-	-	70,400
Stock-based compensation	-	-	-	154,917	-	-	-	154,917
Expiry of stock options	-	-	(8,281)	(2,847)	2,847	-	-	-
Other comprehensive income for the period	-	-	•	-	-	(2,986)	-	(2,986)
Loss for the period	-	-	-	-	-	-	(1,017,663)	(1,017,663)
Balance – December 31, 2008	42,541,181	19,467,462	8,368,052	3,445,047	224,311	(656)	(17,277,547)	5,858,617

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(a development stage company) Statements of Cash Flows

(Unaudited)

	Three mont	ths ended	Nine mont		Period from anuary 23, 2004 (inception) to	
	Decemb		Decemb		December 31, 2008	
	2008	2007	2008	2007		
	\$	\$	\$	\$	S	
Cash provided by (used in)						
Operating activities						
Loss for the period	(1,017,663)	(1,477,264)	(3,771,794)	(5,269,542)	(17,277,547)	
Amortization of property and equipment	67,076	28,168	180,466	72,709	362,566	
Amortization of technology rights	-	12,720	-	33,159	56,313	
Stock-based compensation	225,317	126,706	665,743	732,284	2,594,281	
Other non-cash expenses	-	-	-	-	235,115	
Changes in non-cash working capital (note 6)	(84,318)	51,640	(602,491)	196,579	(132,583)	
	(809,588)	(1,258,030)	(3,528,076)	(4,234,811)	(14,161,855)	
Investing activities						
Purchase of marketable securities	(1,171,489)	(247,638)	(4,726,771)	(247,638)	(26,400,681)	
Maturity or sale of marketable securities	1,795,825	498,508	7,180,865	4,569,918	22,389,532	
Purchase of property and equipment	-	(64,478)	(110,939)	(209,633)	(868,092)	
Purchase of technology rights	-	-	-	(15,000)	(56,313)	
	624,336	186,392	2,343,155	4,097,647	(4,935,554)	
Financing activities						
Issuance of common shares, net of cash issue costs	272,622	-	272,622	160,944	4,655,751	
Issuance of common share units, net of cash issue co	-	-	-	-	11,973,069	
Issuance of common shares on exercise of warrants	-	-	-	523,408	2,980,920	
Issuance of common shares on exercise of options	-	97,500	-	115,500	521,368	
Other financing activities		-	-	-	266,778	
	272,622	97,500	272,622	799,852	20,397,886	
Net increase (decrease) in cash	87,370	(974,138)	(912,299)	662,688	1,300,477	
Cash - beginning of period	1,213,107	3,297,420	2,212,776	1,660,594	-	
Cash - end of period	1,300,477	2,323,282	1,300,477	2,323,282	1,300,477	
Cash and cash equivalents are comrpised of:						
Cash on deposit	341,539	894,102				
Money market securities	058 038	1 420 180				

	1,300,477	2,323,282
Money market securities	958,938	1,429,180
Cash on ucposh	541,559	894,102

(a development stage company) Notes to Financial Statements **December 31, 2008 and 2007** (Unaudited)

#### 1 Nature of operations and going concern

These unaudited interim financial statements of Amorfix Life Sciences Ltd. (the company or Amorfix) have been prepared by management in accordance with Canadian generally accepted accounting principles (Canadian GAAP) for interim financial statements. Accordingly, they do not contain all the disclosures required by Canadian GAAP for annual financial statements. These financial statements should be read in conjunction with the audited financial statements for the year ended March 31, 2008 as they follow the same accounting policies and methods of application as these audited financial statements except as described in note 2.

Amorfix Life Sciences Ltd. (the company or Amorfix) is an emerging theranostics company focused on the diagnosis and treatment of neurodegenerative diseases, where aggregated misfolded proteins (AMPs) are prevalent. 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 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 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 has incurred loss of \$3,771,794 for the nine months ended December 31, 2008 and has a deficit of \$17,277,547 as at December 31, 2008. 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 \$5,353,091 is sufficient to fund its operations through to the end of December 2009, 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 for cash flow generation including product out-licensing, contracts for blood screening testing for variant Creutzfeldt-Jakob Disease prevalence studies, and other non-dilutive sources of funding, however there is 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.

(a development stage company) Notes to Financial Statements **December 31, 2008 and 2007** (Unaudited)

#### 2 Change in accounting policies

Effective April 1, 2008, the company adopted the Canadian Institute of Chartered Accountants' (CICA) Handbook Section 3862, *Financial Instruments – Disclosure*; Section 3863, *Financial Instruments – Presentation*; Section 1535, *Capital Disclosures* and changes to Section 1400, *General Standards of Financial Statement Presentation*. These sections relate to disclosure and presentation only and do not have an impact on the company's financial results.

Section 3862 describes the required disclosure of the nature and extent of risks arising from financial instruments to which an entity is exposed and how the entity manages those risks.

Section 3863 establishes the standards for presentation of financial instruments and non-financial derivatives. It carries forward the existing requirements for presentation of financial instruments from Section 3861, *Financial Instruments –Presentation and Disclosure*.

Section 1535 describes the required disclosure of an entity's objectives, policies and processes for managing capital. An entity should disclose a description of what it manages as capital, the nature of externally imposed capital requirements and its compliance thereto, how it is meeting is objectives for managing capital, and summary quantitative data about what it manages as capital.

Section 1400 has been amended to change the guidance related to management's responsibility to assess the ability of the entity to continue as a going concern. Disclosure is required for material uncertainties related to events or conditions that may cast doubt on the ability to continue as a going concern.

#### Future accounting changes:

#### Goodwill and intangible assets

In November 2007, the CICA issued 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. These standards are effective for the Company beginning on April 1, 2009. The company is currently assessing the impact that these standards will have on its financial statements.

#### International financial reporting standards

The Accounting Standards Board of Canada has announced that public companies in Canada are to adopt International Financial Reporting Standards (IFRS) for fiscal years beginning on or after January 1, 2011. The company is in the process of assessing the effects of the standards on its financial statements.

(a development stage company) Notes to Financial Statements **December 31, 2008 and 2007** (Unaudited)

#### **3** Marketable securities

Amorfix invests primarily in high credit quality corporate debt instruments with maturities staggered over the next ten 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. Accordingly, all marketable securities are classified as current assets in the accompanying balance sheets. The weighted average yield of the debt instruments held at December 31, 2008 was 4.13%.

#### 4 Share capital

The company has authorized an unlimited number of common shares and preferred shares and has issued 42,541,181 common shares and no preferred shares as at December 31, 2008. During the three and nine months ended December 31, 2008 the following common shares were issued:

- a) In November 2008, on the achievement of the second research milestone under its research and investment agreement with Biogen Idec MA (Biogen), Biogen subscribed for 608,250 common shares of the company at \$0.31 per share for gross proceeds to Amorfix of \$187,485 (US\$150,000). Proceeds net of share issue costs were \$185,195.
- b) In December 2008, on the achievement of the third research milestone Biogen subscribed for 254,551 common shares of the company at \$0.35 per share for gross proceeds to Amorfix of \$89,565 (US\$75,000). Proceeds net of share issue costs were \$87,427.

#### 5 Warrants and stock-based awards

a) The company has issued warrants and options for the purchase of common shares. All outstanding warrants are exercisable. As at December 31, 2008, the following warrants and options (other than stock options) were outstanding:

	Exercise price \$	Number outstanding	Expiry date
Common share purchase warrants	1.95	4,462,521	March 8, 2009
		4,462,521	

b) During the three and nine months ended December 31, 2008, the company issued nil (2007 - nil) and nil (2007 - 120,000) stock options, with a fair value of \$nil (2007 - \$nil) and \$nil (2007 - \$116,960) respectively. For the three and nine months ended December 31, 2008, the company recorded stock-based compensation expense of \$154,917 (2007 - \$126,706) and \$595,343 (2007 - \$732,204) respectively. The

(a development stage company) Notes to Financial Statements **December 31, 2008 and 2007** (Unaudited)

fair value of the stock options granted was estimated using the Black-Scholes option pricing model with the following assumptions:

	Three months ended December 31, 2008	Three months ended December 31, 2007	Nine months ended December 31, 2008	Nine months ended December 31, 2007
Risk-free interest rate	-	-	-	3.9 %
Dividend yield	-	-	-	0%
Expected volatility	-	-	-	66%
Expected life of options	-	-	-	5

- c) On November 5, 2008, the company's shareholders approved the adoption of a deferred share unit (DSU) plan for senior officers of the company. Under the DSU plan, rights to the company's shares (units) may be awarded to senior officers, on a deferred payment basis, to a maximum of 1,000,000 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. Upon adoption of the DSU plan, a total of 160,000 units, with a grant date fair value of \$0.44 per unit, were awarded to senior officers and the company recorded stock-based compensation of \$70,400.
- d) On January 12, 2009, the company issued 799,750 stock options with an exercise price of \$0.65 and 186,092 DSU units with a grant date fair value of \$0.65 per unit.

#### 6 Supplementary cash flow information

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

	Three month Decembe		Nine months December	ended	Period from anuary 23, 2004 (inception) to December 31,
	2008	2007	2008	2007	2008
	\$	\$	\$	\$	\$
Amounts receivable	14,707	(26,296)	119,787	117,981	(71,192)
Tax credits receivable	(69,918)	(50,000)	(219,918)	(66,555)	(620,000)
Prepaid expenses and deposits	3,278	(109,546)	67,495	(69,461)	(69,360)
Accounts payable and accrued liabilities	(32,385)	237,482	(569,855)	214,614	627,969
	(84,318)	51,640	(602,491)	196,579	(132,583)
Supplemental cash flow information Common shares, warrants and options					
issued on reverse takeover	<u> </u>	<u> </u>	<u> </u>		349,204

No income tax or interest was paid by the company.

(a development stage company) Notes to Financial Statements **December 31, 2008 and 2007** (Unaudited)

#### 7 Financial instruments risks

Financial instruments of the company consist of cash and cash equivalents, marketable securities, amounts receivable, and accounts payable and accrued liabilities. As at December 31, 2008, 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 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.

#### 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 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 planned commitments. As at December 31, 2008 the company held cash and cash equivalents and marketable securities in the amount of \$458,317 denominated in US dollars.

(a development stage company) Notes to Financial Statements **December 31, 2008 and 2007** (Unaudited)

#### 8 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 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.

#### 9 Segmented information

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

#### 10 Commitments

In December 2008, the Company entered into an agreement with the University of British Columbia (UBC), with Dr. Neil Cashman, an officer and shareholder of the company, as principal investigator, to fund research in Dr. Cashman's laboratory related to the Amorfix AD therapeutic program in the amount of \$426,619. During the three and nine months ended December 31 2008, \$71,619 (2007 - \$nil) was paid to UBC and as at December 31, 2008, \$71,000 (2007- nil) was included in accounts payable and accrued liabilities relating to this agreement. The balance of the commitment will be funded over the next twelve months.

(a development stage company)

**Financial Statements** 

### Second Quarter Ended September 30, 2008 Fiscal 2009

These unaudited interim financial statements were not reviewed by external auditors.

Trading symbol: TSX: AMF

For more information please contact: James Parsons, Chief Financial Officer Email: james.parsons@amorfix.com

www.amorfix.com

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(a development stage company) Balance Sheets

		September 30, 2008 \$ ( unaudited)	March 31, 2008 \$
Assets			
<b>Current assets</b> Cash and cash equivalents Marketable securities Amounts receivable Tax credits receivable Prepaid expenses and deposits	1999 - 1997 - sender medarg solo	1,213,107 4,637,815 92,946 550,082 72,638	2,212,776 6,467,490 198,026 400,082 136,855
Total current assets		6,566,588	9,415,229
Property and equipment, net	er en al la construcción de la desta destrucción de la construcción de la construcción de la construcción de la	572,602	575,053
		7,139,190	9,990,282
Liabilities			
<b>Current liabilities</b> Accounts payable and accrued liabilities		757,863	1.005.000
	-		1,295,333
Total current liabilities		757,863	1,295,333
Shareholders' equity			
Common shares Warrants and options Contributed surplus Accumulated other comprehensive inco Deficit	me -	19,194,840 3,222,577 221,464 2,330 (16,259,884)	19,194,840 2,815,838 187,777 2,247 (13,505,753)
	-	6,381,327	8,694,949
		7,139,190	9,990,282
Going concern (note 1)			

Going concern (note 1) Subsequent event (note 10)

(a development stage company)

### Statements of Operations and Comprehensive Loss

(Unaudited)

	Three mor Septem 2008		Six mont Septen 2008	Period from January 23, 2004 (inception) to September 30, 2008	
	\$	\$	S	\$	\$
Revenues					
Interest earned	58,525	124,805	134,378	259,922	902,201
Expenses					
Research and development	890,514	1,669,098	2,257,681	3,201,522	13,072,657
General and administrative	253,814	423,947	517,438	785,698	3,257,932
Amortization of property and equipment	62,144	26,462	113,390	44,541	295,490
Amortization of technology rights		12,720	0	20,439	56,313
	1,206,472	2,132,227	2,888,509	4,052,200	16,682,392
Loss before the undernoted	(1,147,947)	(2,007,422)	(2,754,131)	(3,792,278)	(15,780,191)
Costs related to reverse takeover	<u> </u>				479,693
Loss for the period	(1,147,947)	(2,007,422)	(2,754,131)	(3,792,278)	(16,259,884)
Other comprehensive income (loss)					
Unrealized gain (loss) on available-for-sale marketable securities	6,709	23,578	83	(10,079)	
Comprehensive loss for the period	(1,141,238)	(1,983,844)	(2,754,048)	(3,802,357)	
Basic and diluted loss per common share	(0.03)	(0.05)	(0.07)	(0.09)	
Weighted average number of common shares outstanding	41,678,380	41,157,982	41,678,380	41,020,621	

See accompanying notes to the interim financial statements.

(a development stage company) Statements of Shareholders' Equity (Unaudited)

	Common	shares	Warrants and	l options te 5)	Contributed surplus	Accumulated other comprehensive income (loss)	Deficit	Total
	Number	Amount \$	Number	Amount \$	Amount \$	Amount S	Amount S	Amount \$
Balance - March 31, 2007	40,456,749	18,028,305	8,558,047	2,404,259	4,056	-	(6,365,772)	14,070,848
Adjustment on adoption of new accounting policy	-	-	-	-	-	(50,000)	50,000	-
Balance – April 1, 2007	40,456,749	18,028,305	8,558,047	2,404,259	4,056	(50,000)	(6,365,772)	14,070,848
Exercise of stock options	36,000	30,816	(36,000)	(12,816)	-	-	-	18,000
Exercise of agent options and warrants	559,898	448,637	(559,898)	(115,124)	-	-	-	333,513
Expiry of warrants	-		(17,280)	(2,246)	2,246	-	-	-
Issuance of stock options	-	-	120,000	(_,_ · · · )	_,	_	_	
Stock-based compensation	-	-	120,000	307,983	_			307,983
Other comprehensive loss for the period	-	-	-	507,505	_	(33,657)	-	(33,657)
Loss for the period	_		-	_		(55,057)	(1,784,856)	(1,784,856)
Balance - June 30, 2007	41,052,647	18,507,758	8,064,869	2,582,056	6,302	(83,657)		
Issuance of common shares for cash at \$1.76 per share	91,445	160,944	8,004,803	2,382,030	0,502	(85,057)	(8,100,628)	12,911,831
Exercise of agent options and warrants	289,288	307,106	(289,288)	(117,211)	-	-	-	160,944
Expiry of stock options	209,200	507,100	(66,750)	(585)	585	-	-	189,895
Stock-based compensation	-	-	(00,750)	297,595	282	-	-	- 297,595
Other comprehensive income for the period	-	-	-		_	23,578	-	23,578
Loss for the period	-	-	-	-	-	-	(2.007,422)	(2,007,422)
Balance – September 30, 2007	41,433,380	18,975,808	7,708,831	2,761,855	6,887	(60,079)	(10,108,050)	11,576,421
Exercise of stock options	195,000	166,920	(195,000)	(69,420)	-	(00,075)	(10,100,050)	97,500
Expiry of stock options	-	-	(159,000)	(156,040)	156,040	_	-	,,500
Stock-based compensation	_	_		126,706	,			126 706
Other comprehensive income for the period	-	-	-	120,700	-	26,470	-	126,706 26,470
Loss for the period	-	-	-	-	-		(1,477,264)	(1,477,264)
Balance – December 31, 2007	41,628,380	19,142,728	7,354,831	2,663,101	162,927	(33,609)	(11,585,314)	10,349,833
Exercise of agent options and warrants	50,000	52,112	(50,000)	(7,112)		-	-	45,000
Issuance of stock options	-	-	1,040,125	-	-	-	-	-
Expiry of stock options	-	-	(29,125)	(24,850)	24,850	-	-	-
Stock-based compensation	-	-	-	184,699	-	-	-	184,699
Other comprehensive income for the period	-	-	-	-	-	35,856	-	35,856
Loss for the period	-	-	-	-	-	-	(1,920,439)	(1,920,439)
Balance, March 31, 2008	41,678,380	19,194,840	8,315,831	2,815,838	187,777	2,247	(13,505,753)	8,694,949

(a development stage company) Statement of Shareholders' Equity (Unaudited)

	Common	Common shares		Warrants and options (Note 5)		Accumulated other comprehensive income (loss)	Deficit	Total
	Number	Amount \$	Number	Amount \$	Amount S	Amount \$	Amount \$	Amount \$
Balance – April 1, 2008	41,678,380	19,194,840	8,315,831	2,815,838	187,777	2,247	(13,505,753)	8,694,949
Expiry of stock options	-	-	(30,750)	(24,850)	24,850		(15,505,755)	-
Stock-based compensation	-	-	-	221,087	,	-	_	221,087
Other comprehensive loss for the period	-	-	-		-	(6,626)	-	(6,626)
Loss for the period		-	-	-	-	-	(1,606,184)	(1,606,184)
Balance - June 30, 2008	41,628,380	19,194,840	8,285,081	3,012,075	212,627	(4,379)	(15,111,937)	7,303,226
Expiry of stock options	_		(44,938)	(175)	175			
Stock-based compensation	-	-	-	219,339	-	-	-	219,339
Expiry of warrants	-	-	(23,810)	(8,662)	8,662	_		219,999
Other comprehensive income for the period	_	-		(-,		6,709	-	- 6,709
Loss for the period	-	-	-	-	-	5,709	- (1,147,947)	
Balance – September 30, 2008	41,628,380	19,194,840	8,216,333	3 222 577	221 464			(1,147,947)
	-1,028,380	17,194,040	0,210,555	3,222,577	221,464	2,330	(16,259,884)	6,381,327

(a development stage company)

Statements of Cash Flows (Unaudited)

	Three mon	the ended	Six month		Period from anuary 23, 2004 (inception) to	
	Septemb		Six month Septemi		September 30,	
	2008	2007	2008	2007	2008 September 30,	
	\$	\$	\$	\$	S	
Cash provided by (used in)						
Operating activities						
Loss for the period	(1,147,947)	(2,007,422)	(2,754,131)	(3,792,278)	(16,259,884)	
Amortization of property and equipment	62,144	26,462	113,390	44,541	295,490	
Amortization of technology rights	-	12,720	-	20,439	56,313	
Stock-based compensation	219,339	297,595	440,426	605,578	2,368,964	
Other non-cash expenses	-	-	-	-	235,115	
Changes in non-cash working capital (note 6)	(169,578)	186,494	(518,173)	144,939	(48,265)	
	(1,036,042)	(1,484,151)	(2,718,488)	(2,976,781)	(13,352,267)	
Investing activities						
Purchase of marketable securities	(1,840,819)	-	(3,555,282)	-	(25,229,192)	
Maturity or sale of marketable securities	3,517,801	3,375,752	5,385,040	4,071,410	20,593,707	
Purchase of property and equipment	(22,001)	(34,640)	(110,939)	(145,155)	(868,092)	
Purchase of technology rights	-	(15,000)	-	(15,000)	(56,313)	
	1,654,981	3,326,112	1,718,819	3,911,255	(5,559,890)	
Financing activities						
Issuance of common shares, net of cash issue costs	-	160,944	-	160,944	4,383,129	
Issuance of common share units, net of cash issue costs	-	-	-	-	11,973,069	
Issuance of common shares on exercise of warrants	-	189,895	-	523,408	2,980,920	
Issuance of common shares on exercise of options	-	-	-	18,000	521,368	
Other financing activities	-	-	-	-	266,778	
	-	350,839	-	702,352	20,125,264	
Net increase (decrease) in cash	618,939	2,192,800	(999,669)	1,636,826	1,213,107	
Cash - beginning of period	594,168	1,104,620	2,212,776	1,660,594		
Cash - end of period	1,213,107	3,297,420	1,213,107	3,297,420	1,213,107	
Cash and cash equivalents are comprised of:						
Cash on deposit:	269,706	330,955				

Money market securities	1,213,007	3,297,420
Money market securities	943,301	2,966,465
Cash on deposit:	269.706	330.955

(a development stage company) Notes to Financial Statements **September 30, 2008 and 2007** (Unaudited)

#### 1 Nature of operations and going concern

These unaudited interim financial statements of Amorfix Life Sciences Ltd. (the company or Amorfix) have been prepared by management in accordance with Canadian generally accepted accounting principles (Canadian GAAP) for interim financial statements. Accordingly, they do not contain all the disclosures required by Canadian GAAP for annual financial statements. These financial statements should be read in conjunction with the audited financial statements for the year ended March 31, 2008 as they follow the same accounting policies and methods of application as these audited financial statements except as described in note 2.

Amorfix Life Sciences Ltd. (the company or Amorfix) is an emerging theranostics company focused on the diagnosis and treatment of neurodegenerative diseases, where aggregated misfolded proteins (AMPs) are prevalent. 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 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 programs or the company's ability to fund these programs going forward.

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(a development stage company) Notes to Financial Statements **September 30, 2008 and 2007** (Unaudited)

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#### **3** Marketable securities

Amorfix invests primarily in high credit quality corporate debt instruments with maturities staggered over the next nine 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

(a development stage company) Notes to Financial Statements **September 30, 2008 and 2007** (Unaudited)

liquidity. Accordingly, all marketable securities are classified as current assets in the accompanying balance sheets. The weighted average yield of the debt instruments held at September 30, 2008 was 3.9%.

#### 4 Share capital

The company has authorized an unlimited number of common shares and preferred shares and has issued 41,678,380 common shares and no preferred shares as at September 30, 2008.

#### 5 Warrants and options

a) The company has issued warrants and options for the purchase of common shares. All outstanding warrants are exercisable. As at September 30, 2008, the following warrants and options (other than stock options) were outstanding:

	Exercise price \$	Number outstanding	Expiry date
Common share purchase warrants	1.95	4,462,521	March 8, 2009
		4,462,521	

b) During the three and six months ended September 30, 2008, the company issued nil (2007 - nil) and nil (2007 - 120,000) stock options, with a fair value of \$nil (2007 - \$nil) and \$nil (2007 - \$116,960) respectively. For the three and six months ended September 30, 2008, the company recorded stock-based compensation expense of \$219,339 (2007 -\$297,595) and \$440,426 (2007 - \$605,578) respectively. The fair value of the stock options granted was estimated using the Black-Scholes option pricing model with the following assumptions:

	Three months ended September 30, 2008	Three months ended September 30, 2007	Six months ended September 30, 2008	Six months ended September 30, 2007
Risk-free interest rate	-	-	-	3.9 %
Dividend yield	-	-	-	0%
Expected volatility	-	-	-	66%
Expected life of options	-	-	-	5

(a development stage company) Notes to Financial Statements September 30, 2008 and 2007 (Unaudited)

#### 6 Supplementary cash flow information

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

				ſ	Period from anuary 23, 2004
	Three months ended September 30,		Six months Septembe		(inception) to September 30,
	2008	2007	2008	2007	2008
	\$	\$	\$	\$	\$
Amounts receivable	116,230	195,386	105,080	144,277	(85,899)
Tax credits receivable	(75,000)	(50,000)	(150,000)	(16,555)	(550,082)
Prepaid expenses and deposits	8,657	723	64,217	40,085	(72,638)
Accounts payable and accrued liabilities	(219,465)	40,385	(537,470)	(22,868)	660,354
	(169,578)	186,494	(518,173)	144,939	(48,265)
Supplemental cash flow information Common shares, warrants and options					
issued on reverse takeover	•	-	-	-	349,204

No income tax or interest was paid by the company.

#### 7 Financial instruments risks

Financial instruments of the company consist of cash and cash equivalents, marketable securities, amounts receivable, and accounts payable and accrued liabilities. As at September 30, 2008, 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 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.

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 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

(a development stage company) Notes to Financial Statements **September 30, 2008 and 2007** (Unaudited)

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. As at September 30, 2008 the company held cash and cash equivalents and marketable securities in the amount of \$196,488 denominated in US dollars.

#### 8 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 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.

#### 9 Segmented information

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

#### 10 Subsequent event

On November 5, 2008, the company's shareholders approved the adoption of a deferred share unit (DSU) plan for senior officers of the company. Under the DSU plan, rights to the company's shares (units) may be awarded to senior officers, on a deferred payment basis, to a maximum of 1,000,000 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. Upon adoption of the DSU plan, a total of 160,000 units were awarded to senior officers.

(a development stage company)

**Financial Statements** 

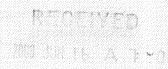
## First Quarter Ended June 30, 2008 Fiscal 2009

These unaudited interim financial statements were not reviewed by external auditors.

Trading symbol: TSX: AMF

**For more information please contact**: James Parsons, Chief Financial Officer Email: james.parsons@amorfix.com

www.amorfix.com



(a development stage company) Balance Sheets

	June 30, 2008 \$ ( unaudited)	March 31, 2008 \$
Assets		
Current assets Cash and cash equivalents Marketable securities Amounts receivable Tax credits receivable Prepaid expenses and deposits	594,168 6,308,088 209,176 475,082 81,295	2,212,776 6,467,490 198,026 400,082 136,855
Total current assets	7,667,809	9,415,229
Property and equipment, net	612,745	575,053
	8,280,554	9,990,282
Liabilities		
Current liabilities Accounts payable and accrued liabilities	977,328	1,295,333
Total current liabilities	977,328	1,295,333
Shareholders' Equity		
Common shares Warrants and options Contributed surplus Accumulated other comprehensive income (loss) Deficit	19,194,840 3,012,075 212,627 (4,379) (15,111,937) 7,303,226	19,194,840 2,815,838 187,777 2,247 (13,505,753) 8,694,949
	8,280,554	9,990,282

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Going concern (note 1)

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## (a development stage company) Statements of Operations and Comprehensive Loss (Unaudited)

	Three months ended June 30, 2008 \$	Three months ended June 30, 2007 \$	Period from January 23, 2004 (inception) To June 30, 2008 \$
Revenue Interest earned	75,853	135,117	843,676
Expenses Research and development General and administrative Amortization of property and equipment Amortization of technology rights	1,367,167 263,624 51,246 - 1,682,037	1,532,424 361,751 18,079 7,719 1,919,973	12,182,143 3,004,118 233,346 56,313 15,475,920
Loss before the undernoted	(1,606,184)	(1,784,856)	(14,632,244)
Costs related to reverse takeover			479,693
Loss for the period	(1,606,184)	(1,784,856)	(15,111,937)
Other comprehensive income (loss) Unrealized loss on available-for-sale marketable securities Comprehensive loss for the period	(6,626) (1,612,810)	(33,657) (1,818,513)	
Basic and diluted loss per common share	(0.04)	(0.04)	
Weighted average number of common shares outstanding	41,678,380	40,881,750	

Going concern (note 1)

## (a development stage company) Statements of Shareholders' Equity

(Unaudited)

	Common	shares	Warrants and (Not	l options te 5)	Contributed surplus	Accumulated other comprehensive loss	Deficit	Total
	Number	Amount \$	Number	Amount \$	Amount \$	Amount \$	Amount \$	Amount \$
<b>Balance - March 31, 2007</b> Adjustment on adoption of new accounting policy	40,456,749	18,028,305	8,558,047	2,404,259	4,056	(50,000)	(6,365,772) 50,000	14,070,848
Balance – April 1, 2007	40,456,749	18,028,305	8,558,047	2,404,259	4,056	(50,000)	(6,365,772)	14,070,848
Exercise of stock options	36,000	30,816	(36,000)	(12,816)	-	-	-	18,000
Exercise of agent options and warrants	559,898	448,637	(559,898)	(115,124)	-	-	-	333,513
Expiry of warrants	-		(17,280)	(2,246)	2,246	-	-	-
Issuance of stock options	-	-	120,000	-	-	-	•	-
Stock-based compensation	-	-	-	307,983	-	-	-	307,983
Other comprehensive loss for the period	-	-	-	-	-	(33,657)	-	(33,657)
Loss for the period	-	-	-	-	-	-	(1,784,856)	(1,784,856)
Balance - June 30, 2007	41,052,647	18,507,758	8,064,869	2,582,056	6,302	(83,657)	(8,100,628)	12,911,831
Issuance of common shares for cash at \$1.76 per share	91,445	160,944	-	-	-	-	-	160,944
Exercise of agent options and warrants	289,288	307,106	(289,288)	(117,211)	-	-	-	189,895
Expiry of stock options	-	-	(66,750)	(585)	585	-	-	-
Stock-based compensation	-	-	-	297,595	-	-	-	297,595
Other comprehensive income for the period	-	-	-	-	-	23,578	-	23,578
Loss for the period	•	-	-			-	(2,007,422)	(2,007,422)
Balance – September 30, 2007	41,433,380	18,975,808	7,708,831	2,761,855	6,887	(60,079)	(10,108,050)	11,576,421
Exercise of stock options	195,000	166,920	(195,000)	(69,420)	-	-	-	97,500
Expiry of stock options	-	-	(159,000)	(156,040)	156,040	-	-	-
Stock-based compensation	-	-	-	126,706	-	-	-	126,706
Other comprehensive income for the period	-	-	-	-	-	26,470	-	26,470
Loss for the period	-	-	-	-	-	-	(1,477,264)	(1,477,264)
Balance – December 31, 2007	41,628,380	19,142,728	7,354,831	2,663,101	162,927	(33,609)	(11,585,314)	10,349,833
Exercise of agent options and warrants	50,000	52,112	(50,000)	(7,112)	-	-	-	45,000
Issuance of stock options	-	-	1,040,125	-	-	-	-	-
Expiry of stock options	-	-	(29,125)	(24,850)	24,850	-	-	-
Stock-based compensation	-	-	-	184,699	-	-	-	184,699
Other comprehensive income for the period	-	-	-	-	-	35,856	-	35,856
Loss for the period	-	-	-			-	(1,920,439)	(1,920,439)
Balance, March 31, 2008	41,678,380	19,194,840	8,315,831	2,815,838	187,777	2,247	(13,505,753)	8,694,949

## (a development stage company) Statement of Shareholders' Equity (Unaudited)

	Common shares		Warrants and options (Note 4)		Contributed surplus	Accumulated other comprehensive loss	Deficit	Total
	Number	Amount S	Number	Amount \$	Amount S	Amount S	Amount \$	Amount \$
Balance – April 1, 2008	41,678,380	19,194,840	8,315,831	2,815,838	187,777	2,247	(13,505,753)	8,694,949
Expiry of stock options	-	-	(30,750)	(24,850)	24,850	-	-	-
Stock-based compensation	-	-	-	221,087	-	-	-	221,087
Other comprehensive loss for the period	-	-	-		-	(6,626)	-	(6,626)
Loss for the period	-	-		-	<u> </u>		(1,606,184)	(1,606,184)
Balance – June 30, 2008	41,628,380	19,194,840	8,285,081	3,012,075	212,627	(4,379)	(15,111,937)	7,303,226

(a development stage company) Statements of Cash Flows

(Unaudited)

Cash provided by (used in)	Three months ended June 30, 2008 \$	Three months ended June 30, 2007 \$	Period from January 23, 2004 (inception) to June 30, 2008 \$
<b>Operating activities</b> Loss for the period Amortization of property and equipment Amortization of technology rights Stock-based compensation Other non-cash expenses Changes in non-cash working capital (note 6)	(1,606,184) 51,246 221,087 (348,595)	(1,784,856) 18,079 7,719 307,983 (41,555)	(15,111,937) 233,346 56,313 2,149,625 235,115 121,313
-	(1,682,446)	(1,492,630)	(12,316,225)
Investing activities Purchase of marketable securities Sale of marketable securities Purchase of property and equipment Purchase of technology rights	(1,714,463) 1,867,239 (88,938)	695,658 (110,515)	(23,388,373) 17,075,906 (846,091) (56,313)
_	63,838	585,143	(7,214,871)
Financing activities Issuance of common shares, net of cash issue costs Issuance of common share units, net of cash issue costs Issuance of common shares on exercise of agent options and warrants Issuance of common shares on exercise of options		- 333,513 18,000	4,383,129 11,973,069 2,980,920 521,368
Other financing activities		· ·	266,778
		351,513	20,125,264
Net (decrease) increase in cash and cash equivalents during the period	(1,618,608)	(555,974)	594,168
Cash and cash equivalents - Beginning of period	2,212,776	1,660,594	
Cash and cash equivalents - End of period	594,168	1,104,620	594,168
Cash and cash equivalents are comprised of: Cash on deposit Money market securities	349,688 244,480 594,168	830,925 273,695 1,104,620	

(a development stage company) Notes to Financial Statements **June 30, 2008** (Unaudited)

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

These unaudited interim financial statements of Amorfix Life Sciences Ltd. (the company or Amorfix) have been prepared by management in accordance with Canadian generally accepted accounting principles (Canadian GAAP) for interim financial statements. Accordingly, they do not contain all the disclosures required by Canadian GAAP for annual financial statements. These financial statements should be read in conjunction with the audited financial statements for the year ended March 31, 2008 as they follow the same accounting policies and methods of application as these audited financial statements except as described in note 2.

Amorfix Life Sciences Ltd. (the company or Amorfix) is an emerging theranostics company focused on the diagnosis and treatment of neurodegenerative diseases, where aggregated misfolded proteins (AMPs) are prevalent. 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 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 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 has incurred a loss of \$1,606,184 for the three months ended June 30, 2008 and has a deficit of \$15,111,937 as at June 30, 2008. 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 \$6,690,481 is sufficient to fund its operations through to the end of August 2009, 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 for cash flow generation including product out-licensing, contracts for blood screening testing for variant Creutzfeldt-Jakob Disease prevalence studies, and other non-dilutive sources of funding, however there is 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.

(a development stage company) Notes to Financial Statements **June 30, 2008** (Unaudited)

## 2 Change in accounting policies

Effective April 1, 2008, Amorfix adopted the Canadian Institute of Chartered Accountants' (CICA) Handbook Section 3862, *Financial Instruments – Disclosure*; Section 3863, *Financial Instruments – Presentation*; Section 1535, *Capital Disclosures* and changes to Section 1400, *General Standards of Financial Statement Presentation*. These sections relate to disclosure and presentation only and do not have an impact on the Company's financial results.

Section 3862 describes the required disclosure of the nature and extent of risks arising from financial instruments to which an entity is exposed and how the entity manages those risks.

Section 3863 establishes the standards for presentation of financial instruments and non-financial derivatives. It carries forward the existing requirements for presentation of financial instruments from Section 3861, *Financial Instruments –Presentation and Disclosure*.

Section 1535 describes the required disclosure of an entity's objectives, policies and processes for managing capital. An entity should disclose a description of what it manages as capital, the nature of externally imposed capital requirements and its compliance thereto, how it is meeting is objectives for managing capital, and summary quantitative data about what it manages as capital.

Section 1400 has been amended to change the guidance related to management's responsibility to assess the ability of the entity to continue as a going concern. Disclosure is required for material uncertainties related to events or conditions that may cast doubt on the ability to continue as a going concern.

## Future accounting changes:

## Goodwill and intangible assets

In November 2007, the CICA issued 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. These standards are effective for the company for its interim financial statements beginning on October 1, 2008. The Company is currently assessing the impact that these standards will have on its financial statements.

## **3** Marketable securities

Amorfix invests primarily in high credit quality corporate debt instruments with maturities staggered over the next 11 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. Accordingly, all marketable securities are classified as current assets in the accompanying balance sheets. The weighted average yield of the debt instruments held at June 30, 2008 was 4.5%.

(a development stage company) Notes to Financial Statements **June 30, 2008** (Unaudited)

4 Share capital

The company has authorized an unlimited number of common shares and preferred shares and has issued 41,678,380 common shares and no preferred shares as at June 30, 2008. As at June 30, 2008, a total of 1,533,750 common shares of the company remain in escrow related to a 2005 amalgamation agreement. These shares will be released from escrow on September 30, 2008.

## 5 Warrants and options

a) The company has issued warrants and options for the purchase of common shares. All outstanding warrants are exercisable. As at June 30, 2008, the following warrants and options (other than stock options) were outstanding:

	Exercise price \$	Number outstanding	Expiry date
Common share purchase warrants	1.05	23,810	September 11, 2008
Common share purchase warrants	1.95	3,847,001	March 8, 2009
Common share purchase warrants	1.95	615,520	March 8, 2009
		4,486,331	

b) During the three months ended June 30, 2008, the company issued nil (2007 - 120,000) stock options with a fair value of \$nil (2007 - \$116,960) and recorded stock-based compensation expense of \$221,087 (2007 - \$307,983). The fair value of the stock options granted was estimated using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended June 30, 2008	Three Months Ended June 30, 2007
Risk-free interest rate	-	3.9%
Dividend yield	-	0
Expected volatility	-	66%
Expected life of options (years)	-	5

(a development stage company) Notes to Financial Statements **June 30, 2008** (Unaudited)

## 6 Supplementary cash flow information

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

	Three months ended June 30, 2008 \$	Three months ended June 30, 2007 \$	January 23, 2004 (inception) to March 31, 2008 \$
Amounts receivable Tax credits receivable	(11,150) (75,000)	(51,109) 33,445	(202,129) (475,082)
Prepaid expenses and deposits Accounts payable and accrued	55,560	39,362	(81,295)
liabilities	(318,005)	(63,253)	879,819
	(348,595)	(41,555)	121,313
Supplemental cash flow information Common share purchase warrants issued as agents' compensation	<u> </u>		349,204

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No income tax or interest was paid by the company.

## 7 Financial instruments risks

Financial instruments of the company consist of cash and cash equivalents, marketable securities, amounts receivable, and accounts payable and accrued liabilities. As at June 30, 2008, 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 manages its cash and cash equivalents and marketable securities in accordance with an investment policy that established guidelines for investment eligibility, credit quality, liquidity and foreign currency exposure.

## 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 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.

(a development stage company) Notes to Financial Statements **June 30, 2008** (Unaudited)

## b) Liquidity Risk

The company's exposure to liquidity risk is dependent on purchasing commitments and obligations or 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. As at June 30, 2008 the company held cash and cash equivalents and marketable securities in the amount of \$238,705 denominated in US dollars.

## 8 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 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.

### 9 Segmented information

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

#### AMORFIX LIFE SCIENCES LTD

3403 American Drive, Mississauga, ON, L4V 1T4 Telephone No.: (416)-847-6898 Fax No.: (416) 847-6899

## MANAGEMENT PROXY CIRCULAR

as at August 6, 2008

This Management Proxy Circular is furnished in connection with the solicitation of proxies by the management of Amorfix Life Sciences Ltd. (the "Corporation") for use at the annual general meeting (the "Meeting") of its shareholders to be held on Wednesday, November 5, 2008 at 3:30 p.m. (Eastern Time) at the Corporation's offices at 3403 American Drive, Mississauga, Ontario and for the purposes set forth in the accompanying notice of the Meeting.

In this Management Proxy Circular, references to "the Corporation", "we" and "our" refer to Amorfix Life Sciences Ltd. "Common Shares" means common shares without par value in the capital of the Corporation. "Beneficial Shareholders" means shareholders who do not hold Common Shares in their own name and "intermediaries" refers to brokers, investment firms, clearing houses and similar entities that own securities on behalf of Beneficial Shareholders.

### GENERAL PROXY INFORMATION

#### Solicitation of Proxies

The solicitation of proxies will be primarily by mail, but proxies may be solicited personally or by telephone by directors, officers and regular employees of the Corporation. The Corporation will bear all costs of this solicitation. We have arranged for intermediaries to forward the meeting materials to beneficial owners of Common Shares held as of record by those intermediaries and we may reimburse the intermediaries for their reasonable fees and disbursements in that regard.

### **Appointment of Proxyholders**

The individuals named in the accompanying form of proxy (the "Proxy") are officers and/or directors of the Corporation. If you are a shareholder entitled to vote at the Meeting, you have the right to appoint a person or company other than either of the persons designated in the Proxy, who need not be a shareholder, to attend and act for you on your behalf at the Meeting. You may do so either by inserting the name of that other person in the blank space provided in the Proxy or by completing and delivering another suitable form of proxy.

The only methods by which you may appoint a person as proxy are submitting a proxy by mail, hand delivery or fax.

#### Voting by Proxyholder

The persons named in the Proxy will vote or withhold from voting the Common Shares represented thereby in accordance with your instructions on any ballot that may be called for. If you specify a choice with respect to any matter to be acted upon, your Common Shares will be voted accordingly. The Proxy confers discretionary authority on persons named therein with respect to:

- (a) each matter or group of matters identified therein for which a choice is not specified, other than the appointment of an auditor and the election of directors,
- (b) any amendment to or variation of any matter identified therein, and
- (c) any other matter that properly comes before the Meeting.

# In respect of a matter for which a choice is not specified in the Proxy, the persons named in the Proxy will vote the Common Shares represented by the Proxy for the approval of such matter.

#### **Registered Shareholders**

If you are a registered shareholder, you may wish to vote by proxy whether or not you attend the Meeting in person. If you submit a Proxy, you must complete, date and sign the Proxy and return it to the Corporation's transfer agent, Olympia Trust, 120 Adelaide Street West, Suite 920, Toronto, Ontario, M5H 1T1 or by fax at (416) 364-1827 no later than 5:00 p.m. (Eastern Time) on Monday, November 3, 2008 or, if the Meeting is adjourned, at least 48 hours (excluding Saturdays and holidays) before any adjourned Meeting is reconvened thereof at which the proxy is to be used.

#### **Beneficial Shareholders**

The following information is of significant importance to many shareholders who do not hold Common Shares in their own name. Beneficial Shareholders should note that the only proxies that can be recognized and acted upon at the Meeting are those deposited by registered shareholders (those whose names appear on the records of the Corporation as the registered holders of Common Shares).

If Common Shares are listed in an account statement provided to a shareholder by a broker, then in almost all cases those Common Shares will not be registered in the shareholder's name on the records of the Corporation. Such Common Shares will more likely be registered under the names of the shareholder's broker or an agent of that broker. In the United States, the vast majority of such Common Shares are registered under the name of Cede & Co. as nominee for The Depository Trust Company (which acts as depositary for many U.S. brokerage firms and custodian banks), and in Canada, under the name of CDS & Co. (the registration name for The Canadian Depository for Securities Limited, which acts as nominee for many Canadian brokerage firms).

Intermediaries are required to seek voting instructions from Beneficial Shareholders in advance of shareholders' meetings. Every intermediary has its own mailing procedures and provides its own return instructions to clients.

#### If you are a Beneficial Shareholder:

You should carefully follow the instructions of your broker or intermediary in order to ensure that your Common Shares are voted at the Meeting.

The form of proxy supplied to you by your broker will be similar to the Proxy provided to registered shareholders by the Corporation. However, its purpose is limited to instructing the intermediaries on how to vote on your behalf. Most brokers now delegate responsibility for obtaining instructions from clients to ADP Investor Communication Services ("ADP") in the United States and in Canada. ADP mails a voting instruction form in lieu of a Proxy provided by the Corporation. The voting instruction form will name the same persons as the Corporation's Proxy to represent you at the Meeting. You have the right to appoint a person (who need not be a Beneficial Shareholder of the Corporation), other than the persons designated in the voting instruction form, to represent you at the Meeting. To exercise this right, you should insert the name of the desired representative in the blank space provided in the voting instruction form. The completed voting instruction form must then be returned to ADP by mail or facsimile or given to ADP by phone or over the internet, in accordance with ADP's instructions. ADP then tabulates the results of all instructions received and provides appropriate instructions respecting the voting of Common Shares to be represented at the Meeting. If you receive a voting instruction form must be completed and returned to ADP, in accordance with its instructions, well in advance of the Meeting in order to have the Common Shares voted.

Although, as a Beneficial Shareholder, you may not be recognized directly at the Meeting for the purposes of voting Common Shares registered in the name of your broker, you, or a person designated by you, may attend at the Meeting as proxyholder for your broker and vote your Common Shares in that capacity. If you wish to attend at the Meeting and indirectly vote your Common Shares as proxyholder for your broker, or have a person designated by you do so, you should enter your own name, or the name of the person you wish to designate, in the blank space on your voting instruction form provided to you and return the same to your broker in accordance with the instructions provided by such broker (or agent), well in advance of the Meeting.

Alternatively, you can request in writing that your broker send you a legal proxy which would enable you, or a person designated by you, to attend at the Meeting and vote your Common Shares.

#### **Revocation of Proxies**

In addition to revocation in any other manner permitted by law, a registered shareholder who has given a proxy may revoke it by:

(a) executing a proxy bearing a later date or by executing a valid notice of revocation, either of the foregoing to be executed by the registered shareholder or the registered shareholder's authorized attorney in writing, or, if the registered shareholder is a corporation, under its corporate seal by an officer or attorney duly authorized, and by delivering the proxy bearing a later date to Olympia Trust or at the address of the registered office of the Corporation at Suite 920, 120 Adelaide Street West, Toronto, Ontario, M5H 1T1at any time up to and including the last business day that precedes the day of the Meeting or, if the Meeting is adjourned, the last business day that precedes any reconvening thereof, or to the chairman of the Meeting on the day of the Meeting or any reconvening thereof, or in any other manner provided by law, or

(b) personally attending the Meeting and voting the registered shareholder's Common Shares.

A revocation of a proxy will not affect a matter on which a vote is taken before the revocation.

### INTEREST OF CERTAIN PERSONS OR COMPANIES IN MATTERS TO BE ACTED UPON

No director or executive officer of the Corporation, nor any person who has held such a position since the beginning of the last completed financial year end of the Corporation, nor any proposed nominee for election as a director of the Corporation, nor any associate or affiliate of the foregoing persons, has any substantial or material interest, direct or indirect, by way of beneficial ownership of securities or otherwise, in any matter to be acted on at the Meeting other than the election of directors and as set out herein.

### **VOTING SECURITIES AND PRINCIPAL HOLDERS OF VOTING SECURITIES**

The Board of Directors of the Corporation has fixed August 3, 2008 as the record date (the "Record Date") for determination of persons entitled to receive notice of the Meeting. Only shareholders of record at the close of business on the Record Date who either attend the Meeting personally or complete, sign and deliver a form of proxy in the manner and subject to the provisions described above will be entitled to vote or to have their Common Shares voted at the Meeting.

As of August 6, 2008, there were 41,678,380 Common Shares issued and outstanding, each carrying the right to one vote. No group of shareholders has the right to elect a specified number of directors, nor are there cumulative or similar voting rights attached to the Common Shares. The Corporation is also authorized to issue an unlimited number of preferred shares. Since inception, no preferred shares have been issued.

To the knowledge of the directors and executive officers of the Corporation, the only persons or corporations that beneficially owned, directly or indirectly, or exercised control or direction over, Common Shares carrying more than 10% of the voting rights attached to all outstanding Common Shares of the Corporation as at August 6, 2008 are:

Shareholder Name	Number of Shares Held	Percentage of Issued Shares
Dr. Neil Cashman	4,410,000	10.58%

The number of Common Shares held by Dr. Cashman was provided by him.

#### FINANCIAL STATEMENTS

The audited financial statements of the Corporation for the year ended March 31, 2008 and the report of the auditor thereof will be placed before the Meeting. The audited financial statements and the report of the auditor, together with related management's discussion and analysis, were mailed to shareholders who requested a copy of this information. Additional copies may be obtained from the Chief Financial Officer of the Corporation upon request and will be available at the Meeting.

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### **VOTES NECESSARY TO PASS RESOLUTIONS**

A simple majority of affirmative votes cast at the Meeting is required to pass the resolutions described herein. If there are more nominees for election as directors or appointment of the Corporation's auditor than there are vacancies to fill, those nominees receiving the greatest number of votes will be elected or appointed, as the case may be, until all such vacancies have been filled. If the number of nominees for election or appointment is equal to the number of vacancies to be filled all such nominees will be declared elected or appointed by acclamation.

#### **ELECTION OF DIRECTORS**

The Articles of the Corporation provide that the number of directors of the Corporation will be a minimum of three and a maximum of ten. The term of office of each of the six current directors will end at the conclusion of the Meeting. Unless the director's office is earlier vacated in accordance with the provisions of the *Canada Business Corporations Act* ("CBCA"), each director elected will hold office until the conclusion of the next annual meeting of the Corporation, or if no director is then elected, until a successor is elected.

The following table sets out the names of management's six nominees for election as directors, all major offices and positions with the Corporation and any of its significant affiliates each now holds, each nominee's principal occupation, business or employment (for the five preceding years for new director nominees), the period of time during which each has been a director of the Corporation and the number of Common Shares of the Corporation beneficially owned by each, directly or indirectly, or over which each exercised control or direction, as at August 6, 2008.

Nominee Position with the Corporation and Province and Country of Residence	Principal Occupation or Employment for Last Five Years <sup>(5)</sup>	Period as a Director of the Corporation	Common Shares Beneficially Owned or Controlled <sup>(5)</sup>
Graham Strachan <sup>(1)(2)(3)(4)</sup> Chairman and Director Ontario, Canada	Principal GLS Business Development Inc.	Since Sept. 21, 2005	29,400
George Adams Director, President & CEO Ontario, Canada	President & CEO Amorfix Life Sciences Ltd. from April 1, 2005	Since Sept. 21, 2005	844,300 <sup>(6)</sup>
	President and Chief Executive Officer, University of Toronto Innovations Foundation from 1999 to October 2004		
	President, Hemo-Stat Ltd. from 1989 to present		
Hans Black <sup>(1)(3)(4)</sup> Director Quebec, Canada	Chairman Interinvest Corporation	Since Nov. 27, 2006	54,000
William Lambert <sup>(1)(3)(4)</sup> Director Ontario, Canada	Special Partner Birch Hill Equity Partners	Since June 9, 2006	645 <b>,</b> 200 <sup>(7)</sup>

Nominee Position with the Corporation and Province and Country of Residence	Principal Occupation or Employment for Last Five Years <sup>(5)</sup>	Period as a Director of the Corporation	Common Shares Beneficially Owned or Controlled <sup>(5)</sup>
Aziz Mekouar <sup>(2)(4)</sup>	Ambassador of Morocco to the United States	Since Jan. 3, 2008	nil
Director	States		
Maryland, USA			
Michael Sonnenreich <sup>(2)(3)(4)</sup> Director District of Columbia, USA	President Kikaku American International	Since Jan. 9, 2007	62,000

#### Notes

- (1) Member of the Audit Committee.
- (2) Member of the Compensation Committee.
- (3) Member of the Corporate Governance and Nominating Committee.
- (4) Independent within the meaning of the Canadian Security Administrators' Multinational Instrument 52-110 Audit Committees (MI 52-110)
- (5) The information as to principal occupation, business or employment and Common Shares beneficially owned, directly or indirectly, or controlled is based on information furnished by the respective nominees and from information available at <u>www.sedi.ca</u>.
- (6) Dr. Adams holds 94,300 Common Shares directly and 750,000 Common Shares indirectly through Hemo-Stat Ltd.
- (7) Mr. Lambert holds 250,000 Common Shares directly and exercises control or direction over 395,200 Common Shares, which are registered in the name of the Lambert Family Trust.

### **APPOINTMENT OF AUDITOR**

PricewaterhouseCoopers, Chartered Accountants, Royal Trust Tower, Suite 3000, Toronto Dominion Centre, Toronto, Ontario, M5K, 1G8 will be nominated at the Meeting for reappointment as auditor of the Corporation at a remuneration to be fixed by the directors. PricewaterhouseCoopers has been the auditor of the Corporation since its amalgamation on September 21, 2005.

## AUDIT COMMITTEE AND RELATIONSHIP WITH AUDITOR

Multilateral Instrument 52-110 Audit Committees ("MI 52-110") requires the Corporation to disclose annually in its annual information form certain information concerning the constitution of its audit committee and its relationship with its independent auditor. The disclosure required on the Audit Committee of the Corporation pursuant to MI 52-110 can be located in the Corporation's Annual Information Form dated June 11, 2008, which is available at <u>www.sedar.com</u>.

#### **CORPORATE GOVERNANCE**

The Canadian Securities Administrators (the "CSA") have adopted National Policy 58-201 *Corporate Governance Guidelines*, which provides non-prescriptive guidelines on corporate governance practices for reporting issuers such as the Corporation. In addition, the CSA have implemented National Instrument 58-101 *Disclosure of Corporate Governance Practices* ("NI 58-101"), which prescribes certain disclosure by the Corporation of its corporate governance practices. The required disclosure under NI 58-101 is attached as Schedule A hereto.

## **COMPENSATION OF EXECUTIVE OFFICERS**

#### **Executive Compensation**

The Corporation has three executive officers. During the Corporation's financial year ended March 31, 2008 the aggregate direct remuneration paid or payable to the Corporation's executive officers by the Corporation was \$540,000.

"Named Executive Officer" means each Chief Executive Officer, each Chief Financial Officer and each of the three most highly compensated executive officers, other than each Chief Executive Officer and Chief Financial Officer, who were serving as executive officers at the end of the most recently completed fiscal year and whose total salary and bonus exceeds \$150,000.

Dr. George Adams, the Corporation's Chief Executive Officer and James Parsons, the Corporation's Chief Financial Officer are the "Named Executive Officers" of the Corporation for the purposes of the following disclosure. The compensation paid to the Named Executive Officers during the Corporation's three most recently completed financial years is as set out below:

		Annu	al Compen	sation	Long Te	erm Compen	sation	
				Awa	ards	Payouts		
NAMED EXECUTIVE				Other Annual	Securities Under	Shares or Units Subject to Resale		All Other
OFFICERS			<b>D</b> (2)	Compen-	Options	Restric-	LTIP	Compen-
Name and		Salary <sup>(1)</sup>	Bonus <sup>(2)</sup>	sation	Granted	tions	Payouts	sation
Principal Position	Year	(\$)	(\$)	(\$)	(#)	(\$)	(\$)	(\$)
Dr. George Adams	2008	277,500	-	-	150,000	86,400 <sup>(3)</sup>	-	-
President and	2007	236,250	-	-	482,000 <sup>(2)</sup>	-	-	-
Chief Executive Officer	2006	150,000	-	-	450,000 <sup>(2)</sup>	-	-	-
James Parsons	2008	184,700	-	-	200,000	48,000 <sup>(3)</sup>	-	-
Chief Financial	2007	175,120	-	-	193,500 <sup>(2)</sup>	-	-	-
Officer	2006	110,548	-	-	81,000 <sup>(2)</sup>	-	-	-

Notes:

- 1. Dr. Adams salary for the calendar year 2008 was \$300,000 and Mr. Parsons salary for the calendar year was \$200,000.
- 2. Dr. Adams and Mr. Parsons elected to receive performance bonuses in the form of stock options in lieu of cash related to the 2006 and 2007 years. In April 2007, as bonus compensation related to the fiscal 2007 year, Dr. Adams received 110,000 stock options and Mr. Parsons received 27,500 stock options; options had an exercise price of \$0.85 and a term of 5 years. In January 2007, bonus compensation was adjusted to a calendar year basis. Based on achievement of corporate objectives, Dr. Adams received 97,000 stock options and Mr. Parsons received 58,000 stock options; options had an exercise price of \$1.43 and a term of 5 years. These bonus options are included in the Securities Under Options Granted in the above table.
- 3. Dr. Adams and Mr. Parsons were awarded performance bonuses based on the achievement of corporate objectives for the 2007 calendar year. The Corporation established a DSU Plan to provide an alternate form of compensation to satisfy bonus compensation for senior officers. The implementation of the DSU Plan is subject to approval of shareholders of the Corporation and acceptance by the TSX. The Board of Directors awarded 92,903 DSUs to Dr. Adams and 51,613 DSUs to Mr. Parsons based on the

above noted bonuses subject to the approval of the Plan by shareholders. See also "Particulars of Matters to be Acted Upon" below.

The share options granted to the Named Executive Officers during the financial year ended March 31, 2008 were as follows:

NAMED EXECUTIVE OFFICERS	Securities Under Options Granted (#)	% of Total Options Granted to Employees in Financial Year	Exercise or Base Price (\$/Security)	Market Value of Securities Underlying Options on the Date of Grant (\$/Security)	Expiration Date
Dr. George Adams	150,000	13%	\$0.93	\$0.93	February 6, 2018
James Parsons	200,000	17%	\$0.93	\$0.93	February 6, 2018

## Option Grants During the Most Recently Completed Financial Year

No share options were exercised by the Named Executive Officers during the financial year ended March 31, 2008.

## Aggregate Option Exercises During the Most Recently Completed Financial Year and Financial Year-End Option Values

NAMED EXECUTIVE OFFICERS Name	Securities Acquired on Exercise (#)	Aggregate Value Realized (\$)	Unexercised Options at FY- End (#) Exercisable/ Unexercisable <sup>(1)</sup>	Value of Unexercised in- the-Money Options at FY- End (\$) Exercisable/ Unexercisable <sup>(1)</sup>
Dr. George Adams	-	-	707,000/375,000	116,250/23,250
James Parsons	-	-	189,000/285,500	20,925/4,185

Notes:

1. Value of options is based on the March 31, 2008 closing price of the Corporation's shares on the Toronto Stock Exchange (the "TSX") of \$0.81. The Corporation's Common Shares began trading solely on the TSX on July 25, 2007.

No share options were re-priced on behalf of the Named Executive Officers during the financial year ended March 31, 2008.

## Termination of Employment, Change in Responsibilities and Employment Contracts

Effective January 1, 2008, the Corporation entered into a one year employment agreement with Dr. Adams which provided for his employment as President and Chief Executive Officer of the Corporation. The agreement provides for compensation with respect to Dr. Adams' annual base salary and participation in the Corporation's bonus plan and stock option plan. Dr. Adams' salary, bonus and options awarded are disclosed in the summary compensation table for Named Executive Officers above. Dr. Adams is entitled to benefits similar to those enjoyed by the Corporation's other senior management pursuant to the Corporation's normal benefit plan, practices and policies. Dr. Adams' agreement provides for severance pay of twelve months remuneration plus immediate vesting of all stock options due to be vested in the twelve months following termination upon four months written notice. Dr. Adams' agreement also provides for severance pay of eighteen months

remuneration plus immediate vesting of all stock options if his employment is terminated within 6 months after a change of control of the Corporation. Dr. Adams is also subject to customary restrictive covenants following the termination of his employment.

Effective January 1, 2008, the Corporation entered into a one year employment agreement with Mr. Parsons which provided for his employment as Chief Financial Officer of the Corporation. The agreement provides for compensation with respect to Mr. Parsons' annual base salary and participation in the Corporation's bonus plan and stock option plan. Mr. Parsons' salary, bonus and options awarded are disclosed in the summary compensation table for Named Executive Officers above. Mr. Parsons is entitled to benefits similar to those enjoyed by the Corporation's other senior management pursuant to the Corporation's normal benefit plan, practices and policies. Mr. Parsons' agreement provides for severance pay of nine months remuneration plus immediate vesting of all stock options due to be vested in the nine months following termination upon four months written notice. Mr. Parsons' is also subject to customary restrictive covenants following the termination of his employment. Prior to 2008, Mr. Parsons provided services as a consultant part-time to the Corporation.

### **Compensation of Directors**

The Corporation compensates its directors through the issuance of stock options. No cash compensation was paid to directors. For the financial year ended March 31, 2008, the directors other than the Named Executive Officer, received the following stock options:

Name of Director	Options Granted	Exercise or Base Price (\$/Security)	Market Value of Securities Underlying Options on the Date of Grant (\$/Security)	Expiration Date
Dr. Black	75,000	\$0.93	\$0.93	February 6, 2018
Mr. Lambert	75,000	\$0.93	\$0.93	February 6, 2018
Mr. Mekouar	75,000	\$0.93	\$0.93	February 6, 2018
Mr. Sonnenreich	75,000	\$0.93	\$0.93	February 6, 2018
Mr. Strachan	75,000	\$0.93	\$0.93	February 6, 2018

None of the above-noted directors exercised any options during the financial year.

## **Report on Executive Compensation**

The Corporation's policy with respect to the compensation of the Chief Executive Officer and the other Named Executive Officers and other officers of the Corporation is based upon the principles that total compensation must: (1) be competitive in order to help attract and retain the talent needed to lead and grow the Corporation's business; (2) provide a strong incentive for executives and key employees to work towards the achievement of the Corporation's goals; and (3) ensure that the interests of management and the Corporation's shareholders are aligned.

When determining the compensation of its executive officers, the Compensation Committee considers: (i) recruiting and retaining executives critical to the success of the Corporation and the enhancement of shareholder value: (ii) providing fair and competitive compensation compared to the remuneration paid by other reporting issuers similarly placed within the same business as the Corporation (iii) balancing the interests of management and the Corporation's shareholders; (iv) rewarding performance, both on an individual basis and with respect to operations in general. In order to achieve these objectives, the compensation paid to the Corporation's executive officers consists of three components: (i) base salary; (ii) annual bonus based on actual performance relative to annual targets; and (iii) long-term incentive in the form of stock options. In making such determination, external sources are consulted when deemed necessary by the Compensation Committee.

The total compensation paid to the Chief Executive Officer and each of the other Named Executive Officers of the Corporation consists primarily of base salary and a bonus based on the executive's overall experience, responsibility and the achievement of corporate and personal objectives determined by the Board of Directors, together with recommendations from the Chief Executive Officer. The Named Executive Officers also receive option grants in accordance with the Corporation's stock option plan upon their appointments and may receive additional option grants from time to time based on the achievement of certain corporate objectives and overall corporate progress. The value of options granted is considered in the determination of total compensation, as is the value of benefits and any other perquisites received by a particular individual. The Corporation does not have a predetermined relative emphasis for each of the various components of compensation.

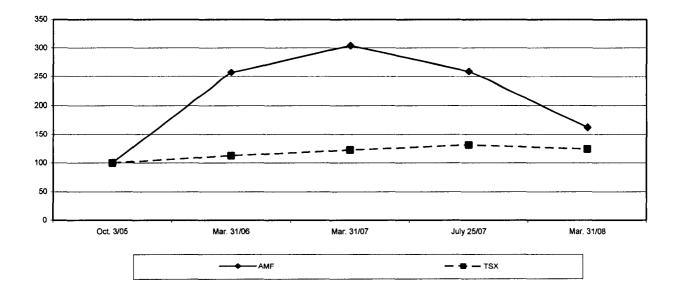
The Chief Executive Officer's base salary has been determined after considering the salary levels of other executives with similar responsibilities and experience. The Chief Executive Officer's base salary was compared to salary levels of comparable executives at a variety of companies, with particular emphasis on biotechnology companies.

Awards of bonuses depend upon whether the Corporation has met objectives established by the Compensation Committee and approved by the Board of Directors for the year. The amount of such bonuses is not subject to any minimum amount.

The members of the Compensation Committee are described under "Corporate Governance".

#### **Performance Graph**

The following graph compares the total cumulative return to a shareholder who invested \$100 in Common Shares of the Corporation on October 3, 2005 (date of listing on the TSX-V) to the year end of March 31, 2008 with the cumulative total return of the S&P/TSX Composite Index ("TSX Index"). The Common Shares began trading on the TSX on July 25, 2007.



#### SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

During the financial year ended March 31, 2008, Common Shares authorized for issuance under equity compensation plans were authorized pursuant to the Corporation's 2005 stock option plan which was amended and replaced on September 20, 2007 (the "2007 Option Plan"). Options granted under the 2007 Option Plan after September 20, 2007 expire on a date not later than ten years after the issuance of such option. Options granted prior to the September 20, 2007 amendment of the stock option plan have an expiry not later than five years after issuance.

	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Plan Category	(a)	(b)	(c)
Equity compensation plans approved by securityholders - the 2007 Option Plan	3,829,500	\$1.03	1,846,500
Equity compensation plans not approved by securityholders		n/a	n/a
Total	3,829,500	\$1.03	1,846,500

## **Equity Compensation Plan Information**

## PARTICULARS OF MATTERS TO BE ACTED UPON

At the Meeting, shareholders will be asked to consider and approve resolutions to ratify the adoption of a Deferred Share Unit plan (the "DSU Plan") and set the maximum number of Common Shares that may be reserved for issuance (the "Authorized DSU Shares") under such DSU Plan at 1,000,000 Common Shares. The text of the resolutions are set out in Exhibit 2 hereto.

The Board of Directors approved the adoption of the DSU Plan effective June 11, 2008 subject to the approval of the shareholders of the Company and acceptance by the TSX. The TSX has conditional accepted the DSU Plan, subject to shareholder approval. A copy of the DSU Plan is available to any shareholder upon request in writing to the Chief Financial Officer of the Corporation. If approved by shareholders, the DSU Plan will be filed on SEDAR subsequent to the Meeting and will be available at www.sedar.com.

The purpose of the DSU Plan is to provide an alternative form of compensation to satisfy annual and special bonuses payable to "Eligible Persons", which is currently defined in the DSU Plan to mean senior officers of the Company and its subsidiaries. The amendment provisions of the DSU Plan (as described below) permit the Board of Directors to, among other things, expand the class of Eligible Persons to include any "Service Provider", being a person who is a bona fide director, officer, employee or consultant of the Company or its affiliates, or a company of which 100% of the share capital is beneficially owned by one or more such persons.

The DSU Plan provides that the Board of Directors may, from time to time, issue deferred share units ("DSUs") to any Eligible Person at the time of declaring or awarding any bonuses. The number of DSUs granted is determined by dividing the applicable bonus amount by the fair market value of the Common Shares as at the last trading day before the award date, where the fair market value is defined as the five-day volume weighted average trading price as calculated in accordance with the policies of the TSX (so long as the Common Shares are listed on the TSX).

Under the terms of the DSU Plan:

• an awardee of DSUs who ceases to be an Eligible Person for any reason other than as a result of death may elect to receive one Common Share for each DSU net of applicable withholding tax on or before December 15 of the first calendar year commencing after the cessation date (and failing such election, will be deemed to have elected to redeem all of his or her DSUs on such deadline);

- in the event of the death, the Corporation will pay cash to or for the benefit of the legal representative of the Eligible Person equal to the fair market value of the Common Shares (on the date of death net of any applicable withholding tax) which would be deliverable in respect of the DSUs if the awardee had ceased to be an Eligible Person other than as a result of death;
- DSUs may not be assigned or transferred except to the legal representative of a deceased Eligible Person in the event of death;
- the maximum number of Common Shares that may be reserved for issuance to any one person pursuant to DSUs and options granted under the 2007 Option Plan may not exceed 5% of the outstanding Common Shares on a non-diluted basis (the "Outstanding Issue") at any time;
- the maximum that may be reserved for issuance to all insiders under all share compensation arrangements, may not exceed 10% of the Outstanding Issue at any time; and
- the maximum that may be issued to all insiders under all share compensation arrangements within a oneyear period, may not exceed 10% of the Outstanding Issue.

The Board of Directors has the right, in its absolute discretion, to amend, modify or terminate the DSU Plan, subject to TSX acceptance and, in certain specified circumstances, shareholder approval. The DSU Plan specifies that shareholder approval must be obtained to make the following amendments:

(i) increase the number of Common Shares reserved for issuance under the DSU Plan;

(ii) permit assignments of DSUs to or exercises thereof by persons other than Eligible Persons or the legal representative of a deceased Eligible Person, except for an amendment that would permit the assignment of a DSU for estate planning or estate settlement purposes; and

(iii) amend the Plan to provide for other types of compensation through equity issuance, unless the change to the Plan or a DSU results from any dividend paid in shares, share subdivision, combination or exchange of shares, merger, consolidation, spin-off or other distribution of Corporation assets to shareholders, or any other change in the capital of the Corporation affecting Common Shares.

Other than the specific circumstances above, the Board of Directors is authorized to make amendments without obtaining shareholder approval, including, without limitation, the following:

(iv) amendments to the terms and conditions of the DSU Plan necessary to ensure that the DSU Plan complies with the applicable regulatory requirements;

(v) making adjustments to outstanding DSUs in the event of certain corporate transactions;

(vi) a change to the termination provisions of a security or the DSU Plan which does not entail an extension beyond the original termination date;

(vii) amendments to the provisions of the DSU Plan respecting administration of the DSU Plan and eligibility for participation under the DSU Plan, including, without limitation, to expand the class of Eligible Persons to include any or all Service Providers; and

(viii) amendments to the DSU Plan that are of a "housekeeping nature".

If the DSU Plan is approved by shareholders, the Corporation will have two security-based compensation arrangements pursuant to which Common Shares may be issued from treasury, as follows:

• the 2007 Option Plan pursuant to which 6,000,000 Common Shares are issuable, representing 14.4% of the issued and outstanding Common Shares of the Corporation as of the date hereof; and

• the DSU Plan pursuant to which 1,000,000 Common Shares are issuable, representing 2.4% of the issued and outstanding Common Shares of the Corporation.

Accordingly, an aggregate of 7,000,000 Common Shares would be issuable under all security-based compensation arrangements of the Corporation, representing 16.8% of the issued and outstanding Common Shares of the Corporation as of the date hereof.

As of the date hereof, a total of 160,000 DSU Units, representing 0.4 % of the total number of issued and outstanding Common Shares, have been awarded to officers of the Corporation (namely, the Chief Executive Officer, Chief Scientific Officer and the Chief Financial Officer) subject to shareholder approval of the DSU Plan. These DSUs cannot be converted until such time that the shareholders of the Corporation have approved and ratified the DSU Plan. In the event that the shareholders fail to approve the DSU Plan, these awards will be cancelled.

After taking into account those DSU Units that have been awarded subject to approval of the DSU Plan, the Corporation will be able to issue up to a further 840,000 Common Shares pursuant to the DSU Plan, representing approximately 2.0% of the total number of issued and outstanding Common Shares as of August 6, 2008.

The Board of Directors recommends that shareholders vote in favour of the ordinary resolutions to approve the DSU Plan and set the Authorized DSU Shares at 1,000,000. In the absence of a contrary instruction, the individuals named in the enclosed Proxy intend to vote in favour of these ordinary resolutions.

### **INDEBTEDNESS OF DIRECTORS AND EXECUTIVE OFFICERS**

No directors, proposed nominees for election as directors, executive officers or their respective associates or affiliates, or other management of the Corporation were indebted to the Corporation as of the end most recently completed financial year or as at the date hereof.

## INTEREST OF INFORMED PERSONS IN MATERIAL TRANSACTIONS

An informed person is one who generally speaking is a director or executive officer or a 10% shareholder of the Corporation. To the knowledge of management of the Corporation, no informed person or nominee for election as a director of the Corporation or any associate or affiliate of any informed person or proposed director had any interest in any transaction which has materially affected or would materially affect the Corporation or any of its subsidiaries during the year ended March 31, 2008, or has any interest in any material transaction in the current year.

### **MANAGEMENT CONTRACTS**

Except as set out herein, there are no management functions of the Corporation which are to any substantial degree performed by a person or company other than the directors or senior officers of the Corporation.

### DIRECTORS' AND OFFICERS' LIABILITY INSURANCE

The Corporation maintains directors' and officers' liability insurance on behalf of its directors and officers to protect them against liability incurred by them in their capacity as directors and officers of the Corporation. The premium paid by the Corporation from the period November 7, 2007 to November 7, 2008 was \$18,252. The aggregate limit of liability under the policy is \$5,000,000 for the policy period, with a corporate deductible of \$25,000 per claim with specific exclusions customary in policies of this nature. There is no deductible payable by directors and officers.

### **ADDITIONAL INFORMATION**

Additional information relating to the Corporation is on <u>www.Sedar.com</u> including the Annual Information Form for the financial year ended March 31, 2008. Financial information is provided in the Corporation's comparative financial statements and management discussion and analysis. The Corporation will provide to any person or company, upon request to the Chief Financial Officer of the Corporation, one copy of the comparative financial statements of the Corporation filed with the applicable securities regulatory authorities for the Corporation's most recently completed financial year in respect to for which such financial statements have been issued, together with the report of the auditor, related management's discussion and analysis and any interim financial statements of the Corporation filed with the applicable securities regulatory authorities subsequent to the filing of the annual financial statements.

#### **OTHER MATTERS**

The Directors are not aware of any other matters which they anticipate will come before the Meeting as of the date of mailing of this Management Proxy Circular.

#### **DIRECTORS' APPROVAL**

The contents of this Management Proxy Circular and its distribution to shareholders have been approved by the Board of Directors of the Corporation.

#### By order of the Board of Directors

Geage Alam

Dr. George Adams President and Chief Executive Officer

DATED at Toronto, Ontario, August 6, 2008.

## SCHEDULE A

### 1. Board of Directors

Directors are considered to be independent if they have no direct or indirect material relationship with the Corporation. A "material relationship" is a relationship which could, in the view of the Corporation's Board of Directors, be reasonably expected to interfere with the exercise of a director's independent judgment.

The board facilitates its independent supervision over management by holding meetings of the Board of Directors and by having a majority of the Board as independent directors.

The independent members of the Board of Directors of the Corporation are Mr. Graham Strachan (Chair), Mr. William Lambert, Dr. Hans Black, Mr. Michael Sonnenreich and Mr. Aziz Mekouar.

Dr. George Adams is a non-independent director and officer of the Corporation.

### **Public Directorships**

Mr. Graham Strachan is also a director of Arius Research Inc., a reporting issuer.

Mr. William Lambert is also a director of Marsulex Inc., a reporting issuer.

Dr. Hans Black is also a director of Abitibi-Consolidated, a reporting issuer.

Dr. George Adams is also a director of Sernova Corporation, a reporting issuer.

The board of directors meets according to an annual agenda and calls additional meetings during the year as the need arises. The frequency and length of meetings and the nature of agenda items depend upon the circumstances. Meetings are conducted in an atmosphere that encourages participation and independence. Other than the various committee meetings, the independent directors have not held regularly scheduled meetings at which non-independent directors and members of management are not in attendance. However, the Board of Directors believes that appropriate structures and procedures are in place to ensure that it can function independently of management and the Board of Directors periodically holds independent sessions at the end of Board meetings. Additionally, the committees of the Board are composed entirely of independent directors and hold meetings at which the independent directors discuss matters they deem relevant to the Corporation. Independent directors are also in frequent informal communication with one another.

## **Attendance of Directors**

A list of the number of Board of Directors and Committee meetings held and attended by directors in fiscal 2008 is set out below, along with the attendance record of each director of the Corporation.

Board of directors	7
Audit committee	5
Compensation committee	5
Governance and Nominating Committee	5

Name of Director	Attendance at Board of Director Meetings	Attendance at Committee Meetings <sup>(3)</sup>
George Adams	8 of 9 <sup>(4)</sup>	
Hans Black	9 of 9	10 of 10
William Lambert	9 of 9	10 of 10
Aziz Mekouar	3 of 3	2 of 2
Michael Sonnenreich	9 of 9	9 of 9
Graham Strachan	9 of 9	14 of 14

### Summary of Attendance of Directors for the Fiscal Year Ended March 31, 2008

Notes:

- 1. Mr. Aziz Mekouar became a director effective January 3, 2008.
- 2. Mr. Donald McCaffrey attended Board of Director and Committee meetings prior to his resignation in September 2007.
- 3. All directors are welcome to attend any committee meetings regardless of membership. Dr. Adams participated in all committee meetings throughout the year.
- 4. One Board of Directors meeting was held solely with the independent directors.

### 2. Board Mandate

The Board Charter is attached hereto as Exhibit 1.

### 3. Position Descriptions

The Board of Directors is guided by charters for the Board of Directors and each Board Committee. The Board and Committee charters set out the roles and responsibilities for the Chair of the Board of Directors and the Chairs of the Board committees. The Chief Executive Officer also has a formal written job position description. The board of directors delegates specific duties and responsibilities to board committees and management and imposes certain limitations as to the authority of the committees and management including for example discretionary spending limits within the annual capital expenditure budget. The Chief Executive Officer, together with senior management, is responsible for ensuring that the corporate objectives, developed annually with the Board of Directors, are met in order to enhance shareholder value.

### 4. Orientation and Continuing Education

When new directors are appointed, they receive orientation, commensurate with their previous experience, on the Corporation's business, strategy, technology and industry and on the responsibilities of directors.

Board meetings may also include presentations by the Corporation's management and employees to give the directors additional insight into the Corporation's business.

During the year, management and the Board periodically hold informal conference calls to provide corporate updates and provide additional information supporting Director education.

### 5. Ethical Business Conduct

The Board of Directors has found that the fiduciary duties placed on individual directors by the Corporation's governing corporate legislation and the common law and the restrictions placed by applicable corporate legislation on an individual directors' participation in decisions of the Board in which the director has an interest have been sufficient to ensure that the Board operates independently of management and in the best interests of the Corporation. The Board of Directors has also adopted a Code of Business Conduct and Ethics ("Code") intended to document the principles of conduct and ethics to be followed by Amorfix's employees, officers and

directors. A copy of the Corporation's Code can be obtained by written request to the Corporation's Chief Financial Officer, at 3403 American Drive, Mississauga, Ontario, L4V 1T4.

#### 6. Nomination of Directors

The Board of Directors has a Corporate Governance and Nomination committee. The committee is responsible for identifying and recommending new candidates, having regard to the appropriate size of the Board of Directors and the necessary competencies and skills of the Board of Directors as a whole and of each director individually. New nominees should have a track record in general business management, special expertise in an area of strategic interest to the Corporation, and the ability to devote the time required.

In addition, the committee shall assist the full Board in fulfilling its responsibilities to assure that the Corporation is governed in a manner consistent with the interests of the shareholders of the Corporation. Without limiting the foregoing, the committee shall advise the Board with respect to Board organization and function; assessing the effectiveness of the Board as a whole as well as discuss the contribution of individual members; orienting new directors; and other matters relating to corporate governance and the rights and interests of the Corporation's shareholders.

The Corporate Governance and Nomination committee is composed of Dr. Hans Black (chair), William Lambert, Graham Strachan and Michael Sonnenreich, all independent directors.

#### 7. Compensation

The Compensation Committee is responsible for determining all forms of compensation to be granted to the Chief Executive Officer of the Corporation and the directors, and for reviewing the Chief Executive Officer's recommendations respecting compensation of the other senior executives of the Corporation, to ensure such arrangements reflect the responsibilities and risks associated with each position. See "Report on Executive Compensation."

The members of the Compensation committee were Don McCaffrey (chair), Graham Strachan and William Lambert. In September, 2007, the Compensation committee was recomposed as Graham Strachan (chair), Michael Sonnenreich and Aziz Mekouar.

#### 8. Other Board Committees

There are no other committees of the Board.

#### 9. Assessments

The Corporate Governance and Nominating Committee is responsible for annually conducting assessments of the effectiveness of the Board, as well as the effectiveness and contribution of each Board committee and each individual director. There is no formal assessment procedure.

## **EXHIBIT 1**

## Charter of the Board of Directors of Amorfix Life Sciences Ltd.

## I. PURPOSE

The Board of Directors of Amorfix Life Sciences Ltd. (the "Company") is responsible for the general supervision of the management of the business. The Board of Directors will discharge its responsibilities directly and through its committees, currently consisting of the Audit Committee, the Compensation Committee and the Corporate Governance and Nominating Committee. The Board of Directors shall meet regularly to review the business operations, corporate governance and financial results of the Company.

## II. COMPOSITION

The Board of Directors shall be constituted at all times of a majority of independent directors in accordance with Multilateral Instrument 58-201. A director is considered to be "independent" if he or she has no direct or indirect material relationship which could in the view of the Board of Directors reasonably interfere with the exercise of a director's independent judgment. Notwithstanding the foregoing, a director shall be considered to have a material relationship with the Company (and therefore shall be considered a "dependent" director) if he or she falls in one of the categories listed in Multilateral Instrument 58-201.

## **III. RESPONSIBILITIES**

The Board of Directors' mandate is the stewardship of the Company and its responsibilities include, without limitation to its general mandate, the following specific responsibilities:

- The assignment to the various committees of directors the general responsibility for developing the Company's approach to: (i) corporate governance and nomination of directors related issues; (ii) financial reporting and internal controls; and (iii) issues relating to compensation of officers and employees.
- With the assistance of the Corporate Governance and Nominating Committee:
  - Reviewing the composition of the Board of Directors and ensuring it respects its independence criteria.
  - The assessment, at least annually, of the effectiveness of the Board of Directors as a whole, the committees of the Board of Directors and the contribution of individual directors, including, consideration of the appropriate size of the Board of Directors.
  - Ensuring that an appropriate review selection process for new nominees to the Board of Directors is in place.
  - Ensuring that an appropriate orientation and education program for new members of the Board of Directors is in place.
  - Approving disclosure and securities compliance policies, including communications policies of the Company.
- With the assistance of the Audit Committee:

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- Reviewing and monitoring the integrity of the Company's internal controls and management information systems.
- Reviewing and monitoring the Company's ethical behaviour and compliance with laws and regulations, audit and accounting principles and the Company's own governing documents.
- Identification of the principal risks of the Company's business and ensuring that appropriate systems are in place to manage these risks.
- Reviewing and approving significant operational and financial matters and the provision of direction to management on these matters.
- With the assistance of the Compensation Committee and the President and Chief Executive Officer, the approval of the compensation of the senior management team.
- With the assistance of the Compensation Committee, the review and approval of corporate objectives and goals applicable to the Company's senior management.
- The selection, appointment, monitoring evaluation and, if necessary, the replacement of the senior management to ensure management succession.
- The adoption of a strategic planning process, approval at least annually of a strategic plan that takes into account business opportunities and business risks identified by the Board and/or the Audit Committee and monitoring performance against such plans.
- Reviewing with senior management major corporate decisions which require Board approval and approving such decisions as they arise. This includes the review and pre-approval of all actions, plans and decisions requiring Board approval as set out in the Company's policies and procedures, including but not limited to business plans, operating budgets and revisions thereto, financings, major purchases and leases of facilities and equipment.
- Performing such other functions as prescribed by law or assigned to the Board of Directors in the Company's corporate documents and by-laws.
- Meetings of the Board of Directors shall also include regular meetings of the independent members of the Board without management being present.
- The Board will communicate its expectations of management through various established practices including but not limited to the review and approval of the Company's annual business plan and operating budget, individual senior management objectives, and corporate policies. The Board further expects that management will comply with all applicable laws and regulations.

## IV. Other

On a yearly basis, the Board will review its Charter and where appropriate will make changes.

## EXHIBIT 2

## Resolutions to Approve DSU Plan of Amorfix Life Sciences Ltd.

"BE IT RESOLVED, that:

1. The DSU Plan of the Corporation as tabled at the meeting, and as substantially described in the Information Circular of the Corporation dated August 6, 2008, is hereby ratified, confirmed and approved;

2. The maximum number of Common Shares that may be reserved for issuance pursuant to the DSU Plan is hereby set at 1,000,000;

3. Anyone director or officer of the Corporation be and is hereby authorized and directed, for and on behalf of the Corporation, to do or to cause to be done all such acts and things as in such person's opinion may be necessary or desirable in order to carry out the intent of the foregoing resolutions, and executing and delivering such other documents as may be necessary or desirable, such determination to be conclusively evidenced by the taking of any such actions by such director or officer; and

4. Notwithstanding that the above resolutions have been duly passed by the shareholders of the Corporation, the Board of Directors, in its discretion, may choose not to implement any or all of such resolutions."

Errata: the record date as noted on page 3 under **VOTING SECURITIES AND PRINCIPAL HOLDERS OF VOTING SECURITIES** of this Management Proxy Circular should read "September 29, 2008" not "August 3, 2008".

## 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, 2009 AND 2008

The following information prepared as of June 10, 2009 should be read in conjunction with Amorfix Life Sciences Ltd.'s (Amorfix or the Company) March 31, 2009 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 10, 2009.

#### **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 timeconsuming 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.

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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<sup>TM</sup> (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 (DSE) on disease-relevant proteins as an innovative approach to treat these currently incurable disorders.

## **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 product is expected to be a blood diagnostic test (EP-vCJD<sup>TM</sup> 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

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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 researchbased 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<sup>TM</sup> 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<sup>TM</sup>) 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<sup>TM</sup> Blood Screening Assay using British blood samples. NIBSC set out three steps: the first will 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<sup>TM</sup> 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. The UK authorities have put forward to the European Community 99.9% specificity as an acceptable performance for a vCJD test on blood donor samples. The Company believes that these first results suggest that it can meet or exceed this requirement.

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<sup>TM</sup> 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 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 is consistent with a recent 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 10,000 blood samples 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 initial markets sought by the Amorfix vCJD technology for diagnostic use are in Europe due to the higher prevalence of BSE positive cattle and the resultant higher prevalence of people who have died from vCJD. A blood screening test for vCJD is currently not regulated, however, a process was established in late 2007 under the direction of the European Commission's IVD Technical Group to establish regulatory guidelines and a Common Technical Specification (CTS) for such tests. Amorfix joined the European Diagnostic Manufacturers Association (EDMA) in order to participate directly in the process for writing regulation for vCJD blood screening assays. A CTS would establish minimum standards for sensitivity and specificity that a vCJD blood screening assay must achieve to receive a CE mark registration. A CE mark registration would allow the product to be marketed and sold in Europe, subject to individual member state regulations.

The Company's vCJD assay development program is currently focused on continuing the France feasibility study and the completion of steps set out by the NIBSC expert committee prior to completing the remaining activities to scale up and commercialize the test. The Company is not in control of the timing of receiving any of the panels or receiving the results thereon from NIBSC, and significant process delays have previously occurred with the UK government agencies. There can be no certainty that Amorfix will be successful at completing the NIBSC process or commercializing its assay on its expected timelines or at all.

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.

Subsequent to year end, 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.

The Company's initial target markets for its EP-vCJD<sup>TM</sup> human blood screening assay are those countries that had the highest incidences of BSE-positive cattle. The blood transfusion market in Europe is estimated to be 20 million donations per year with half of this in the three largest countries of United Kingdom, France and Germany combined. Final commercial product sales and distribution of this assay is expected to require contracts and a regulatory-like approval process with individual country government health agencies.

## **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 has not been able to detect aggregated Abeta in human blood plasma or cerebral spinal fluid samples. The Company has discontinued further research on the human AD blood test at this time.

The Company is assessing other potential commercial applications for this very sensitive aggregated Abeta protein assay and has identified a potential 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  $A^4$  test will accelerate the development and evaluation of new treatments for AD.

Validation results for the  $A^4$  test will be presented at the International Congress on AD in July 2009 and the Company plans to offer the  $A^4$  test as a service to drug discovery companies and academic researchers working to discover new treatments for AD.

#### **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. Subsequent to year end, 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 will develop 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.

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.

## **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<sup>™</sup> 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 now 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 funded approximately half of its \$540,000 cash and in-kind contribution commitment to the program to date and will fund the balance over the next 12 months.

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 is expanding its research program to identifying novel disease-specific epitopes on misfolded proteins. The Company 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 as previously shown. The Company is establishing strategic alliances to expand its capabilities to develop immunotherapeutics to numerous proteins.

## **Results of Operations**

#### **Annual Results of Operations**

#### (Note: reference to a year means the respective fiscal year ended March 31)

Since inception, the Company has incurred losses while advancing the research and development of the EP technology for the detection of AMPs in blood and its therapeutic SOD1 technologies for ALS and other diseases. Net loss for the year ended March31, 2009 was \$5,148,133 compared to a loss of \$7,189,981 for the year ended March 31, 2008. The reduced net loss resulted mainly from deferring commercialization efforts related to the vCJD program until the NIBSC process is complete, and due to reduced operating expenses to conserve cash.

For the year ended March 31, 2009, interest revenue was \$244,499 compared to \$477,615 for the year ended March 31, 2008. The decrease was due to lower investment holdings in the current year.

Research and development expenditures for the year ended March 31, 2009 were \$4,126,945 compared to \$6,240,108 for the year ended March 31, 2008. Salaries and personnel-related expenses decreased by \$610,548 to \$2,711,340 for the year ended March 31, 2009 due mainly to staffing reductions related to the deferral of commercialization work for vCJD until the UK NIBSC process is completed, staffing reductions in the ALS therapeutics program, and other cash conservation initiatives. Research and development program expenses (which includes all direct and indirect research and development costs other than personnel costs) decreased by \$1,474,123 to \$1,824,057 in the year ended March 31, 2009 due mainly to lower vCJD program expenses associated with scale-up and commercialization and lower program expenses for the ALS therapeutic program offset by the initiation of expenditures related to the AD therapeutic program and research costs related to new misfolded protein targets. Salary and program costs were partially offset by investment tax credits and federal grants recorded for the year ended March 31, 2009 of \$408,452 as compared with \$379,960 for the year ended March 31, 2008.

General and administration costs for the year ended March 31, 2009 were \$1,040,468 compared to \$1,259,197 for the year ended March 31, 2008. Lower expenses for the year ended March 31, 2009 resulted mainly from lower exchange filing fees and professional fees than in the comparable period. In July 2007, the Company graduated to the TSX exchange and incurred significant exchange filing fees associated with that transaction.

Amortization expense for the year ended March 31, 2009 was \$225,219 compared to \$168,291 for the year ended March 31, 2008. The increase in amortization expense is

due mainly to purchases of laboratory equipment to support the development of diagnostic assays and amortization of leasehold improvement costs associated with the biological containment facility established in the new premises in Mississauga, Ontario in the fourth quarter of 2008. The increase was partially offset by no amortization of technology rights in the year ended March 31, 2009 as all technology rights were fully amortized as at March 31, 2008.

### Liquidity and Capital Resources

Amorfix is a development stage company as it has not received any 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, agents' compensation warrants and options 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.

The Company has incurred a loss of \$5,148,133 for the year ended March 31, 2009 and has a deficit of \$18,760,886 as at March 31, 2009. 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 \$4,458,065, together with net proceeds of its April 2009 financing is sufficient to fund its operations through to the end of December 2010, 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 totaled \$4,130,597 for the year ended March 31, 2009 as compared with \$5,562,288 for the year ended March 31, 2008. The decreased cash burn in the current fiscal year was due mostly to lower research and development and operating costs, offset by a higher amount of accounts payable that was paid out in the current year.

During the year ended March 31, 2009, the Company purchased \$113,276 of property and equipment compared to \$492,739 in the comparable period last year. Property and equipment which includes leasehold improvements, is purchased principally for research and development purposes. Purchases are lower in fiscal 2009 than in the comparable period as a result of the establishment of a biological containment facility in the premises in Mississauga, Ontario in the fourth quarter of 2008.

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; 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.

## **Results of Operations – Fourth Quarter 2009 and 2008**

Net loss for the quarter ended March 31, 2009 was \$1,376,339 compared to \$1,920,439 for the quarter ended March 31, 2008.

For the quarter ended March 31, 2009, interest revenue was \$55,915 as compared to \$105,873 in the comparable period. Interest revenue was lower in the quarter ended March 31, 2009 due to lower investment holdings in the current period.

For the quarter ended March 31, 2009, research and development expenditures were \$1,064,393 compared to \$1,680,454 for the quarter ended March 31, 2008. Salaries and personnel-related expenses decreased by \$396,419 to \$631,998 due to staff reductions made during the year relating the deferral of the vCJD program commercialization, reductions in the ALS program, and general cost saving measures. Research and development program expenses decreased by \$277,921 to \$482,343 due mainly to lower vCJD and ALS therapeutic program expenses in the fourth quarter of 2009 partially offset by development expenses related to new misfolded protein targets. Investment tax credits and grants were \$49,948 for the quarter ended March 31, 2009 compared to \$108,227 for the quarter ended March 31, 2008.

For the quarter ended March 31, 2009, general and administrative costs were \$323,108, or \$39,673 higher than the quarter ended March 31, 2008. The increase was due mainly to higher stock-based compensation expenses, partially offset by lower salaries expense.

Amortization expense for the quarter ended March 31, 2009 was \$44,753 compared to \$62,423 for the quarter ended March 31, 2008 due mainly to no amortization of technology rights in the current quarter as all technology rights were fully amortized as at March 31, 2008.

## Liquidity and Capital Resources

Cash burn for the quarter ended March 31, 2009 was \$602,521 compared to \$1,327,477 for the quarter ended March 31, 2008. The decreased burn rate was due to lower staffing

and lower research and development program expenditures in the fourth quarter of 2009. Working capital at March 31, 2009 was \$4,458,065 compared to \$8,119,896 at March 31, 2008. Working capital is comprised mainly of cash and cash equivalents and marketable securities and decreased due mainly to research and development expenditures in fiscal 2009.

### **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, 2009 the Company held cash and cash equivalents and marketable securities in the amount of US\$329,223.

The Company earns interest revenue from its cash, cash equivalents and marketable securities. For the year ended March 31, 2009 the Company recorded interest revenue of \$244,499 as compared with \$477,615 earned in the year ended March 31, 2008. The Company considers all cash and cash equivalents as held-for-trading. As at March 31, 2009, 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 year ended March 31, 2009 the Company recorded an unrealized gain on marketable securities of \$16,351 as compared with an unrealized gain of \$52,247 in the comparable period.

## **Critical Accounting Estimates**

## Equity based instruments

The Company used the Black-Scholes option pricing model to value common share purchase warrants and stock options issued by the Company. This pricing model requires 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 Black-Scholes model 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, 2008, Amorfix adopted the following new accounting pronouncements from the CICA Handbook: Section 3862, *Financial Instruments – Disclosures*; Section 3863, *Financial Instruments – Presentation*; Section 1535, *Capital Disclosures*, and changes to Section 1400, *General Standards of Financial Statement Presentation*. These sections relate to disclosure and presentation only and did not have an impact on the Company's financial results.

In November 2007, the CICA issued 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). These standards are effective for the Company beginning on April 1, 2009. The Company is currently assessing the impact that these standards will have on its financial statements.

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 will consider 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 is currently in the process of assessing the differences between its current accounting policies and IFRS and cannot at this time quantify the effect the adoption of the standards will have on its financial statements.

## **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.

Subsequent to year end, 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. 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, following the expiry of the four month hold period, the volume-weighted average price of Amorfix's common shares on the TSX over a period of ten consecutive trading days 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, Amorfix paid \$232,460 cash in finder fees and issued 348,400 finder warrants. 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 number of issued and outstanding common shares of Amorfix as at March 31, 2009 and June 10, 2009 is presented below:

	# Shares
Outstanding April 1, 2008	41,678,380
Issued	862,801
Outstanding March 31, 2009	42,541,181
Issued	5,146,300
Outstanding June 10, 2009	47,687,481

#### Warrants

The following tables reflect the activity of the warrants for the year ended March 31, 2009 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	\$1.0	Warrants \$1.05 September 11, 2008		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, 2008	23,810	25,000	4,462,521	8,701,915	-		•	-	
Issued	-		-	-	-		-	-	
Expired	(23,810)	(25,000)	-	-	-	-	-	-	
Closing balance, March 31, 2009	-	-	4,462,521	8,701,915	-	-	-	-	
Issued	-	-	-	-	2,573,150	2,573,150	348,400	236,912	
Closing balance, June 10, 2009	•		4,462,521	8,701,915	2,573,150	2,573,150	348,400	236,912	

## **Stock Options**

The following table reflects the activity under the Company's stock option plan for the year ended March 31, 2009 and to the date of this Management's Discussion and Analysis:

	# Options	Weighted Average Exercise Price
Outstanding April 1, 2008	3,829,500	\$ 1.03
Granted	799,750	\$ 0.65
Expired	(86,875)	\$ 0.99
Outstanding March 31, 2009	4,542,375	\$ 0.96
Granted	100,000	\$ 0.76
Outstanding, June 10, 2009	4,642,375	\$ 0.96
Exercisable June 10, 2009	3,520,385	\$ 0.98

## **DSU Plan**

On November 5, 2008, the Company's shareholders approved the adoption of a deferred share unit (DSU) plan for senior officers of the Company. Under the DSU plan, rights to the Company's shares (units) may be awarded to senior officers, on a deferred payment basis, to a maximum of 1,000,000 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. The following table reflects the activity under the Company's DSU plan since inception in November 2008 to the date of this Management's Discussion and Analysis.

	#
	Units
Awarded during the year	346,092
Outstanding March 31, 2009 and June 10, 2009	346,092

## **Selected Annual Financial Information**

	Year ended				
Key Financial Indicators	March 31, 2009	March 31, 2008	March 31, 2007	March 31, 2006	March 31, 2005
Revenue - Interest earned	\$244,499	\$477,615	\$253,701	\$36,507	\$0
Expense - Research and development	\$4,126,945	\$6,240,108	\$3,407,098	\$1,100,745	\$67,025
Expense - General and administrative	\$1,040,468	\$1,259,197	\$1,021,478	\$409,917	\$96,706
Net loss	(\$5,148,133)	(\$7,189,981)	(\$4,233,754)	(\$1,967,014)	(\$165,004)
Net loss per common share	(\$0.12)	(\$0.17)	(\$0.13)	(\$0.10)	(\$0.02)
Working capital	\$4,458,065	\$8,119,896	\$13,835,243	\$5,214,438	\$461,389
Cash flow used in Operations	(\$4,130,597)	(\$5,562,288)	(\$3,395,629)	(\$1,543,703)	(\$132,159)
Total assets	\$5,517,184	\$9,990,282	\$14,734,330	\$5,547,405	\$592,384
Net cash proceeds from equity financing	\$272,622	\$160,944	\$9,651,097	\$5,886,152	\$658,005
Weighted average common shares outstanding	41,985,488	41,297,742	31,757,381	19,306,005	10,004,619

## **Quarterly Selected Financial Information**

The following tables sets out selected financial information for the Company for the preceding eight quarters. The quarterly net losses from the first quarter through the fourth quarter of fiscal 2008 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 fiscal 2009 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 that do not affect the timing of key Company milestones.

	2009				2008			
	4th	3rd	2nd	l st	4th	3rd	2nd	l st
	Quarter							
Interest earned	\$ 55,915	\$ 54,206	\$58,525	\$75,853	\$105,873	\$111,820	\$124,805	\$135,117
Net loss	(\$1,376,339)	(\$1,017,663)	(\$1,147,947)	(\$1,606,184)	(\$1,920,439)	(\$1,477,264)	(\$2,007,422)	(\$1,784,856)
Net loss per common share	(\$0.03)	(\$0.02)	(\$0.03)	(\$0.04)	(\$0.05)	(\$0.04)	(\$0.05)	(\$0.04)

The Company's year end is March 31.

## **Contractual Arrangements and Commitments**

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. During 2009, \$142,619 was paid to UBC and, as at March 31, 2009, \$71,000 was included in accounts payable and accrued liabilities.

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 royalty payments to UBC based on revenue earned from the licensed technology. The Company has committed to invest \$500,000 over two years to further the development of the licensed technology, of which \$121,800 has already been incurred as at March 31, 2009.

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.

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

243,200
227,500
229,300
134,500

## **Related Parties**

Certain members of management who are also shareholders were under contract to provide employment services to the Company. During 2009, the Company incurred \$145,541 (2008 - \$328,841) of expenses for two contracts, with \$8,058 (2008 - \$83,672) payable as at March 31, 2009. These transactions occurred in the normal course of operations and were measured at the exchange amount, which is the amount of consideration established and agreed by the related parties.

In February 2007, the Company entered into an agreement with UBC and Vancouver Coastal Health Authority, with Dr. Neil Cashman who is an officer and shareholder of the Company, as principal investigator, to fund research related to the Amorfix ALS therapeutic program in the amount of \$300,000. During 2009, \$45,000 (2008 - \$135,000) was paid to UBC and, as at March 31, 2009, \$nil (2008 - \$45,000) was included in accounts payable and accrued liabilities.

The Company has acquired licenses and technologies from Dr. Cashman, an officer and shareholder of the Company. Please see Contractual Agreements and Commitments.

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 scaleup, 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, 2009, Amorfix has a deficit of \$18,760,886. 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 partnership 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, 2009. 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, 2009 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, 2009, 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, 2009 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 <u>www.sedar.com</u>.

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

## FOR THE THREE AND NINE MONTHS ENDED DECEMBER 31, 2008 AND 2007

The following information for Amorfix Life Sciences Ltd. (the "Company" or "Amorfix") prepared as of February 10, 2009 should be read in conjunction with the Company's March 31, 2008 annual audited financial statements and related notes and Management's Discussion and Analysis of Operating Results and Financial Condition which are prepared in accordance with Canadian generally accepted accounting principles (GAAP) and the Annual Information Form dated June 11, 2008. Amounts are in Canadian dollars unless otherwise.

#### **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.

#### **Risks and Uncertainties**

We operate in a highly competitive environment that involves significant risks and uncertainties, some of which are outside our control. We are subject to risks associated with the biotechnology industry, including risks inherent in research and development, commencement, completion and results of preclinical and clinical studies, the controlled use of hazardous materials, uncertainties related to product approval and decisions of regulatory agencies with respect to our diagnostic and therapeutic product candidates, the lack of product revenue and our history of losses in the development stage, enforcement and protection of our intellectual property, the requirement and the ability to raise additional capital, potential competitors, the ability to attract and maintain relationships with collaborative partners, dependence on key personnel, government regulations, and the ability to successfully market our diagnostic and therapeutic candidates. Readers should review the more detailed discussion of such risk and uncertainties set out in "Risk Factors" in the Corporation's Annual Information Form for the financial year ended March 31, 2008 and "Risks and Uncertainties" in the Management's Discussion and Analysis of Operating Results and Financial Condition accompanying the March 31, 2008 annual audited financial statements.

## **The Company**

Amorfix is an emerging theranostics company focused on the diagnosis and treatment of neurodegenerative 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 degenerative diseases such as Alzheimer's Disease (AD) and Amyotrophic Lateral Sclerosis (ALS).

Amorfix believes that through various applications of its technology, it may be successful in developing products which can detect the presence of AMPs in 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 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 is also developing innovative therapies for some of these currently incurable disorders and plans to develop prophylactics such as vaccines for both the agricultural and human marketplaces.

## **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. Recently, 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 its Epitope Protection (EP) platform technology will allow it to develop 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 product is expected to be a blood diagnostic test (EP-vCJD<sup>TM</sup> 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 Controls (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. 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 support 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 researchbased 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<sup>TM</sup> Blood Screening Assay. During this period, the Company applied to access human vCJD blood samples as part of the process that had been established by NIBSC. 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. The UK HPA subsequently slowed down the tender process.

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 2007 blinded panel compared to its research grade assay blinded panel results from a year earlier.

From July 2007 to present, the Company focused on 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<sup>TM</sup>) 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<sup>TM</sup> Blood Screening Assay using British blood samples. The Company believes this process will have three steps: the first will 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<sup>™</sup> 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 the British National Institute for Biological Standards and Controls (NIBSC) outside London, England. 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. The UK authorities have put forward to the European Community 99.9% specificity as an acceptable performance for a vCJD test on blood donor samples. The Company believes that these first results suggest that it can meet or exceed this requirement.

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<sup>TM</sup> 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). As the HPA has not yet awarded the tender contract to supply blood screening tests for a prevalence study of vCJD, the Company believes that the tender may not be awarded until the Company and any potential competitors complete the NIBSC process.

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 is consistent with a recent 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.

Subsequent to the end of the third guarter, 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 10,000 blood samples 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. A blood screening test for vCJD is currently not regulated, however, the process to determine if and how a test should be regulated in Europe has been initiated at the request of the UK. On October 26, 2007 Amorfix attended the workshop for vCJD diagnostic assays sponsored by the Medical Device branch of the Enterprise and Industry Directorate-General of the European Commission. The Company was the only attendee to present a blood diagnostic test for vCJD that was in the process of being commercialized. Amorfix joined the European Diagnostic Manufacturers Association (EDMA) in order to participate directly in the regulatory process for establishing an in vitro diagnostic (IVD) test for vCJD. Amorfix has attended the European Commission's IVD Technical Group meeting as a representative of EDMA and continues to participate to assist in the establishment of a regulatory framework or Common Technical Specification (CTS) for an in vitro diagnostic test for vCJD. A CTS would establish standards of measurement that a vCJD blood screening assay must achieve to receive a CE mark registration. A CE mark registration would allow the product to be marketed and sold in Europe, subject to individual EU country regulations.

The Company's vCJD assay development is currently focused on continuing the France feasibility study and the completion of the steps set out by the NIBSC expert committee prior to completing the remaining activities to scale up and commercialize the test. The Company is not in control of the timing of receiving any of the panels or receiving the results thereon from NIBSC, and significant process delays have previously occurred with the UK government agencies. There can be no certainty that Amorfix will be successful at completing the NIBSC process or commercializing its assay on its expected timelines or at all.

The Company's initial target markets for its EP-vCJD<sup>TM</sup> human blood screening assay are those countries that had the highest incidences of BSE-positive cattle. The blood transfusion market in Europe is estimated to be 20 million donations per year with half of this in the three largest countries of United Kingdom, France and Germany combined. Final commercial product sales and distribution of this assay is expected to require contracts and a regulatory-like approval process with individual country government health agencies.

## **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 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, in the amount of \$322,000 that supports a portion of the salaries of the research staff for this project. To date, Amorfix has received \$255,906 of grant support under the IRAP program.

From December 2006 to March 2008, the Company initiated and progressed its AD diagnostic assay development by screening and selecting monoclonal antibodies, established a sample preparation protocol to enrich for the Abeta proteins, assessed several different assay formats and began to optimize 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 has not been able to detect aggregated Abeta in human blood plasma or cerebral spinal fluid samples. The Company has discontinued further research on the human AD blood test at this time. As the Company has developed the most sensitive test in the world for detecting aggregated Abeta protein, it is assessing other potential commercial applications for this test.

#### **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. Amorfix scientists are continuing to refine the assay to improve its sensitivity, specificity and reproducibility of the test. 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<sup>™</sup> 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 is seeking partners to support further development and commercialization of the sheep scrapie test.

#### **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).

### **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. Biogen subscribed for 289,187 common shares of the Company at \$1.46 per share for gross proceeds to Amorfix of \$422,213 (US\$375,000).

The research and investment agreement with Biogen included three research milestones, which if achieved by the Company, required Biogen to make further investment in Amorfix to retain their option to license Amorfix's technology.

In July 2007, the Company announced the achievement of the first research milestone, the development of disease-specific antibodies to misfolded SOD1, and an additional Biogen investment of US\$150,000 in Amorfix. Consequently, Biogen subscribed for 91,445 common shares of Amorfix at a price of \$1.76 per share for gross proceeds of \$160,944 (US\$150,000).

On October 20, 2008, the Company announced the achievement of the second research milestone under the Biogen agreement. The DSE monoclonal antibody treatments demonstrated statistically significant improvement in survival over controls in a mouse model of ALS. In November, 2008, Biogen subscribed for 608,250 common shares of Amorfix at a price of \$0.31 per share for gross proceeds of \$187,485 (US\$150,000).

In December, 2008 the Company announced the achievement of the third research milestone and an additional Biogen investment of 254,551 common shares of Amorfix at a price of \$0.35 per share for gross proceeds of \$89,565 (US\$75,000).

On February 10, 2009, Biogen allowed its option to license Amorfix SOD1 technologies for use in the treatment of ALS to lapse. Amorfix will continue to develop vaccines and antibodies for ALS and is now free to fully engage other companies that have expressed interest in partnering this technology.

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.

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, also known as Lou Gehrig's Disease. 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. Amorfix is currently assessing potential mouse models of AD that could be used to test candidate antibodies and vaccines that target misfolded SOD1.

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 will fund approximately \$540,000 in cash and in-kind contributions to the program over 12 months.

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 application relates 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 (DSE) 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.

## **Results of Operations**

Since inception, the Company has incurred losses while advancing the research and development of the EP technology for the detection of AMPs in blood and its therapeutic SOD1 technologies for ALS and other diseases. Net loss for the three months ended December 31, 2008 was \$1,017,663 compared to a loss of \$1,477,264 in the comparable period last year. For the nine months ended December 31, 2008, the net loss was \$3,771,794 compared to \$5,269,542 in the comparable period last year. The reduced net loss in the three and nine months ended December 31, 2008 resulted mainly from deferring commercialization efforts related to the vCJD program until the NIBSC process is complete, and due to reduced operating expenses to conserve cash.

For the three and nine months ended December 31, 2008, investment income was significantly lower than the comparable periods due to smaller investment holdings in the current periods.

Research and development expenditures for the three months ended December 31, 2008 were \$804,871 compared to \$1,358,132 for the three months ended December 31, 2007 and for the nine months ended December 31, 2008 were \$3,062,552 compared to \$4,559,654 for the comparable period last year. Salaries and personnel-related expenses decreased by \$213,377 to \$522,230 for the three months ended December 31, 2008 and by \$214,129 to \$2,079,342 for the nine months ended December 31, 2008 due mainly to staffing reductions made at the end of June 2008 related to the deferral of commercialization work for vCJD until the UK NIBSC process is completed, and other cash conservation initiatives. Research and development program expenses (which includes all direct and indirect research and development costs other than personnel costs) decreased by \$329.517 to \$388.868 in the three months ended December 31, 2008 and by \$1,196,202 to \$1,341,714 in the nine months ended December 31, 2008 due mainly to lower vCJD program expenses associated with scale up and commercialization and lower program expenses for the ALS therapeutic program offset by the initiation of expenses related to the AD therapeutic program. Salary and program costs were partially offset by investment tax credits and federal grants recorded in the three months and nine months ended December 31, 2008 of \$106,227 and \$358,504 respectively, as compared with \$95,860 and \$271,733 in the comparable periods last year.

General and administration costs for the three months ended December 31, 2008 were \$199,922 compared to \$190,064 for the three months ended December 31, 2007, and for the nine months ended December 31, 2008 were \$717,360 compared to \$975,762 for the comparable period last year. Slightly higher expenses for the three months ended December 31, 2008 resulted from lower salaries expense and consultant fees related to cost saving initiatives offset by higher stock-based compensation expense. Lower expenses for the nine months ended December 31, 2008 resulted mainly from lower stock-based compensation expense and lower exchange filing fees than in the comparable period. In July 2007, the company graduated to the TSX exchange and incurred significant exchange filing fees associated with that transaction.

Amortization expense for the three and nine months ended December 31, 2008 was higher than the comparable periods last year due mainly to purchases of laboratory equipment to support the development of diagnostic assays and amortization of leasehold improvement costs associated with the biological containment facility established in the new premises in Mississauga, Ontario in the fourth quarter of 2008. The increase was partially offset by no amortization of technology rights in the three and nine months ended December 31, 2008 as all technology rights were fully amortized as at March 31, 2008.

## Liquidity and Capital Resources

Amorfix is a development stage company as it has not received any 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, agents' compensation warrants and options 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.

The Company has incurred a loss of \$3,771,794 for the nine months ended December 31, 2008 and has a deficit of \$17,277,547 as at December 31, 2008. 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 \$5,353,091 is sufficient to fund its operations through to the end of December 2009, 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 outlicensing, 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 totaled \$809,588 for the three months ended December 31, 2008 compared to \$1,258,030 for the three months ended December 31, 2007. For the nine months ended December 31, 2008, the company's cash burn was \$3,528,076 as compared with \$4,234,811 in the comparable period last year. The decreased cash burn for the three and nine months ended December 31, 2008 from the comparable periods in 2007 was due mostly to lower development and operating costs, offset by a higher amount of accounts payable that was paid out in the nine months ended December 31, 2008.

During the three months ended December 31, 2008, the Company purchased \$nil of property and equipment compared to \$64,478 in the comparable period last year. During the nine months ended December 31, 2008 the Company purchased \$110,939 of property and equipment as compared with \$209,633 in the comparable period last year. Property and equipment which includes leasehold improvements, is purchased principally 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; 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. As at December 31, 2008 the company held cash and cash equivalents and marketable securities in the amount of \$458,317 denominated in US dollars.

The Company earns interest income from its cash, cash equivalents and marketable securities. For the three and nine months ended December 31, 2008 the company recorded interest income of \$54,206 and \$188,584 respectively as compared with \$111,820 and \$371,742 earned in the three and nine months ended December 31, 2007. The Company considers all cash and cash equivalents as held for trading. As at December 31, 2008, 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'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 three and nine months ended December 31, 2008 the company

recorded an unrealized loss on marketable securities of \$2,986 and \$2,903 respectively as compared with an unrealized gain of \$26,470 and \$16,391 respectively in the comparable periods.

## **Critical Accounting Estimates**

## Equity based instruments

The Company used the Black-Scholes option pricing model to value common share purchase warrants and options and employee stock options issued by the Company. This pricing model requires 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. Management has selected these variables and applied the Black-Scholes model 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, 2008, Amorfix adopted the following new accounting pronouncements from the CICA Handbook: Section 3862, *Financial Instruments – Disclosures*; Section 3863, *Financial Instruments – Presentation*; Section 1535, *Capital Disclosures*, and changes to Section 1400, *General Standards of Financial Statement Presentation*. These sections relate to disclosure and presentation only and did not have an impact on the Company's financial results.

In November 2007, the CICA issued 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. These standards are effective for the Company beginning on April 1, 2009. The company is currently assessing the impact that these standards will have on its financial statements.

The Accounting Standards Board of Canada has announced that public companies in Canada are to adopt International Financial Reporting Standards (IFRS) for fiscal years beginning on or after January 1, 2011. The company is in the process of analyzing the effects of the standards on its financial statements.

Additional information on these accounting changes and new pronouncements can be found in the notes to the interim financial statements for the three and nine months ended December 31, 2008.

## **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 December 31, 2008 and February 10, 2009 was 42,541,181. From January 1, 2009 to February 10, 2009, no additional warrants or options were exercised.

On September 30, 2008, the remaining common shares held by the founding shareholders and management were released from escrow.

## Warrants and Options

The following tables reflect the activity of the warrants and options (other than stock options) for the nine months ended December 31, 2008 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	Warn \$1.0 September	5	Common share Purchase Warrants \$1.95 March 8, 2009		
	#	\$	#	\$	
Opening balance, April 1, 2008	23,810	25,000	4,462,521	8,701,915	
Issued	-	-	-	-	
Expired	(23,810)	(25,000)	-	-	
Closing balance, December 31, 2008 and February 10, 2009	-	-	4,462,521	8,701,915	

## **Stock Options**

The following table reflects the activity under the Company's stock option plan for the three and nine months ended December 31, 2008 and to the date of this Management's Discussion and Analysis:

	# Options	Weighted Average Exercise Price
Outstanding April 1, 2008	3,829,500	\$ 1.03
Granted	-	-
Expired	(30,750)	\$ 1.11
Outstanding June 30, 2008	3,798,750	\$ 1.03
Granted	-	-
Expired	(44,938)	\$ 0.93
Outstanding September 30, 2008	3,753,812	\$ 1.03
Granted	-	-
Expired	(8,281)	\$ 0.93
Outstanding December 31, 2008	3,745,531	\$ 1.03
Granted	799,750	\$ 0.65

Outstanding, February 10, 2009	4,545,281	\$ 0.97
Exercisable February 10, 2009	3,265,241	\$ 0.98

On November 5, 2008, the Company's shareholders approved the adoption of a deferred share unit (DSU) plan for senior officers of the company. Under the DSU plan, rights to the company's shares (units) may be awarded to senior officers, on a deferred payment basis, to a maximum of 1,000,000 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. The following table reflects the activity under the Company's DSU plan since inception in November 2008 to the date of this Management's Discussion and Analysis.

	#
	Units
Outstanding April 1, 2008 and September 30, 2008	-
Awarded	160,000
Outstanding December 31, 2008	160,000
Awarded	186,092
Outstanding, February 10, 2009	346,092

## **Quarterly Selected Financial Information**

The following tables sets out selected financial information for the Company for the preceding eight quarters. The quarterly net losses from the fourth quarter of fiscal 2007 through the fourth quarter of fiscal 2008 reflected higher costs from development of a commercial-grade vCJD assay with associated scale-up and quality system costs, as well as the initiation of new development programs for the Alzheimer's disease ante-mortem blood diagnostic test and the ALS therapeutic program in 2007. The decreased net loss in fiscal 2009 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 that do not affect the timing of key Company milestones.

	2009			2008				2007
	3rd	2nd	l st	4th	3rd	2nd	lst	4th
	Quarter	Quarter	Quarter	Quarter	Quarter	Quarter	Quarter	Quarter
Revenue	54,206	\$58,525	\$75,853	\$105,873	\$111,820	\$124,805	\$135,117	\$82,702
Net loss	(1,017,663)	(\$1,147,947)	(\$1,606,184)	(\$1,920,439)	(\$1,477,264)	(\$2,007,422)	(\$1,784,856)	(\$1,829,533)
Net loss per common share	(\$0.02)	(\$0.03)	(\$0.04)	(\$0.05)	(\$0.04)	(\$0,05)	(\$0.04)	(\$0.05)

The Company's year end is March 31.

## **Contractual Arrangements and Commitments**

In December 2008, the Company entered into an agreement with the University of British Columbia (UBC), with Dr. Neil Cashman, an officer and shareholder of the company, as principal investigator, to fund research in Dr. Cashman's laboratory related to the Amorfix AD therapeutic program in the amount of \$426,619. During the three and nine months ended December 31 2008, \$71,619 (2007 - \$nil) was paid to UBC and as at

December 31, 2008, \$71,000 (2007- nil) was included in accounts payable and accrued liabilities relating to this agreement. The balance of the commitment will be funded over the next twelve months.

## **Internal Control over Financial Reporting**

No change in the Company's internal control over financial reporting occurred during the three month period ended December 31, 2008 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 can also be found on SEDAR at <u>www.sedar.com</u>.

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

## FOR THE THREE AND SIX MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

The following information for Amorfix Life Sciences Ltd. (the "Company" or "Amorfix") prepared as of November 5, 2008 should be read in conjunction with the Company's March 31, 2008 annual audited financial statements and related notes and Management's Discussion and Analysis of Operating Results and Financial Condition which are prepared in accordance with Canadian generally accepted accounting principles (GAAP) and the Annual Information Form dated June 11, 2008. Amounts are in Canadian dollars unless otherwise.

## **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.

#### **Risks and Uncertainties**

We operate in a highly competitive environment that involves significant risks and uncertainties, some of which are outside our control. We are subject to risks associated with the biotechnology industry, including risks inherent in research and development, commencement, completion and results of preclinical and clinical studies, the controlled use of hazardous materials, uncertainties related to product approval and decisions of regulatory agencies with respect to our diagnostic and therapeutic product candidates, the lack of product revenue and our history of losses in the development stage, enforcement and protection of our intellectual property, the requirement and the ability to raise additional capital, potential competitors, the ability to attract and maintain relationships with collaborative partners, dependence on key personnel, government regulations, and the ability to successfully market our diagnostic and therapeutic candidates. Readers should review the more detailed discussion of such risk and uncertainties set out in "Risk Factors" in the Corporation's Annual Information Form for the financial year ended March 31, 2008 and "Risks and Uncertainties" in the Management's Discussion and Analysis of Operating Results and Financial Condition accompanying the March 31, 2008 annual audited financial statements.

## The Company

Amorfix is an emerging theranostics company focused on the diagnosis and treatment of neurodegenerative 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 degenerative diseases such as Alzheimer's Disease (AD) and Amyotrophic Lateral Sclerosis (ALS)

Amorfix believes that through various applications of its technology, it may be successful in developing products which can detect the presence of AMPs in 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 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 is also developing innovative therapies for some of these currently incurable disorders and plans to develop prophylactics such as vaccines for both the agricultural and human marketplaces.

## **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. Recently, 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 its Epitope Protection (EP) platform technology will allow it to develop 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 product is expected to be a blood diagnostic test (EP-vCJD<sup>TM</sup> 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 Controls (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. 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 support 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 researchbased 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<sup>TM</sup> Blood Screening Assay. During this period, the Company applied to access human vCJD blood samples as part of the process that had been established by NIBSC. 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. The UK HPA subsequently slowed down the tender process.

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 2007 blinded panel compared to its research grade assay blinded panel results from a year earlier.

From July 2007 to present, the Company focused on 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<sup>TM</sup>) was able to detect prion disease in symptomatic sheep. Subsequent to year end, in April 2008, the sheep scrapie blood screening assay was successful at detecting prion disease in presymptomatic scrapie sheep. Amorfix continues to develop the EP-TSE<sup>TM</sup> assay to improve the robustness and sensitivity of the assay and is assessing the potential market opportunity for the development of a commercial version of the test for the veterinary market.

In February 2008, the Expert Advisory Group 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<sup>TM</sup> Blood Screening Assay using British blood samples. The Company believes this process will have three steps: the first will 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<sup>™</sup> 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 the British National Institute for Biological Standards and Controls (NIBSC) outside London, England. 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. The UK authorities have put forward to the European Community 99.9% specificity as an acceptable performance for a vCJD test on blood donor samples. The Company believes that these first results suggest that it can meet or exceed this requirement. NIBSC has 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.

As the HPA has not yet awarded the tender contract to supply blood screening tests for a prevalence study of vCJD using 60,000 British blood samples, the Company believes that the tender may not be awarded until the Company and any potential competitors complete the NIBSC process.

A blood screening test for vCJD is currently not regulated, however, the process to determine if and how a test should be regulated in Europe has been initiated at the request of the UK. On October 26, 2007 Amorfix attended the workshop for vCJD diagnostic assays sponsored by the Medical Device branch of the Enterprise and Industry

Directorate-General of the European Commission. The Company was the only attendee to present a blood diagnostic test for vCJD that was in the process of being commercialized. Amorfix subsequently joined the European Diagnostic Manufacturers Association (EDMA) in order to participate directly in the regulatory process for establishing an in vitro diagnostic (IVD) test for vCJD. Amorfix attended the European Commission's IVD Technical Group meeting as a representative of EDMA in June 2008. The meeting was attended by representatives of many of the EU member country Competent Authorities to address regulatory issues including establishing a regulatory framework or Common Technical Specification (CTS) for an in vitro diagnostic test for vCJD. A CTS would establish standards of measurement that a vCJD blood screening assay must achieve to receive a CE mark registration. A CE mark registration would allow the product to be marketed and sold in Europe, subject to individual EU country regulations.

On October 7, 2008, Amorfix attended the EU Commission's vCJD Expert's Group Meeting in Brussels, Belgium held to discuss comments received on the European Diagnostic Manufacturers' Association's June 2008 proposal on standards for vCJD Blood Screening Devices. Reviewer comments will be summarized in a guidance document that will be considered in November 2008 at the next EU In Vitro Diagnostic Technical Group meeting for the drafting of a Common Technical Specification for vCJD tests.

The Company's vCJD assay development is currently focused on completion of the steps set out by the NIBSC expert committee prior to completing the remaining activities to scale up and commercialize the test. The Company is not in control of the timing of receiving any of the panels or receiving the results thereon from NIBSC, and significant process delays have previously occurred with the UK government agencies. There can be no certainty that Amorfix will be successful at completing the NIBSC process or commercializing its assay on its expected timelines or at all.

The Company's initial target markets for its  $EP-vCJD^{TM}$  human blood screening assay are those countries that had the highest incidences of BSE-positive cattle. The blood transfusion market in Europe is estimated to be 20 million donations per year with half of this in the three largest countries of United Kingdom, France and Germany combined. Final commercial product sales and distribution of this assay is expected to require contracts and a regulatory-like approval process with individual country government health agencies.

#### **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 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, in the amount of \$322,000 that supports a portion of the salaries of the research staff for this project. To date, Amorfix has received \$230,848 of grant support under the IRAP program.

From December 2006 to March 2008, the Company initiated and progressed its AD diagnostic assay development by screening and selecting monoclonal antibodies, established a sample preparation protocol to enrich for the Abeta proteins, assessed several different assay formats and began to optimize 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 Company achieved its target sensitivity for the AD test and is now testing patient samples of blood plasma and cerebral spinal fluid. If unsuccessful at detecting aggregated Abeta in AD patient samples, the Company will make a decision to continue to improve the assay and repeat human AD patient sample testing or abandon the project.

#### **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. Amorfix scientists are continuing to refine the assay to improve its sensitivity, specificity and reproducibility of the test. 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<sup>™</sup> 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 is seeking partners to support further development and commercialization of the sheep scrapie test.

#### **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).

#### **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. Biogen subscribed for 289,187 common

shares of the Company at \$1.46 per share for gross proceeds to Amorfix of \$422,213 (US\$375,000).

In July 2007, the Company announced the achievement of the first research milestone, the development of disease-specific antibodies to misfolded SOD1, and an additional Biogen investment of US\$150,000 in Amorfix to retain their option to license Amorfix's technology. Consequently, Biogen subscribed for 91,445 common shares of Amorfix at a price of \$1.76 per share for gross proceeds to Amorfix of \$160,944 (US\$150,000).

On October 20, 2008, the Company announced the achievement of the second research milestone under the Biogen agreement. The DSE monoclonal antibody treatments demonstrated statistically significant improvement in survival over controls in a mouse model of ALS. With the achievement of this second milestone, Biogen Idec must invest a further US\$150,000 in Amorfix to maintain its rights to license the antibodies for use in ALS. If Biogen exercises its option, over the term of the agreement Amorfix will be eligible to receive milestone payments in excess of US\$25 million plus royalties on sales. Biogen will be responsible for all development and commercialization costs.

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.

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, also known as Lou Gehrig's Disease. 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. Amorfix is currently assessing potential mouse models of AD that could be used to test candidate antibodies and vaccines that target misfolded SOD1.

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 will include preclinical efficacy studies for both antibody treatments and vaccines and will be conducted in Dr. Cashman's laboratory at the Brain Research Center at the University of British Columbia in collaboration with Amorfix scientists, and will be supported by a \$227,500 grant from the Canadian Institutes for Health Research (CIHR). Amorfix will contribute approximately \$650,000 to the program over 12 months.

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

application relates to the methods and two compositions for treating and detecting conditions, disease and disorders mediated by non-native SOD1.

#### **Results of Operations**

Since inception, the Company has incurred losses while advancing the research and development of the EP technology for the detection of AMPs in blood and its therapeutic SOD1 technologies for ALS and other diseases. Net loss for the three months ended September 30, 2008 was \$1,147,947 compared to a loss of \$2,007,422 in the comparable period last year. For the six months ended September 30, 2008, the net loss was \$2,754,131 compared to \$3,792,278 in the comparable period. The reduced net loss in the three and six months ended September 30, 2008 resulted mostly from deferring commercialization efforts related to the vCJD program until the NIBSC process is complete, and to reduced operating expenses to conserve cash.

For the three and six months ended September 30, 2008, investment income was significantly lower than the comparable periods due to smaller investment holdings in the current periods.

Research and development expenditures for the three months ended September 30, 2008 were \$890,514 compared to \$1,669,098 for the three months ended September 30, 2007 and for the six months ended September 30, 2008 were \$2,257,681 compared to \$3,201,522 for the comparable period last year. Salaries and personnel-related expenses decreased by \$135,178 to \$652,922 for the three months ended September 30, 2008 and by \$752 to \$1,557,112 for the six months ended September 30, 2008 due mainly to staffing reductions made at the end of June 2008 related to the deferral of commercialization work for vCJD until the UK NIBSC process is complete, and other cash conservation initiatives. Research and development program expenses (which includes all direct and indirect research and development costs other than personnel costs) decreased by \$610,383 to \$361,945 in the three months ended September 30, 2008 and by \$866,685 to \$952,846 in the six months ended September 30, 2008 due mainly to lower vCJD program expenses associated with scale up and commercialization and lower program expenses for the ALS therapeutic program. Salary and program costs were partially offset by investment tax credits and federal grants recorded in the three months and six months ended September 30, 2008 of \$124,353 and \$252,277 respectively, as compared with \$91,330 and \$175,873 in the comparable periods last year.

General and administration costs for the three months ended September 30, 2008 were \$253,814 compared to \$423,947 for the three months ended September 30, 2007, and for the six months ended September 30, 2008 were \$517,438 compared to \$785,698 for the comparable period last year. Lower expenses for the three and six months ended September 30, 2008 resulted mainly from lower stock-based compensation expense and lower exchange filing fees. In July 2007, the company graduated to the TSX exchange and incurred significant exchange filing fees associated with that transaction.

Amortization expense for the three and six months ended September 30, 2008 was higher than the comparable periods last year due mainly to purchases of laboratory equipment to support the development of diagnostic assays and amortization of leasehold improvement costs associated with the biological containment facility established in the new premises in Mississauga, Ontario in the fourth quarter of 2008. The increase was partially offset by no amortization of technology rights in the three and six months ended September 30, 2008 as all technology rights were fully amortized as at March 31, 2008.

## **Liquidity and Capital Resources**

Amorfix is a development stage company as it has not received any 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, agents' compensation warrants and options 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.

The Company has incurred a loss of \$1,147,947 for the three months ended September 30, 2008 and has a deficit of \$16,259,884 as at September 30, 2008. 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 \$5,808,725 is sufficient to fund its operations through to the end of November 2009, 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 outlicensing, 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 totaled \$1,036,042 for the three months ended September 30, 2008 compared to \$1,484,151 for the three months ended September 30, 2007. For the six months ended September 30, 2008, the company's cash burn was \$2,718,488 as compared with \$2,976,781 in the comparable period last year. The decreased cash burn for the three and six months ended September 30, 2007 was due mostly from lower development and operating costs, offset by a higher amount of accounts payable that was paid out in the current periods ended September 30, 2008.

During the three months ended September 30, 2008, the Company purchased \$22,001 of property and equipment used principally for research and development purposes compared to \$34,640 in the comparable period last year. During the six months ended September 30, 2008 the Company purchased \$110,939 as compared with \$145,155 in the comparable period last year.

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; 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. As at September 30, 2008 the company held cash and cash equivalents and marketable securities in the amount of \$196,488 denominated in US dollars.

The Company earns interest income from its cash, cash equivalents and marketable securities. For the three and six months ended September 30, 2008 the company recorded interest income of \$58,525 and 134, 378 respectively as compared with \$124,805 and \$259,922 earned in the three and six months ended September 30, 2007. The Company

considers all cash and cash equivalents as held for trading. As at September 30, 2008, 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'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 three and six months ended September 30, 2008 the company recorded an unrealized gain of \$6,709 and \$83 respectively as compared with an unrealized gain of \$23,578 for the three months ended September 30, 2007 and an unrealized loss of \$10,079 for the six months ended September 30, 2007.

# **Critical Accounting Estimates**

# Equity based instruments

The Company used the Black-Scholes option pricing model to value common share purchase warrants and options and employee stock options issued by the Company. This pricing model requires 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. Management has selected these variables and applied the Black-Scholes model 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, 2008, Amorfix adopted the following new accounting pronouncements from the CICA Handbook: Section 3862, *Financial Instruments – Disclosures*; Section 3863, *Financial Instruments – Presentation*; Section 1535, *Capital Disclosures*, and changes to Section 1400, *General Standards of Financial Statement Presentation*. These sections relate to disclosure and presentation only and did not have an impact on the Company's financial results.

In November 2007, the CICA issued 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. This standard is effective for the Company for its interim financial statements beginning on October 1, 2008. The Company is currently assessing the impact that this section will have on its financial statements.

The Accounting Standards Board of Canada has announced that public companies in Canada are to adopt International Financial Reporting Standards (IFRS) for fiscal years

beginning on or after January 1, 2011. The company is in the process of analyzing the effects of the standards on its financial statements.

Additional information on these accounting changes and new pronouncements can be found in the notes to the interim financial statements for the three and six months ended September 30, 2008.

#### **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 September 30, 2008 and November 5, 2008 was 41,678,380. From October 1, 2008 to November 5, 2008, no additional warrants or options were exercised.

On September 30, 2008, the remaining common shares held by the founding shareholders and management were released from escrow.

## Warrants and Options

The following tables reflect the activity of the warrants and options (other than stock options) for the six months ended September 30, 2008 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	Warrants \$1.05 September 11, 2008			Common share Purchase Warrants \$1.95 March 8, 2009	
	· #	\$	#	\$	
Opening balance, April 1, 2008	23,810	25,000	4,462,521	8,701,915	
Issued	-	-	-	-	
Expired	(23,810)	(25,000)	-	-	
Closing balance, September 30 and November 5, 2008	*	-	4,462,521	8,701,915	

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## **Stock Options**

The following table reflects the activity under the Company's stock option plan for the three and six months ended September 30, 2008 and to the date of this Management's Discussion and Analysis:

	# Options	Weighted Average Exercise Price
Outstanding April 1, 2008	3,829,500	\$ 1.03
Granted	-	-
Expired	(30,750)	\$ 1.11
Outstanding June 30, 2008	3,798,750	\$ 1.03
Granted	-	-
Expired	(44,938)	\$ 0.93
Outstanding September 30 and November 5, 2008	3,753,812	\$ 1.03
Exercisable November 5, 2008	2,645,353	\$ 0.99

On November 5, 2008, the Company's shareholders approved the adoption of a deferred share unit (DSU) plan for senior officers of the company. Under the DSU plan, rights to the company's shares (units) may be awarded to senior officers, on a deferred payment basis, to a maximum of 1,000,000 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. Upon adoption of the DSU plan, a total of 160,000 units were awarded to senior officers.

# **Quarterly Selected Financial Information**

The following tables sets out selected financial information for the Company for the preceding eight quarters. The increased quarterly net loss beginning in the fourth quarter of fiscal 2007 and continuing to the fourth quarter of fiscal 2008 reflects higher costs from development of a commercial-grade vCJD assay with associated scale-up and quality system costs, as well as the initiation of new development programs for the Alzheimer's disease ante-mortem blood diagnostic test and the ALS therapeutic program in 2007. The decreased net loss in fiscal 2009 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 that do not affect the timing of key Company milestones.

	2009		2008				2007	
	2nd	l st	4th	3rd	2nd	l st	4th	3rd
	Quarter	Quarter						
Revenue	\$58,525	\$75,853	\$105,873	\$111,820	\$124,805	\$135,117	\$82,702	\$66,140
Net loss	(\$1,147,947)	(\$1,606,184)	(\$1,920,439)	(\$1,477,264)	(\$2,007,422)	(\$1,784,856)	(\$1,829,533)	(\$863,378)
Net loss per common share	(\$0.03)	(\$0.04)	(\$0.05)	(\$0.04)	(\$0.05)	(\$0.04)	(\$0.05)	(\$0.03)

The Company's year end is March 31.

# **Internal Control over Financial Reporting**

No change in the Company's internal control over financial reporting occurred during the three month period ended September 30, 2008 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## **Additional Information**

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Additional information relating to the Company can also be found on SEDAR at <u>www.sedar.com</u>.

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

# FOR THE THREE MONTHS ENDED JUNE 30, 2008 AND 2007

The following information for Amorfix Life Sciences Ltd. (the "Company" or "Amorfix") prepared as of August 6, 2008 should be read in conjunction with the Company's March 31, 2008 annual audited financial statements and related notes and Management's Discussion and Analysis of Operating Results and Financial Condition which are prepared in accordance with Canadian generally accepted accounting principles (GAAP) and the Annual Information Form dated June 11, 2008. Amounts are in Canadian dollars unless otherwise.

#### **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.

#### **Risks and Uncertainties**

We operate in a highly competitive environment that involves significant risks and uncertainties, some of which are outside our control. We are subject to risks associated with the biotechnology industry, including risks inherent in research and development, commencement, completion and results of preclinical and clinical studies, the controlled use of hazardous materials, uncertainties related to product approval and decisions of regulatory agencies with respect to our diagnostic and therapeutic product candidates, the lack of product revenue and our history of losses in the development stage, enforcement and protection of our intellectual property, the requirement and the ability to raise additional capital, potential competitors, the ability to attract and maintain relationships with collaborative partners, dependence on key personnel, government regulations, and the ability to successfully market our diagnostic and therapeutic candidates. Readers should review the more detailed discussion of such risk and uncertainties set out in "Risk Factors" in the Corporation's Annual Information Form for the financial year ended March 31, 2008 and "Risks and Uncertainties" in the Management's Discussion and Analysis of Operating Results and Financial Condition accompanying the March 31, 2008 annual audited financial statements.

## **The Company**

Amorfix is an emerging theranostics company focused on the diagnosis and treatment of neurodegenerative 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 degenerative diseases such as Alzheimer's Disease (AD) and Amyotrophic Lateral Sclerosis (ALS)

Amorfix believes that through various applications of its technology, it may be successful in developing products which can detect the presence of AMPs in 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 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 is also developing innovative therapies for some of these currently incurable disorders and plans to develop prophylactics such as vaccines for both the agricultural and human marketplaces.

#### **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. Recently, 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 its Epitope Protection (EP) platform technology will allow it to develop 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 product is expected to be a blood diagnostic test (EP-vCJD<sup>TM</sup> 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 Controls (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. 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 support 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 researchbased 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<sup>TM</sup> Blood Screening Assay. During this period, the Company applied to access human vCJD blood samples as part of the process that had been established by NIBSC. 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. The UK HPA subsequently slowed down the tender process.

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 2007 blinded panel compared to its research grade assay blinded panel results from a year earlier.

From July 2007 to present, the Company focused on 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<sup>TM</sup>) was able to detect prion disease in symptomatic sheep. Subsequent to year end, in April 2008, the sheep scrapie blood screening assay was successful at detecting prion disease in presymptomatic scrapie sheep. Amorfix continues to develop the EP-TSE<sup>TM</sup> assay to improve the robustness and sensitivity of the assay and is assessing the potential market opportunity for the development of a commercial version of the test for the veterinary market.

In February 2008, the Expert Advisory Group 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<sup>TM</sup> Blood Screening Assay using British blood samples. The Company believes this process will have three steps: the first will 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 variant CJD disease. In the first quarter of fiscal 2009, the Company completed the sheep scrapie blinded panel, submitted the results to NIBSC for assessment, and is waiting for confirmation to progress to test a large number of normal human plasma samples to demonstrate the specificity of Amorfix's EP-vCJD<sup>TM</sup> Blood Screening Assay.

As the HPA has not yet awarded the tender contract to supply blood screening tests for a prevalence study of vCJD using 60,000 British blood samples, the Company believes that the tender may not be awarded until the Company and any potential competitors complete the NIBSC process.

A blood screening test for vCJD is currently not regulated, however, the process to determine if and how a test should be regulated in Europe has been initiated at the request of the UK. On October 26, 2007 Amorfix attended the workshop for vCJD diagnostic assays sponsored by the Medical Device branch of the Enterprise and Industry Directorate-General of the European Commission. The Company was the only attendee to present a blood diagnostic test for vCJD that was in the process of being commercialized. Amorfix subsequently joined the European Diagnostic Manufacturers Association (EDMA) in order to participate directly in the regulatory process for establishing an in vitro diagnostic (IVD) test for vCJD. Amorfix attended the European Commission's IVD Technical Group meeting as a representative of EDMA in June 2008. The meeting was attended by representatives of many of the EU member country Competent Authorities to address regulatory issues including establishing a regulatory framework or Common Technical Specification (CTS) for an in vitro diagnostic test for vCJD. A CTS would establish standards of measurement that a vCJD blood screening assay must achieve to receive a CE mark registration. A CE mark registration would allow the product to be marketed and sold in Europe, subject to individual EU country regulations.

The Company's vCJD assay development is currently focused on completion of the steps set out by the NIBSC expert committee prior to completing the remaining activities to scale up and commercialize the test. The Company is not in control of the timing of receiving any of the panels or receiving the results thereon from NIBSC, and significant process delays have previously occurred with the UK government agencies. There can be no certainty that Amorfix will be successful at completing the NIBSC process or commercializing its assay on its expected timelines or at all.

The Company's initial target markets for its EP-vCJD<sup>™</sup> human blood screening assay are those countries that had the highest incidences of BSE-positive cattle. The blood transfusion market in Europe is estimated to be 20 million donations per year with half of this in the three largest countries of United Kingdom, France and Germany combined. Final commercial product sales and distribution of this assay is expected to require contracts and a regulatory-like approval process with individual country government health agencies.

# **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 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 estimated 1.6 million people in North America with Parkinson's disease and 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, in the amount of \$322,000 that supports a portion of the salaries of the research staff for this project. To date, Amorfix has received \$196,494 of grant support under the IRAP program.

From December 2006 to March 2008, the Company initiated and progressed its AD diagnostic assay development by screening and selecting monoclonal antibodies, established a sample preparation protocol to enrich for the Abeta proteins, assessed several different assay formats and began to optimize 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 Company achieved its target sensitivity for the AD test and is now testing patient samples of blood plasma and cerebral spinal fluid. If unsuccessful at detecting aggregated Abeta in AD patient samples, the Company will make a decision to continue to improve the assay and repeat human AD patient sample testing or abandon the project.

# **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. Amorfix scientists are continuing to refine the assay to improve its sensitivity, specificity and reproducibility of the test. 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<sup>™</sup> 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 is seeking partners to support further development and commercialization of the sheep scrapie test.

## **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).

## **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. Biogen subscribed for 289,187 common shares of the Company at \$1.46 per share for gross proceeds to Amorfix of \$422,213 (US\$375,000).

On July 23, 2007, the Company announced the achievement of the first research milestone, the development of disease-specific antibodies to misfolded SOD1, and an additional Biogen investment of US\$150,000 in Amorfix to retain their option to license Amorfix's technology. Consequently, Biogen subscribed for 91,445 common shares of Amorfix at a price of \$1.76 per share for gross proceeds to Amorfix of \$160,944 (US\$150,000). During the remaining term of the option, Biogen may subscribe for up to an additional US\$225,000 of additional common shares of Amorfix based on the achievement of two further predefined research goals. If Biogen exercises its option, over the term of the license agreement Amorfix will be eligible to receive milestone payments in excess of US\$25 million plus royalties on sales. Biogen will be responsible for all development and commercialization costs.

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. During 2007, Amorfix established the proof-of-concept of both of these approaches in pilot studies with mouse models of ALS disease. The next Biogen research milestone involves demonstrating a therapeutic benefit in an animal model of ALS using the candidate antibodies. Amorfix has now initiated larger ALS animal model studies and expects results in the second half of calendar 2008.

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, also known as Lou Gehrig's Disease. 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. Amorfix is currently assessing potential mouse models of AD that could be used to test candidate antibodies and vaccines that target misfolded SOD1.

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 will include preclinical efficacy studies for both antibody treatments and vaccines and will be conducted in Dr. Cashman's laboratory at the Brain Research Center at the University of British Columbia in collaboration with Amorfix scientists, and will be supported by a \$227,500 grant from the Canadian Institutes for Health Research (CIHR). Amorfix will contribute approximately \$650,000 to the program over 12 months.

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 application relates to the methods and two compositions for treating and detecting conditions, disease and disorders mediated by non-native SOD1.

#### **Results of Operations**

Since inception, the Company has incurred losses while advancing the research and development of the EP technology for the detection of AMPs in blood and its therapeutic SOD1 technologies for ALS and other diseases. Net loss for the three months ended June 30, 2008 was \$1,606,184 compared to \$1,784,856 for the three months ended June 30, 2007. The reduced net loss in the three months ended June 30, 2008 resulted from lower research and development program spending and lower stock-based compensation expense.

For the three months ended June 30, 2008, interest revenue was \$75,853 compared to \$135,117 for the three months ended June 30, 2007 due to lower average cash and investment balances.

For the three months ended June 30, 2008, research and development (R&D) expenses were \$1,367,167 compared to \$1,532,424 for the three months ended June 30, 2007. R&D salaries and personnel-related expenses for the three months ended June 30, 2008 were \$904,190 compared to \$769,764 for the three months ended June 30, 2007. Higher costs reflected salaries and personnel related expenses for individuals hired during fiscal 2008 to continue commercialization of the EP-vCJD<sup>TM</sup> test, to develop the sheep scrapie assay and to carry out the ALS research program in conjunction with Biogen. R&D program expenses (which includes all direct and indirect R&D costs other than personnel costs) for the three months ended June 30, 2008 were \$590,901 compared to \$847,203 for the three months ended June 30, 2007. The decreased expenses were mainly due to lower vCJD program expenses associated with the scale-up and commercialization efforts partially offset by higher AD diagnostic program costs in the current quarter. Salary and program costs were partially offset by investment tax credits and federal grants recorded in the three months ended June 30, 2008 of \$127,924 compared to grants of \$84,543 recorded in the comparable period of 2007.

For the three months ended June 30, 2008, general and administrative costs were \$263,624 compared to \$361,751 for the three months ended June 30, 2007. Lower expenses for the three months ended June 30, 2008 resulted mainly from lower stock-based compensation expense.

Amortization expense for the three months ended June 30, 2008 was \$51,246 compared to \$25,798 for the three months ended June 30, 2007. The increase in expense for the three months ended June 30, 2008 was due primarily to amortization of new purchases of laboratory equipment in fiscal 2008 and for the three months ended June 30, 2008 to support the development of diagnostic assays and amortization of leasehold improvement costs associated with the biological containment facility established in the new premises in Mississauga, Ontario in the fourth quarter of 2008. The increase was partially offset by no amortization of technology rights in the three months ended June 30, 2008 as all technology rights were fully amortized as at March 31, 2008.

#### Liquidity and Capital Resources

Amorfix is a development stage company as it has not received any 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, agents' compensation warrants and options 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.

The Company has incurred a loss of \$1,606,184 for the three months ended June 30, 2008 and has a deficit of \$15,111,937 as at June 30, 2008. 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 \$6,690,481 is sufficient to fund its operations through to the end of August 2009, 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 totaled \$1,682,446 for the three months ended June 30, 2008 compared to \$1,492,630 for the three months ended June 30, 2007. The cash burn increased for the three months ended June 30, 2008 over the comparable period in 2007 due mainly to a higher amount of accounts payable at the year-end that was paid out in the quarter ended June 30, 2008 as compared to the quarter ended June 30, 2007, partially offset by lower expenditures in the current period.

During the three months ended June 30, 2008, the Company purchased \$88,938 of property and equipment used principally for research and development purposes compared to \$110,515 in the three months ended June 30, 2007.

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; 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.

# **Critical Accounting Estimates**

# Equity based instruments

The Company used the Black-Scholes option pricing model to value common share purchase warrants and options and employee stock options issued by the Company. This pricing model requires 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. Management has selected these variables and applied the Black-Scholes model 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, 2008, Amorfix adopted the following new accounting pronouncements from the CICA Handbook: Section 3862, *Financial Instruments – Disclosures*; Section 3863, *Financial Instruments – Presentation*; Section 1535, *Capital Disclosures*, and changes to Section 1400, *General Standards of Financial Statement Presentation*. These sections relate to disclosure and presentation only and did not have an impact on the Company's financial results.

In November 2007, the CICA issued 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. This standard is effective for the Company for its interim financial statements beginning on October 1, 2008. The Company is currently assessing the impact that this section will have on its financial statements.

Additional information on these accounting changes and new pronouncements can be found in the notes to the interim financial statements for the three months ended June 30, 2008.

## **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 June 30, 2008 was 41,678,380. From July 1, 2008 to August 6, 2008, no additional warrants or options were exercised.

At June 30, 2008, 1,533,750 common shares held by founding shareholders and management remained in escrow. Effective July 25, 2007, the Company's common shares began trading on the Toronto Stock Exchange (TSX).

## Warrants and Options

The following tables reflect the activity of the warrants and options (other than stock options) for the three months ended June 30, 2008 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	Common shareWarrantsPurchase WarrantsAgent Warra\$1.05\$1.95\$1.95					
Expiry date	September 11, 2008		March 8, 2009		March 8, 2009	
	#	\$	#	\$	#	\$
Opening balance, April 1, 2008	23,810	25,000	3,847,001	7,501,651	615,520	1,200,264
Issued	-	-	-	-		-
Exercised	-	-			-	-
Closing balance, June 30 and August 6, 2008	23,810	25,000	3,847,001	7,501,651	615,520	1,200,264

# **Stock Options**

The following table reflects the activity under the Company's stock option plan for the three months ended June 30, 2008 and to the date of this Management's Discussion and Analysis:

Outstanding April 1, 2008	# <b>Options</b> 3,829,500	Weighted Average Exercise Price \$ 1.03
Granted Expired	(30,750)	- \$ 1.11
Outstanding June 30 and August 6, 2008	3,798,750	\$ 1.03
Exercisable August 6, 2008	2,394,670	\$ 1.00

# **Quarterly Selected Financial Information**

The following tables sets out selected financial information for the Company for the preceding eight quarters. The increased quarterly net loss beginning in the fourth quarter of fiscal 2007 and continuing to the fourth quarter of fiscal 2008 reflects higher costs from development of a commercial-grade vCJD assay with associated scale-up and quality system costs, as well as the initiation of new development programs for the Alzheimer's disease ante-mortem blood diagnostic test and the ALS therapeutic program in 2007. The net loss decrease in the current quarter reflects 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 that do not affect the timing of key Company milestones.

	2009		2008				2007		
	1 st	4th	3rd	2nd	1 st	4th	3rd	2nd	
	Quarter	Quarter	Quarter	Quarter	Quarter	Quarter	Quarter	Quarter	
Revenue	\$75,853	\$105,873	\$111,820	\$124,805	135,117	82,702	66,140	56,882	
Net loss	(\$1,606,184)	(\$1,920,439)	(\$1,477,264)	(\$2,007,422)	(\$1,734,856)	(\$1,829,533)	(\$863,378)	(\$776,474)	
Net loss per									
common share	(\$0.04)	(\$0.05)	(\$0.04)	(\$0.05)	(\$0.04)	(\$0.05)	(\$0.03)	(\$0.03)	

The Company's year end is March 31.

#### **Contractual Arrangements and Commitments**

On February 2006, the Company acquired an exclusive license to develop certain SOD1 technologies owned by Dr. Cashman for diagnostic and therapeutic applications for ALS disease. The Company is required 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.

In April 2006, the Company acquired certain additional SOD1 technologies owned by Dr. Cashman. 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 (UHN). The Company committed to pay small commercial royalties and make milestone payments as follows:

- a) Diagnostics \$15,000 in pre-commercial milestones and \$100,000 on first product approval;
- b) Therapeutics \$300,000 in clinical milestones and \$200,000 on first product approval.

The Company also received a buy-out option from UHN that entitles the Company to acquire the technologies prior to commercialization.

As at June 30, 2008, the Company has commitments with academic researchers and contract research agreements, some of which are cancellable with notice periods, to fund research in the amount of \$51,000 over the next 9 months.

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

	5
2009	220,000
2010	272,700
2011	227,500
2012	229,300
2013	134,500

On termination of the lease for its Mississauga premises, the landlord, at its option, may require the Company to convert the leased premises to warehouse space. The likelihood of this occurring and the potential cost are not determinable at this time.

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

No change in the Company's internal control over financial reporting occurred during the three month period ended June 30, 2008 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

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# **Additional Information**

Additional information relating to the Company can also be found on SEDAR at <u>www.sedar.com</u>.

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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, 2008 AND 2007

The following information prepared as of June 11, 2008 should be read in conjunction with Amorfix Life Sciences Ltd.'s (Amorfix or the Company) March 31, 2008 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 11, 2008.

#### **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 neurodegenerative 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 degenerative diseases such as Alzheimer's Disease (AD) and Amyotrophic Lateral Sclerosis (ALS)

Amorfix believes that through various applications of its technology, it may be successful in developing products which can detect the presence of AMPs in 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 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 also plans to develop innovative therapies for some of these currently incurable disorders and ultimately to develop prophylactics such as vaccines for both the agricultural and human marketplaces.

# **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. Recently, 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 its Epitope Protection (EP) platform technology will allow it to develop 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 product is expected to be a blood diagnostic test (EP-vCJD<sup>TM</sup> 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 Controls (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. 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 support 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 researchbased 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<sup>TM</sup> Blood Screening Assay. During this period, the Company applied to access human vCJD blood samples as part of the process that had been established by NIBSC. 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 manufacturer's 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. The UK HPA subsequently slowed down the tender process.

In February 2008, Amorfix reported the results of a second blinded panel of spiked 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 2007 blinded panel compared to its research grade assay blinded panel results from a year earlier.

From July 2007 to present, the Company focused on 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<sup>TM</sup>) was able to detect prion disease in symptomatic sheep. Subsequent to year end, in April 2008, the sheep scrapie blood screening assay was successful at detecting prion disease in presymptomatic scrapie sheep. Amorfix continues to develop the EP-TSE<sup>TM</sup> assay to improve the robustness and sensitivity of the assay and is assessing the potential market opportunity for the development of a commercial version of the test for the veterinary market.

In February 2008, the Expert Advisory Group 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<sup>TM</sup> Blood Screening Assay using British blood samples. The Company believes this process will have three steps: the first will involve the completion of a blinded sheep 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 variant CJD disease. The Company believes that it will have to successfully pass each step in

order to progress to the next step. Subsequent to year-end, the Company completed the sheep scrapie blinded panel and submitted the results to NIBSC for assessment.

As the NHS has not yet awarded the tender contract to supply blood screening tests for a prevalence study of vCJD using 60,000 British blood samples, the Company believes that the tender may not be awarded until the Company and any potential competitors complete the three step NIBSC process.

A blood screening test for vCJD is currently not regulated, however, the process to determine if and how a test should be regulated in Europe has been initiated at the request of the UK. On October 26, 2007 Amorfix attended the workshop for vCJD diagnostic assays sponsored by the Medical Device branch of the Enterprise and Industry Directorate-General of the European Commission. The Company was the only attendee to present a blood diagnostic test for vCJD that was in the process of being commercialized. Amorfix will support and assist the regulatory process and has joined the European Diagnostic Manufacturers Association (EDMA) as one way to participate in this process. Amorfix will attend a regulatory meeting in Brussels in June 2008 through EDMA. The European Commission has a current projected target date of the end of calendar 2008 to complete the development of a Common Technical Specification (CTS) which will establish standards of measurement that a vCJD blood screening assay must achieve to receive a CE mark registration. A CE mark registration would allow the product to be marketed and sold in Europe, subject to individual EU country regulations.

The Company's vCJD assay development is currently focused on completion of the steps set out by the NIBSC expert committee prior to completing the remaining activities to scale up and commercialize the test. The Company is not in control of the timing of receiving any of the panels or receiving the results thereon from NIBSC, and significant process delays have previously occurred with the UK government agencies. There can be no certainty that Amorfix will be successful at completing the NIBSC three-step process or commercializing its assay on its expected timelines or at all.

The Company's initial target markets for its EP-vCJD<sup>TM</sup> human blood screening assay are those countries that had the highest incidences of BSE-positive cattle. The blood transfusion market in Europe is estimated to be 20 million donations per year with half of this in the three largest countries of United Kingdom, France and Germany combined. Final commercial product sales and distribution of this assay is expected to require contracts and a regulatory-like approval process with individual country government health agencies.

#### **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 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 estimated 1.6 million people in North America with Parkinson's disease and 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 grant from the Government of Canada in December 2006, in the amount of \$322,000 that supports a portion of the salaries of the research staff for this project. For the year ended March 31, 2008, \$130,000 (2007 - \$28,570) of grant support was received.

From December 2006 to March 2008, the Company initiated and progressed its AD diagnostic assay development by screening and selecting monoclonal antibodies, established a sample preparation protocol to enrich for the Abeta proteins, assessed several different assay formats and began to optimize 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. The Company plans to test human AD patient blood samples for the detection of aggregated Abeta based on the current sensitivity of the assay. If unsuccessful at detecting aggregated Abeta in AD patient blood, the Company will make a decision to continue to optimize the assay for greater sensitivity and repeat human AD patient blood sample testing or abandon the project.

#### **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 subsequent to year end 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<sup>TM</sup> 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 is seeking partners to support further development and commercialization of the sheep scrapie test.

## **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).

#### 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. Biogen subscribed for 289,187 common

shares of the Company at \$1.46 per share for gross proceeds to Amorfix of \$422,213 (US\$375,000).

On July 23, 2007, the Company announced the achievement of the first research milestone, the development of disease-specific antibodies to misfolded SOD1, and an additional Biogen investment of US\$150,000 in Amorfix to retain their option to license Amorfix's technology. Consequently, Biogen subscribed for 91,445 common shares of Amorfix at a price of \$1.76 per share for gross proceeds to Amorfix of \$160,944 (US\$150,000). During the remaining term of the option, Biogen may subscribe for up to an additional US\$225,000 of additional common shares of Amorfix based on the achievement of two further predefined research goals. If Biogen exercises its option, over the term of the license agreement Amorfix will be eligible to receive milestone payments in excess of US\$25 million plus royalties on sales. Biogen will be responsible for all development and commercialization costs.

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. During 2007, Amorfix established the proof-of-concept of both of these approaches in pilot studies with mouse models of ALS disease. The next Biogen research milestone involves demonstrating a therapeutic benefit in an animal model of ALS using the candidate antibodies. Amorfix has now initiated larger ALS animal model studies and expects results in the second half of calendar 2008.

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, also known as Lou Gehrig's Disease. 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. Amorfix is currently assessing potential mouse models of AD that could be used to test candidate antibodies and vaccines that target misfolded SOD1.

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 application relates to the methods and two compositions for treating and detecting conditions, disease and disorders mediated by non-native SOD1.

#### **Annual Results of Operations**

(Note: reference to a year means the respective fiscal year ending March 31)

Since inception, the Company has incurred losses while advancing the research and development of the EP technology for the detection of AMPs in blood and its therapeutic SOD1 technologies for ALS and other diseases. Net loss for the year ended March 31, 2008 was \$7,189,981 compared to \$4,233,754 for the year ended March 31, 2007. The higher net loss resulted from expanded and more advanced research and development programs in 2008 compared to 2007.

For the year ended March 31, 2008, interest revenue rose to \$477,615 compared to \$253,701 for the year ended March 31, 2007 due mainly to higher average cash and investment balances resulting from the \$10.0 million private placement financing completed in March 2007. Higher interest rates in 2008 also contributed to higher interest revenue.

For the year ended March 31, 2008, research and development (R&D) expenses were \$6,240,108 compared to \$3,407,098 for the year ended March 31, 2007. R&D salaries and personnel-related expenses for the year ended March 31, 2008 were \$3,321,888 compared to \$2,271,439 for 2007. Higher costs reflected increased staffing levels in 2008 to continue commercialization of the EP-vCJD<sup>TM</sup> test, to develop the sheep scrapie assay and to carry out the ALS research program in conjuction with Biogen. R&D program expenses (which includes all direct and indirect R&D costs other than personnel costs) for the year ended March 31, 2008 were \$3,298,180 compared to \$1,545,447 for 2007. The increased expenses were mainly due to: higher vCJD program expenses associated with scale-up and commercialization; development of the sheep scrapie diagnostic assay; costs of the ALS therapeutic program; costs of an expanded AD diagnostic program in the current year; and the initiation of the AD therapeutic program. Salary and program costs were partially offset by investment tax credits and federal grants recorded in 2008 of \$379,960 compared to grants of \$409,788 recorded in 2007.

For the year ended March 31, 2008, general and administrative costs were \$1,259,197 compared to \$1,021,478 for the year ended March 31, 2007. Higher expenses for the year ended March 31, 2008 resulted mainly from additional staffing to support the expanded activities of the R&D and commercial teams, and legal and exchange filing fees associated with graduating to the TSX exchange in July 2007.

Amortization expense for the year ended March 31, 2008 was \$168,291 compared to \$58,879 for the year ended March 31, 2007. The increase in 2008 was due primarily to amortization of new purchases of laboratory equipment to support the development of diagnostic assays and leasehold improvement costs to establish a biological containment facility in new premises in Mississauga, Ontario in the fourth quarter of 2008. Amortization of to \$10,440 for the year ended March 31, 2007 with all technology rights fully amortized at as at March 31, 2008.

#### Liquidity and Capital Resources

Amorfix is a development stage company as it has not received any 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, agents' compensation warrants and options and stock options.

The Company has incurred a loss of \$7,189,981 for the year ended March 31, 2008 and has a deficit of \$13,505,753 as at March 31, 2008. 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 \$8,119,896 is sufficient to fund its operations through to the end of June 2009, 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 from operations which totalled \$5,562,288 for 2008 compared to \$3,395,629 for 2007. The cash burn increased in 2008 over 2007 due mainly to higher staffing levels and scale-up development costs to advance the EP-vCJD<sup>TM</sup> test closer to commercialization, and due to higher ALS therapeutic program costs for expanded preclinical studies.

In August 2006, the Company issued 289,187 common shares to Biogen Idec (Biogen) at a price of \$1.46 per share for gross proceeds of \$422,213 to support the ALS therapeutic program. On the achievement of the first research milestone under the research, option and investment agreement with Biogen, in July 2007, Biogen subscribed for an additional 91,445 common shares of the Company at \$1.76 per share for gross proceeds to Amorfix of \$160,944 (US\$150,000).

On March 8, 2007, Amorfix issued 7,694,000 common share units at \$1.30 per unit for gross proceeds of \$10,002,000 (\$9,178,884 net of cash issue costs) in a private placement financing.

During 2008, total proceeds of \$683,908 were received from the exercise of common share purchase warrants and options compared to \$2,491,392 during 2007. As at March 31, 2008, the Company had 4,486,331 warrants and options outstanding (excluding stock options) that if exercised in full, would provide the Company with an additional \$8.7 million in funding.

During 2008, the Company purchased \$492,739 of property and equipment used principally for research and development purposes compared to \$168,082 in 2007. The 2008 expenditures included leasehold improvements of \$179,100 at the Mississauga, Ontario location primarily related to construction of a biological containment facility to allow the relocation of TSE lab work from the Sunnybrook campus by June 30, 2008.

As at March 31, 2008, the Company had commitments under contracts with vendors for research and development in the amount of \$51,000 over the next 12 months.

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; 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.

# Results of Operations - Fourth Quarter 2008 and 2007

Net loss for the quarter ended March 31, 2008 was \$1,920,439 compared to \$1,829,533 for the quarter ended March 31, 2007.

For the quarter ended March 31, 2008, interest revenue from short-term investments amounted to \$105,873 compared to \$82,702 in the same quarter last year.

For the quarter ended March 31, 2008, research and development expenditures were \$1,680,454 compared to \$1,429,122 for the quarter ended March 31, 2007. Salaries and personnel-related expenses increased by \$144,254 to \$1,028,417 due mainly to additional personnel hired during 2008 partially offset by lower stock-based compensation expenses. Research and development program expenses decreased by \$95,995 to \$760,264 due mainly to lower vCJD program expenses in the fourth quarter of 2008 as the Company focused its efforts on internal development of the sheep scrapie assay and the UK clinical validation process while deferring certain external scale up, development and validation costs. Investment tax credits and grants were \$108,227 for the quarter ended March 31, 2008 compared to \$203,073 for the comparable period. The Company began accruing investment tax credits in the fourth quarter of 2007 having established a history of successful claims with the Canada Revenue Agency.

For the quarter ended March 31, 2008, general and administrative costs were \$283,435 or \$173,760 lower than the quarter ended March 31, 2007. The decrease was due mainly to lower stock-based compensation expenses of \$226,503 and the recording of an unrealized loss on marketable securities in the fourth quarter of 2007 of \$50,000. These lower costs were partially offset by higher salaries and professional fees in the fourth quarter of 2008,

Amortization expense for the quarter ended March 31, 2008 was \$62,423 compared to \$25,918 for the quarter ended March 31, 2007 due mainly to higher expenditures for laboratory equipment and leasehold improvements, and higher amortization of technology rights in 2008.

# Liquidity and Capital Resources

In the fourth quarter of fiscal 2008, Amorfix issued 50,000 common shares on the exercise of \$0.90 warrants for gross proceeds of \$45,000. In the fourth quarter of fiscal 2007, Amorfix issued 7,694,000 common share units at \$1.30 per unit for gross proceeds of \$10,002,000 (\$9,178,884 net of cash issue costs) in a private placement financing.

Cash burn for the quarter ended March 31, 2008 was \$1,327,477 compared to \$1,262,261 for the quarter ended March 31, 2007. The increased burn rate was due mainly to higher staffing in the fourth quarter of 2008 partially offset by increased accounts payable and accrued liabilities balances at the 2008 year end due mainly to capital expenditures for

the biocontainment facility and calendar year bonus compensation not paid in the fourth quarter of 2008.

Working capital at March 31, 2008 was \$8,119,896 compared to \$13,835,243 at March 31, 2007. Working capital is comprised mainly of cash and cash equivalents and marketable securities and decreased due mainly to research and development expenditures in fiscal 2008.

# **Critical Accounting Estimates**

## Equity based instruments

The Company used the Black-Scholes option pricing model to value common share purchase warrants and options and employee stock options issued by the Company. This pricing model requires 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. Management has selected these variables and applied the Black-Scholes model 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 income tax assets.

## Accounting Changes and New Pronouncements

Effective April 1, 2007, Amorfix adopted The Canadian Institute of Chartered Accountants' (CICA) Handbook Section 1530, *Comprehensive Income*; Section 3251, *Equity*; Section 3855, *Financial Instruments – Recognition and Measurement*; Section 3861, *Financial Instruments – Disclosure and Presentation*; Section 3865, *Hedges* and Section 1506, *Accounting Changes*. The prospective adoption of these new standards resulted in changes in the accounting and presentation for financial instruments.

Effective April 1, 2008, Amorfix will adopt the following new accounting pronouncements from the CICA Handbook: Section 3862, *Financial Instruments – Disclosures*; Section 3863, *Financial Instruments – Presentation*; Section 1535, *Capital Disclosures*, and changes to Section 1400, *General Standards of Financial Statement Presentation*. These sections relate to disclosure and presentation only and will not have an impact on the Company's financial results.

In November 2007, the CICA issued 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. This standard is effective for the Company for its interim financial statements beginning on October 1, 2008. The

Company is currently assessing the impact that this section will have on its financial statements.

Additional information on these accounting changes and new pronouncements can be found in the notes to the annual audited financial statements for the year ended March 31, 2008.

## **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, 2008 was 41,678,380. From April 1, 2008 to June 11, 2008, no additional warrants or options were exercised.

At March 31, 2008, 1,533,750 common shares held by founding shareholders and management remained in escrow. Effective July 25, 2007, the Company's common shares began trading on the Toronto Stock Exchange (TSX).

## Warrants and Options

The following tables reflect the activity of the warrants and options (other than stock options) for the year ended March 31, 2008 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	ę	A gent OptionsSuccess Warrants\$0.75\$0.50April 3, 2007September 21, 2007				Agent Options \$0.85	
Expiry date	April 3,			September 24, 2007			
	#	\$	#	\$	#	\$	
Opening balance, April 1, 2007	41,280	30,960	560,000	280,000	265,186	225,408	
Issued	-		-	-	-	· -	
Exercised	(24,000)	(18,000)	(560,000)	(280,000)	(265, 186)	(225,408)	
Expired	(17,280)	(12,960)	-	-	-	· ·	
Closing balance, March 31, 2008	•	-	-	-	-		

Exercise price Expiry date	Warra \$0.9 February	10	Warr \$1.0 September	5	Purchase \$1.	on share Warrants 95 8, 2009	Š\$1	Warrants .95 8, 2009
	#	\$	#	\$	#	\$	#	S
Opening balance, April 1, 2007	50,000	45,000	23,810	25,000	3,847,001	7,501,651	615,520	1,200,264
Issued	-		-	-	-	-	-	-
Exercised	(50,000)	(45,000)	-	-	-	-	-	-
Closing balance, March 31 and June 11, 2008	-	•	23,810	25,000	3,847,001	7,501,651	615,520	1.200.264

# **Stock Options**

The following table reflects the activity under the Company's stock option plan for the year ended March 31, 2008 and to the date of this Management's Discussion and Analysis:

	# Options	Weighted Average Exercise Price
Outstanding April 1, 2007	3,155,250	\$ 1.00
Granted	1,160,125	\$ 1.00
Exercised	(231,000)	\$ 0.50
Expired	(254,875)	\$ 1.12
Outstanding March 31 and June 11, 2008	3,829,500	\$ 1.03
Exercisable June 11, 2008	2,289,337	\$ 1.01

## **Selected Annual Financial Information**

	Year ended	Year ended	Year ended
Key Financial Indicators	March 31, 2008	March 31, 2007	March 31, 2006
Revenue - Interest earned	\$477,615	\$253,701	\$36,507
Expense - Research and development	\$6,240,108	\$3,407,098	\$1,100,745
Expense - General and administrative	\$1,259,197	\$1,021,478	\$409,917
Net loss	(\$7,189,981)	(\$4,233,754)	(\$1,967,014)
Net loss per common share	(\$0.17)	(\$0.13)	(\$0.10)
Working capital	\$8,119,896	\$13,835,243	\$5,214,438
Cash flow used in Operations	(\$5,562,288)	(\$3,395,629)	(\$1,543,703)
Total assets	\$9,990,282	\$14,734,330	\$5,547,405
Net cash proceeds from equity financing	\$160,944	\$9,651,097	\$5,886,152
Weighted average common shares outstanding	41,297,742	31,757,381	19,306,005

## **Quarterly Selected Financial Information**

The following tables sets out selected financial information for the Company for the preceding eight quarters. The increased quarterly net loss beginning in the fourth quarter of fiscal 2007 and continuing to the most recent quarter reflects higher costs from development of a commercial-grade vCJD assay with associated scale-up and quality system costs, as well as the initiation of new development programs for the Alzheimer's disease ante-mortem blood diagnostic test and the ALS therapeutic program in 2007.

	2008				2007			
	4th	3rd	2nd	lst	4th	3rd	2nd	1 st
	Quarter	Quarter	Quarter	Quarter	Quarter	Quarter	Quarter	Quarter
Revenue	\$105,873	\$111,820	\$124,805	\$135,117	\$82,702	\$66,140	\$56,882	\$47,977
Net loss	(\$1,920,439)	(\$1,477,264)	(\$2,007,422)	(\$1,784,856)	(\$1,829,533)	(\$863,378)	(\$776,474)	(\$764,369)
Net loss per common share	(\$0.05)	(\$0.04)	(\$0.05)	(\$0.04)	(\$0.05)	(\$0.03)	(\$0.03)	(\$0.03)

The Company's year end is March 31.

## **Contractual Arrangements and Commitments**

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 (UHN). As consideration for the license, the Company paid \$5,000 in cash, assumed a liability for \$4,400 in patent costs, committed to fund \$260,000 of SOD1 research at UHN, pay small commercial royalties and make milestone payments as follows:

- a) Diagnostics \$15,000 in pre-commercial milestones and \$100,000 on first product approval;
- b) Therapeutics \$300,000 in clinical milestones and \$200,000 on first product approval.

The Company also received a buy-out option from UHN that entitles the Company to acquire the technologies prior to commercialization. During 2008, \$97,500 (2007 - \$97,500) was paid to UHN and as at March 31, 2008 \$65,000 (2007 - nil) was included in accounts payable and accrued liabilities.

The principal investigator at the UHN subsequently received a \$100,000 Canadian Institutes of Health Research matching grant supporting the SOD1 research program.

As at March 31, 2008, the Company has commitments with academic researchers and contract research agreements, some of which are cancellable with notice periods, to fund research in the amount of \$51,000 over the next 12 months.

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

	5
2009	294,100
2010	272,700
2011	227,500
2012	229,300
2013	134,500

On termination of the lease for its Mississauga premises, the landlord, at its option, may require the Company to convert the leased premises to warehouse space. The likelihood of this occurring and the potential cost are not determinable at this time.

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## **Related Parties**

Certain members of management, who are also shareholders, were under contract to provide employment services to the Company. During 2008, the Company incurred \$489,305 (2007 - \$380,630) of expenses for three contracts, with \$108,163 (2007 - \$32,028) payable as at March 31, 2008. These transactions occurred in the normal course of operations and were measured at the exchange amount, which is the amount of consideration established and agreed by the related parties.

During 2006 and 2007, the Company acquired licenses and technologies from Dr. Cashman for the initiation of the Company's therapeutic drug development program for ALS disease. Please see Contractual Agreements and Commitments.

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. During 2008, \$135,000 (2007 - \$120,000) was paid to UBC and as at March 31, 2008, \$45,000 (2007 - nil) was included in accounts payable and accrued liabilities.

# **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, 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 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. Since January 2004, Amorfix has accumulated net losses of \$13,505,753 (to March 31, 2008). 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 partnership 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 favourable 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 costs to comply with 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 noncompetitive 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, 2008. 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, 2008 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, 2008, 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, 2008 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with Canadian GAAP. 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 can also be found on SEDAR at <u>www.sedar.com</u>.

Attention Business/Financial Editors: Amorfix announces 2009 year end results

TSX: AMF

TORONTO, June 11 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for misfolded protein diseases, today announced its operational and financial results for the year ended March 31, 2009, as well as financial results for the fourth quarter.

2009 Development and Corporate Highlights

vCJD

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In January 2009, Amorfix announced that 10,000 blood donations in France had been tested using its EP-vCJD(TM) test as part of an ongoing large-scale study to demonstrate the feasibility of routine testing for vCJD in a blood transfusion center. The plasma samples 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 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 presently in use worldwide in blood transfusion centres to assure the safety of blood.

In December 2008, Amorfix announced it achieved excellent results in two blinded trials of human blood samples using its EP-vCJD(TM) blood test as part of a validation process conducted by the National Institute for Biological Standards and Control (NIBSC) in the United Kingdom. In this trial, NIBSC provided Amorfix with 500 frozen blinded human plasma samples which included random samples spiked with vCJD brain prions. The EP-vCJDTM 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).

Amorfix is the leading company in the NIBSC process to further validate the EP-vCJD(TM) Blood Screening Assay by testing rare blood samples from vCJD patients to demonstrate the test can detect human blood prions, as well as human brain and spleen prions. Subsequent to year end, Amorfix announced that it was advised that it will be required to test additional prion-infected animal samples, supplied by NIBSC, prior to being granted access to the human vCJD blood samples. Amorfix expects that this additional animal testing may be completed by the end of the summer.

On March 18, 2009, the UK National Health Service (NHS) 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.

<< ALS/AD >>

In the fiscal third quarter, Amorfix announced that its Disease Specific Epitope (DSE) monoclonal antibody treatments, against misfolded superoxide dismutase-1 (SOD1) protein, demonstrated statistically significant improvement in survival over controls in a mouse model of Amyotrophic Lateral Sclerosis (ALS). Amorfix is seeking a partnership 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 a separate partner to develop the vaccines. A special Committee of the Board of Directors has been formed to oversee this process. In July 2008, Amorfix announced the receipt of a Canadian Institutes of Health Research (CIHR) grant of \$227,500 to support preclinical studies to evaluate Amorfix's DSE antibodies and vaccines for the treatment of Alzheimer's Disease (AD) in collaboration with Dr. Cashman at the University of British Columbia. Amorfix expects to have results from these studies by the end of the 2010 fiscal year.

Subsequent to year end, Amorfix announced that the Amorfix Aggregated Abeta Assay (A(4)) has been shown to detect Abeta amyloid in human and animal brain tissue. The initial validation results for the A(4) test will be presented at the International Congress on AD this summer and the company will be offering the A(4) test as a service to drug discovery companies and academic researchers working to discover new treatments for AD. Since the A(4)test is able to detect amyloid build up in animals much earlier than conventional methods, the company believes the test will accelerate the development and evaluation of new treatments for AD.

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Cancer
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Subsequent to year end, Amorfix announced that it plans to expand its portfolio of diagnostic tests through collaboration with companies and academic groups with established biomarkers that can be developed into screening tests. On April 23, 2009, Amorfix announced a collaboration with BioMosaics and Sunnybrook Research Institute (SRI) to develop and commercialize a blood-based assay for early detection of hepatocellular carcinoma (HCC) or primary liver cancer. The collaboration utilizes BioMosaics' and SRI's expertise in the cancer biomarker area and the assay development capability at Amorfix.

> << Other Misfolded Protein Diseases ------>>

Subsequent to year end, Amorfix announced the extension of its therapeutics program to target proteins which may be misfolded in diseases where cells are under stress and more likely to produce misfolded proteins like cancer. The company plans to establish strategic alliances to expand its capabilities to develop immunotherapeutics to numerous proteins and will announce these alliances as they are formed.

Financial Results

For the three months ended March 31, 2009 the company reported a net loss from operations of \$1,376,339 (\$0.03 per share) compared to net loss of \$1,920,439 (\$0.05 per share) for the three months ended March 31, 2008.

For the year ended March 31, 2009 the company reported a net loss from operations of \$5,148,133 (\$0.12 per share) compared to a net loss of \$7,189,981 (\$0.17 per share) for the year ended March 31, 2008.

Research and development (R&D) expenses for the three months ended March 31, 2009 were \$1,064,393 compared with \$1,680,454 for the three months ended March 31, 2008. The decrease was due mainly to staff reductions and reduced program expenses relating to the deferral of vCJD commercialization efforts and the ALS program offset by an increase in new research initiatives related to misfolded protein therapies.

R&D expenses for the year ended March 31, 2009 were \$4,126,945 compared with \$6,240,108 for the corresponding period in 2008. The decrease was due mainly to staffing reductions and reduced program expense reductions relating to the deferral of the commercialization efforts of the vCJD program until the UK NIBSC program is completed, lower program and salary expenses relating to the ALS program partially offset by an increase in new research initiatives related to misfolded protein therapies.

General and administrative expenses for the three months ended March 31, 2009 were \$323,108 compared with \$283,435 for the corresponding period in

2008. The increase was due mainly to higher stock-based compensation expenses partially offset by lower salaries expense.

General and administrative expenses for the year ended March 31, 2009 were \$1,040,468 compared with \$1,259,197 for the corresponding period in 2008. The decrease resulted mainly from lower professional and stock exchange fees than in the comparable period where higher costs were incurred with the graduation to the TSX exchange.

At March 31, 2009, the company had working capital of \$4,458,065 and 42,541,181 common shares outstanding. Subsequent to the fiscal year end, the company announced the completion of a private placement financing of units consisting of one common share and one-half common share purchase warrant for gross proceeds to Amorfix of \$3.3 million.

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Outlook
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The company's fiscal 2010 diagnostic priorities are to:

- complete the NIBSC process to validate the performance of the EP-vCJD(TM) Blood Screening Assay using human vCJD patient samples and to manufacture and supply diagnostic kits for prevalence studies;
- continue to generate assay performance data in France for the vCJD assay in a blood transfusion center;
- form collaborations to further validate the benefits of the A(4) amyloid assay and to launch a service business providing this assay for testing preclinical samples; and
- complete development of a screening test for liver cancer in collaboration with BioMosaics and SRI.

The company's 2010 therapeutic priorities are to:

- engage new partners for the ALS vaccine and antibody DSE programs;
- complete proof-of-concept preclinical studies for Alzheimer's Disease targeting misfolded SOD1;
- leverage the company's core capability of identifying misfolded protein targets and to seek development partnerships for new therapeutic targets.

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Additional information about the Company, including the MD&A and financial results may be found on SEDAR at www.sedar.com.

### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting brain-wasting diseases including ALS, Alzheimer's Disease, Parkinson's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample of normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and the ability to identify AMPs and understand their structure and mechanism of folding are the first steps to developing new treatments for these devastating diseases. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

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 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.

> << Amorfix Life Sciences Ltd. (a development stage company) Balance Sheets

As at March 31 2009 2008 \$ \$ Assets Current assets 2,212,776 6,467,490 198,026 Cash and cash equivalents 564,568 Marketable securities 4,160,798 198,026 Amounts receivable 52,663 211,082 Tax credits receivable 400,082 64,963 136,855 Prepaid expenses and deposits Total current assets 5,054,074 9,415,229 Property and equipment, net 463,110 575,053 5,517,184 9,990,282 Liabilities Current liabilities Accounts payable and accrued liabilities 596,009 1,295,333 Total current liabilities 596,009 1,295,333 Shareholders' Equity 19,194,840 2,815,838 Common shares 19,467,462 Other equity 3,970,704 187,777 Contributed surplus 225,297 18,598 Accumulated other comprehensive income 2,247 Deficit (18,760,886) (13,505,753)

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4,921,175	8,694,949
5,517,184	9,990,282

Amorfix Life Sciences Ltd.

(a development stage company) Statements of Operations and Comprehensive Loss

Statements of Operations and Com		-	Period from January 23, 2004
		Year ended March 31,	(inception)
	2009	2008	2009
-	\$	\$	\$
Revenue Interest earned	244,499	477,615	1,012,322
Expenses			
Research and development		6,240,108	
General and administrative	1,040,468	1,259,197	3,780,962
Amortization of property and equipment	225,219	122,418	407 319
Amortization of technology	223,213	122,410	407,513
rights	-	45,873	56,313
	5,392,632	7,667,596	19,186,515
Loss before the undernoted	(5,148,133)	(7,189,981)	(18,174,193)
Costs related to reverse takeover			479,693
Loss for the period	(5,148,133)	(7,189,981)	(18,653,886)
Other comprehensive income Unrealized gain on available-for-sale marketable securities	16,351	52,247	
Comprehensive loss for the year	(5 131 782)	(7 137 734)	
comprehensive ross for the year			
Basic and diluted loss per common share		(0.17)	
Weighted average number of common shares outstanding	41,985,488	41,297,742	

Amorfix Life Sciences Ltd.			
(a development stage company) Statements of Cash Flows			
			Period from January 23, 2004
		Year ended March 31, 2008 \$	(inception)
Cash provided by (used in)			
Operating activities			
Loss for the period Amortization of property and	(5,148,133)	(7,189,981)	(18,653,886)
equipment Amortization of technology	225,219	122,418	407,319
rights		45,873	
Stock-based compensation Other non-cash expenses	1,085,386	916,983	3,013,924 235,115
Changes in non-cash working			<b>,</b> -
capital	(293,069)	542,419	176,839
	(4,130,597)	(5,562,288)	(14,764,376)
Investing activities			
Purchase of marketable securities	(6,159,771)	(1,608,840)	(27,833,681)
Maturity or sale of marketable securities	8,482,814	7,386,197	23,691,481
Purchase of property and equipment Purchase of technology rights	(113,276) -	( <b>4</b> 92,739) (15,000)	(870,429) (56,313)
	2,209,767	5,269,618	(5,068,942)
Financing activities			
Issuance of common shares, net of cash issue costs Issuance of common share units,	272,622	160,944	4,655,751
net of cash issue costs Issuance of common shares on	-	-	11,973,069
exercise of agent options and warrants	-	568,408	2,980,920
Issuance of common shares on			
exercise of options Other financing activities	-	115,500	521,368 266,778
	272,622	844,852	20,397,886
Net (decrease) increase in cash			
and cash equivalents during the period	(1,648,208)	552,182	564,568

Cash and cash equivalents - Beginning of period	2,212,776	1,660,594	-
Cash and cash equivalents - End of period	564,568	2,212,776	564,568
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/For further information: Dr. George Adams, President & Chief Executive Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6959, Fax: (416) 847-6899, george.adams(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-09

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Attention Business Editors: Blood transfusion service in France completes 20,000 tests and establishes Amorfix EP-vCJD(TM) test in a second blood center

TSX: AMF

TORONTO, May 20 /CNW/ - Amorfix Life Sciences (TSX:AMF), a company focused on treatments and diagnostics for misfolded protein diseases announced it has initiated the second phase of its large-scale study in France to demonstrate the feasibility of routine testing of blood donations for vCJD. Amorfix's EP-vCJD(TM) test has been transferred to the Etablissement Français du Sang de Pyrénées Méditerrannée (EFS-PM) in Montpellier, France for the testing of an additional 20,000 blood donor samples.

Results from testing 20,000 blood donations in the first phase of the study conducted in Strasbourg (with Professor Jean-Pierre Cazenave) will be reported in a paper on June 24, 2009, at le Congrès 2009 de la Société Française de Transfusion Sanguine.

"Equipment set up and training of technicians were completed smoothly and we are pleased to be continuing the study in Montpellier with Dr. Joliette Coste, the Scientific Director of EFS-PM," said Dr. George Adams, CEO of Amorfix. "The routine testing of blood donations for vCJD in any country would require millions of samples to be screened annually at several blood centers. It is important to show the test system can be established easily and perform well at multiple sites and on numerous samples."

In related news, the process to define a CE mark for a blood screening test for vCJD reached a major milestone. The European Union's vCJD Experts Working Group met April 29, 2009 and completed the draft Common Technical Specifications (CTS) and guideline. These draft documents outline the requirements for CE marking of IVDs for vCJD, are now ready for adoption by the IVD Technical Group at their September meeting.

### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting misfolded diseases including neurodegenerative diseases and cancer. It has specific programs in vCJD, ALS and Alzheimer's Disease. Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample containing normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and cancer. Amorfix has shown antibodies and vaccines to misfolded proteins are therapeutic in preclinical animal models. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

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. George Adams, President & Chief Executive Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6959, Fax: (416) 847-6899, george.adams(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 08:00e 20-MAY-09

Attention Business Editors: Amorfix closes \$3.3 million private placement << /THIS NEWS RELEASE IS NOT FOR DISTRIBUTION TO UNITED STATES NEWSWIRE SERVICES OR FOR DISSEMINATION IN THE UNITED STATES/

TSX: AMF

TORONTO, April 29 /CNW/ - Amorfix Life Sciences Ltd. announced today that it has closed a non-brokered private placement, pursuant to which a total of 5,146,300 units (Units) were issued at a price of \$0.65 per Unit for gross proceeds of \$3,345,095. The size of the offering was increased from the amount previously announced to accommodate over-subscriptions.

Amorfix intends to use the net proceeds of the private placement to advance the development and commercialization of its diagnostic tests including its EP-vCJD(TM) blood screening assay and for general corporate purposes.

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, following the expiry of the four month hold period, the volume-weighted average price of Amorfix's common shares on the TSX over a period of ten consecutive trading days exceeds \$1.20. On the occurrence of a trigger event, Amorfix may give notice to holders to accelerate the expiry to a date which is not less than 30 calendar days after such notice is sent to the holders.

In connection with the private placement, Amorfix paid \$226,460 in finder fees and issued 348,400 finder warrants. 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.

All of the securities issued in connection with the private placement are subject to four month hold periods that expire on August 29, 2009.

The securities offered have not been, and will not be, registered under the United States Securities Act of 1933, as amended, and may not be offered or sold in the United States absent registration or any applicable exemption from the registration requirement of such Act. This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any jurisdiction in which such offer, solicitation or sale would be unlawful.

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX: AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting misfolded diseases including neurodegenerative diseases and cancer. It has specific programs in vCJD, ALS and Alzheimer's disease. Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample containing normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and cancer. Amorfix has shown antibodies and vaccines to misfolded proteins are therapeutic in preclinical animal models. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

### **%SEDAR: 00022789E**

/For further information: Dr. George Adams, President & Chief Executive Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6959, Fax: (416) 847-6899, george.adams(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.)

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CO: Amorfix Life Sciences Ltd.
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CNW 20:00e 29-APR-09

Attention Business Editors: Amorfix announces private placement

<< /pre>/THIS NEWS RELEASE IS NOT FOR DISTRIBUTION TO UNITED STATES NEWSWIRE SERVICES OR FOR DISSEMINATION IN THE UNITED STATES/

TSX: AMF

TORONTO, April 24 /CNW/ - Amorfix Life Sciences Ltd., a company focused on treatments and diagnostics for misfolded protein diseases, today announced an offering of up to \$3 million in units (Units) on a non-brokered private placement basis.

Amorfix will use the net proceeds to advance the development and commercialization of its diagnostic and therapeutic programs including its EP-vCJD(TM) blood screening assay and for general corporate purposes.

The Units are being offered at a price of \$0.65 per Unit and each Unit will consist of one common share and one-half of one common share purchase warrant (Warrant). Each whole Warrant will entitle the holder to purchase one common share of Amorfix at a price of \$1.00 for a period of 24 months following the closing date of the offering. The Warrants are subject to earlier expiry in the event that, following the expiry of the four month hold period, the volume-weighted average price of Amorfix's Common Shares on the TSX over a period of 10 consecutive trading days exceeds \$1.20, in which case Amorfix may give notice to holders to accelerate the expiry to a date which is not less than 30 calendar days after such notice is sent to the holders.

The securities may be issued in one or more closings and will be subject to a four-month hold period from the date of each closing. Closing is subject to Toronto Stock Exchange acceptance.

The securities offered have not been, and will not be, registered under the United States Securities Act of 1933, as amended, and may not be offered or sold in the United States absent registration or any applicable exemption from the registration requirement of such Act. This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any jurisdiction in which such offer, solicitation or sale would be unlawful.

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting misfolded diseases including neurodegenerative diseases and cancer. It has specific programs in vCJD, ALS and Alzheimer's disease. Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample containing normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and cancer. Amorfix has shown antibodies and vaccines to misfolded proteins are therapeutic in preclinical animal models. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

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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CO: Amorfix Life Sciences Ltd.
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CNW 08:00e 24-APR-09

Attention Business Editors: Amorfix and BioMosaics collaborate to develop a blood test for liver cancer supported by grant from the Ontario Institute for Cancer Research

TSX: AMF

TORONTO and BURLINGTON, VT, April 23 /CNW/ - Amorfix Life Sciences Ltd. and BioMosaics Inc. today announced a collaboration to develop and commercialize a blood-based assay for early detection of hepatocellular carcinoma (HCC) or primary liver cancer. This effort is possible due to an "Intellectual Property Development and Commercialization Program" investment of \$280,000 from the Ontario Institute for Cancer Research (OICR) to Sunnybrook Research Institute (SRI) at Sunnybrook Health Sciences Centre (Sunnybrook). The collaboration incorporates existing technology for the blood test licensed to BioMosaics, plus new material from SRI needed to improve the test, to be used for assay development at Amorfix. Pending successful development, the product will be commercialized by BioMosaics through its existing distribution network.

The liver cancer blood test is based on antibodies to the biomarker Glypican-3 (GPC3), discovered by Dr. Jorge Filmus at Sunnybrook. The collaboration utilizes BioMosaics' expertise in the cancer biomarker area and the assay development capability at Amorfix. "Our expertise in developing highly sensitive blood assays is part of our core capabilities and we welcome the opportunity to apply our knowledge to achieve a blood test for the early detection of primary liver cancer," said Dr. George Adams, CEO of Amorfix. Antibodies to GPC3 are sold worldwide by BioMosaics for use in pathology laboratories to confirm HCC, and GPC3 is widely accepted as an immunohistochemical biomarker of early HCC. "A robust and sensitive immunoassay for detection of GPC3 circulating in the bloodstream will facilitate monitoring and early detection of liver cancer in high-risk groups such as people with chronic hepatitis," said Dr. Mark Allegretta, President of BioMosaics.

Under this commercial collaboration, BioMosaics will have the opportunity to market the new test directly, as well as through its existing distributors, and Amorfix will receive royalties on commercial product sales, as well as an option to manufacture the assay kits and reagents for global distribution.

#### About HCC

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. The main risk factors are chronic Hepatitis B and Hepatitis C virus infection. About 500 million people in the world have chronic hepatitis. Japan has over 5 million people with chronic Hepatitis B or C, and is the country with the most comprehensive approach to testing for HCC. Patients considered at risk for HCC have blood tests as often as every 3 months and imaging procedures up to twice a year. HCC is the most frequent cancer in China, and causes over 100,000 deaths a year, affecting men mainly 30 to 59 years old. The incidence in North America has doubled in the last 15 years and is increasing. Approximately \$1 billion is currently being spent annually worldwide to screen the disease using surrogate serological markers and imaging such as ultrasound.

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting misfolded diseases including neurodegenerative diseases and cancer. It has specific programs in vCJD, ALS and Alzheimer's Disease. Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample containing normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and cancer. Amorfix has shown antibodies and vaccines to misfolded proteins are therapeutic in preclinical animal models. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

#### About BioMosaics

BioMosaics is a privately-held cancer biomarker development company located in Burlington Vermont. The Company is engaged in the development and commercialization of innovative products for the early diagnosis, prediction, monitoring and treatment of cancer. For more information about BioMosaics, visit www.biomosaics.com.

About Ontario Institute of Cancer Research

OICR is a not-for-profit corporation funded by the Government of Ontario through the Ministry of Research and Innovation. To find out more about OICR and the "Intellectual Property Development and Commercialization Program", visit www.oicr.on.ca/Commercialization/programs2.htm

About Sunnybrook Health Sciences Centre

Sunnybrook Health Sciences Centre is inventing the future of health care. It is an internationally recognized leader in research and education that is fully affiliated with the University of Toronto, and one of Canada's premier academic health sciences centres. To find out more about Sunnybrook, visit www.sunnybrook.ca

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CO: Amorfix Life Sciences Ltd.

CNW 07:00e 23-APR-09

Attention Business Editors: Amorfix corporate update: AMF expands diagnostic and therapeutic focus to include misfolded protein diseases including cancer

TSX: AMF

TORONTO, April 20 /CNW/ - Amorfix Life Sciences (TSX:AMF), a company focused on treatments and diagnostics for misfolded protein diseases wishes to outline its six (6) product development programs.

"Our vCJD test is being used in feasibility testing by the national blood transfusion service in France and our antibodies and vaccines for ALS have shown prolongation of life in preclinical studies," said Dr. George Adams, CEO of Amorfix. "With this success, it is time to expand our focus and apply our expertise to more misfolded protein diseases."

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### DIAGNOSTIC PRODUCTS

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Blood test for variant Creutzfeldt-Jakob Disease (vCJD): Based upon its patent pending Epitope Protection technology, Amorfix has developed the most sensitive (100% at 1:1,000,000 dilution of brain homogenates spiked into blood samples) and specific (99.9% based on 10,000 normal samples) test (EP-vCJD(TM)) for vCJD prions ever reported. This exceptional performance of the vCJD test has been verified in collaboration with the National Institute for Biological Standards and Control (NIBSC) in the United Kingdom. Further, the blood transfusion service in France is conducting large-scale testing of blood donations to demonstrate the feasibility of routine testing of blood donations for vCJD in Strasbourg and is enabling a second blood transfusion centre in Montpellier. The results from the Strasburg study will be presented at le Congrès 2009 de la Société Française de Transfusion Sanguine in Strasbourg, June 22-25, 2009.

Amorfix is the leading company in the NIBSC process to further validate the EP-vCJD(TM) by testing rare blood samples from vCJD patients to demonstrate the test can detect human blood prions, as well as human brain and spleen prions. Amorfix has been informed that it will be required to test additional prion-infected animal samples, supplied by NIBSC, prior to being granted access to the vCJD blood samples. Amorfix expects to carry out this additional animal testing in the next few weeks at the NIBSC laboratories. Testing the human patient samples may also be a requirement prior to initiating prevalence testing in the UK. On March 18, 2009, the UK National Health Service published a tender to supply blood test kits for a 10,000 sample assessment panel, a 50,000 sample prevalence study, and unlimited kits for routine testing.

Tissue test for Abeta amyloid in Alzheimer's disease (A4): The company received an IRAP grant to develop a test for Alzheimer's disease. To date, the test has been shown to detect Abeta amyloid in human and animal brain tissue. The validation results for the A4 test will be presented at the International Congress on AD this summer and the company will be offering the A4 test as a service to drug discovery companies and academic researchers working to discover new treatments for AD. Since the A4 test is able to detect amyloid build up in animals much earlier than conventional methods, the A4 test will accelerate the development and evaluation of new treatments for AD.

Blood test for sheep scrapie: The company has developed a prototype blood test for scrapie in live sheep and shown it can detect infected lambs. An analysis of the market opportunity suggests scrapie must be recognized as a public health issue (that is newer strains of scrapie are shown to cause vCJD) before it would be widely used to eliminate scrapie-infected sheep. Accordingly, the company has suspended further development until testing of the newer strains of scrapie has been reported. New blood tests for misfolded proteins: The excellent results with the vCJD testing platform have given the company an opportunity to expand its menu of diagnostic tests. Amorfix has identified companies and academic groups with established biomarkers that can be developed into screening tests. Announcements will be made as each project is initiated.

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THERAPEUTIC PRODUCTS

ALS (Lou Gehrig's disease): The company has shown its antibodies and vaccines to misfolded SOD1 can prolong life in an animal model of ALS. It is seeking to partner with a biotechnology company to humanize the antibodies and initiate clinical trials. A special Committee of the Board of Directors has been formed to oversee the process. Because vaccines have different development timelines and require special expertise compared to the antibodies, Amorfix is seeking other partners to develop the vaccines. It is hoped these partnerships will be established before the end of the calendar year.

Alzheimer's disease: The company has identified misfolded SOD1 co-located with the Abeta amyloid in the brains of people with AD. Since misfolded SOD1 is known to be toxic for nerve cells, the company has initiated preclinical animal studies with its antibodies and vaccines to determine their therapeutic potential for AD. A CIHR-POP II grant was awarded to conduct these studies which should have first results by the end of the calendar year.

New misfolded protein therapeutics: The company is the world leader in demonstrating antibodies and vaccines to misfolded proteins are therapeutic in neurodegenerative diseases. The process of identifying novel disease-specific epitopes (DSE) on misfolded proteins is extremely complex and represents a unique core expertise of the company and its CSO. The company 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 as previously shown. The company is establishing strategic alliances to expand its capabilities to develop immunotherapeutics to numerous proteins. These alliances will be announced as they are formed.

### About Amorfix

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CO: Amorfix Life Sciences Ltd.
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CNW 08:00e 20-APR-09

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Attention Business Editors: Amorfix extends warrant term by one year

TSX: AMF

TORONTO, Feb. 20 /CNW/ - Amorfix Life Sciences Ltd. announced that it has extended by one year the term of 4,462,521 common share purchase warrants (the "Warrants"), which are exercisable for one common share of Amorfix at an exercise price of \$1.95 and were issued on March 8, 2007 as part of a private placement.

Amorfix has received TSX acceptance, subject to satisfying customary conditions, to extend (the "Extension") the expiry date of the Warrants by one year (from March 8, 2009) to March 8, 2010. The Extension is subject to an earlier expiry in the event that the volume-weighted average price of Amorfix's common shares on the TSX over a period of 10 consecutive trading days exceeds \$2.50, in which case Amorfix may give notice to holders to accelerate the expiry to a date which is not less than 30 calendar days after such notice is sent to the holders.

The effective date of the Extension will be from the current expiry date of March 8, 2009.

25,000 Warrants held by insiders are included in the Extension, subject to disinterested shareholder approval under TSX policies. Amorfix intends to seek such approval at its next AGM. Until Amorfix receives the required disinterested shareholder approval of the Extension, the Warrants held by its insiders cannot be exercised.

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting brain-wasting diseases including ALS, Alzheimer's Disease, Parkinson's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample of normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and the ability to identify AMPs and understand their structure and mechanism of folding are the first steps to developing new treatments for these devastating diseases. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

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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CNW 17:00e 20-FEB-09

Attention Business/Financial Editors: Amorfix announces fiscal 2009 third quarter results

TSX: AMF

TORONTO, Feb. 11 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today announced its operational and financial results for the three and nine months ended December 31, 2008.

Q3-2009 Development and Corporate Highlights

In October 2008 and December 2008 Amorfix announced that its Disease Specific Epitope (DSE) monoclonal antibody treatments demonstrated statistically significant improvement in survival over controls in a mouse model of Amyotrophic Lateral Sclerosis (ALS) and Amorfix's achievement of its second and third milestones under a 2006 research agreement with Biogen Idec, resulting in Biogen's investment in Amorfix in the amount of US\$225,000. On February 10, 2009, Biogen allowed its option to license Amorfix SOD1 technologies for use in the treatment of ALS to lapse. Amorfix will continue to develop vaccines and antibodies for ALS and is now free to fully engage other companies that have expressed interest in partnering to bring the treatments to the clinic.

On December 19, 2008, Amorfix announced its first issued U.S. patent from titled "ALS-Specific Peptide Composition". This patent covers one of the key disease specific epitopes (DSE) in the SOD1 "Jekyll and Hyde" protein which Amorfix has shown is exposed when it misfolds. Amorfix DSE(TM) antibodies bind to this region and the Company believes neutralizes the toxic effects of SOD1 giving the longevity extension Amorfix has previously reported in animal models of ALS.

In December 2008, Amorfix announced it achieved perfect results in two blinded trials of human blood samples using its EP-vCJD(TM) blood test as part of a validation process conducted by the National Institute for Biological Standards and Control (NIBSC) in the United Kingdom. In the most recent trial, NIBSC provided Amorfix with 500 frozen blinded human plasma samples which included random samples spiked with vCJD brain prions. The EP-vCJD(TM) 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). The test scored one sample initially positive (initial reactivity of 99.8%), but upon repeat testing correctly identified the sample as negative (specificity of 100%). In the first blinded trial, Amorfix tested 1,000 fresh UK plasma samples with identical perfect results.

On January 13, 2009, Amorfix announced 10,000 blood donations in France had been tested using its EP-vCJD(TM) test as part of an ongoing large-scale study to demonstrate the feasibility of routine testing for vCJD in a blood transfusion center. The plasma samples 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 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 study will now be expanded to test blood donations in two additional centers in France.

### Financial Results

For the three months ended December 31, 2008 the Company reported a net loss of \$1,017,663 (\$0.02 per share) compared to a net loss of \$1,477,264 (\$0.04 per share) for the comparable period last year. For the nine months ended December 31, 2008 the Company reported a net loss of \$3,771,794 (\$0.09

per share) compared to a net loss of \$5,269,542 (\$0.13 per share) for the nine months ended December 31, 2007.

Research and development expenditures for the three months ended December 31, 2008 were \$804,871 compared to \$1,358,132 for the three months ended December 31, 2007, and for the nine months ended December 31, 2008 were \$3,062,552 compared to \$4,559,654 for the comparable period last year. The decrease in both current year periods was due to lower vCJD program expenses associated with scale up and commercialization in fiscal 2009 and lower expenses due to staffing reductions made in June 2008 related to the deferral of commercialization work for vCJD until the UK NIBSC validation process is complete, and other cash conservation initiatives.

General and administration costs for the three months ended December 31, 2008 were \$199,922 compared to \$190,064 for the three months ended December 31, 2007, and for the nine months ended December 31, 2008 were \$717,360 compared to \$975,762 for the comparable period last year. Slightly higher expenses for the three months ended December 31, 2008 resulted from lower salaries expense and consultant fees related to cost saving initiatives offset by higher stock-based compensation expense. Lower expenses for the nine months ended December 31, 2008 resulted mainly from lower stock-based compensation expense and lower exchange filing fees. In July 2007, Amorfix graduated to the TSX exchange and incurred significant exchange filing fees associated with that transaction.

Cash burn (cash used in operating activities) was \$809,588 for the three months ended December 31, 2008 compared to \$1,258,030 for the three months ended December 31, 2007. For the nine months ended December 31, 2008, the Company's cash burn was \$3,528,076 as compared with \$4,234,811 in the comparable period last year. The decreased cash burn for the three and nine months ended December 31, 2008 from the comparable periods in 2007 was due mostly from lower development and operating costs, offset by a higher amount of accounts payable that was paid out in the nine months ended December 31, 2008.

As at December 31, 2008 the Company had working capital of \$5,353,091 compared to \$8,119,896 as at March 31, 2008.

As at December 31, 2008 the Company had 42,541,181 common shares outstanding.

Outlook

The Company continues to focus its resources on commercialization of its lead diagnostic program with the priorities to expand large-scale testing, continue the verification process, and to promote prevalence testing of blood donors. For our therapeutic programs, the company will focus on advancing the ALS therapies with a new commercial partner, generating additional preclinical vaccine data in Dr. Cashman's academic lab, conducting animal studies with its novel therapies for Alzheimer's disease and expanding its therapeutic pipeline to other diseases where misfolded proteins are thought to have a disease-causing role.

Additional information about the Company, including the MD&A and financial results may be found on SEDAR at www.sedar.com.

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting brain-wasting diseases including ALS, Alzheimer's Disease, Parkinson's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample of normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and the ability to identify AMPs and understand their structure and mechanism of folding are the first steps to developing new treatments for these devastating diseases. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

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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Amorfix Life Sciences Ltd.
(a development stage company)
Balance Sheets</pre>

	December 31, 2008 \$ (unaudited)	March 31, 2008 \$
Assets		
Current assets Cash and cash equivalents Marketable securities Amounts receivable Tax credits receivable Prepaid expenses and deposits	4,010,493 78,239 620,000 69,360	2,212,776 6,467,490 198,026 400,082 136,855
Total current assets	6,078,569	9,415,229
Property and equipment, net	505,526	575,053
	6,584,095	9,990,282
Liabilities		
Current liabilities Accounts payable and accrued liabilities	725,478	1,295,333
Total current liabilities	725,478	1,295,333
Shareholders' equity		<b></b> -
Common shares Other equity Contributed surplus Accumulated other comprehensive (loss) income Deficit	3,445,047 224,311 (656)	19,194,840 2,815,838 187,777 2,247 (13,505,753)

5,858,617 8,694,949

6,584,095 9,990,282

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Amorfix Life Sciences Ltd. (a development stage company) Statements of Operations and Comprehensive Loss (Unaudited)

	December 31,			onths ended ember 31, 2007 \$
Revenues Interest earned	54,206	111,820	188,584	371,742
Expenses				
Research and development General and administrative		1,358,132 190,064		
Amortization of property and equipment Amortization of technology		28,168	180,466	72,709
rights	-	12,720	0	33,159
	1,071,869	1,589,084	3,960,378	5,641,284
****				
Loss before the undernoted Costs related to reverse	(1,017,663)	(1,477,264)	(3,771,794)	(5,269,542)
takeover	_		-	-
Loss for the period	(1,017,663)	(1,477,264)	(3,771,794)	(5,269,542)
Other comprehensive income (loss) Unrealized gain (loss) on available-for-sale marketable securities	(2,986)	26,470	(2,903)	16,391
Comprehensive loss for the period	(1,020,649)	(1,450,794)	(3,774,697)	(5,253,151)
Basic and diluted loss per common share	(0.02)	(0.04)	(0.09)	(0.13)
Weighted average number of common shares out- standing	42,052,754	41,508,217	41,803,625	41,183,744

Amorfix Life Sciences Ltd. (a development stage company) Statements of Cash Flows (Unaudited)

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	Dec	onths ended ember 31, 2007 \$	Dece	
Cash provided by (used in)		·	·	·
Operating activities				
Loss for the period	(1,017,663)	(1,477,264)	(3,771,794)	(5,269,542)
Amortization of property and equipment	67 076	28,168	180,466	72,709
Amortization of technolo		20,100	100,400	12,103
rights	_	12,720	-	33,159
Stock-based compensation	225,317	126,706	665,743	732,284
Other non-cash expenses	-	-	-	-
Changes in non-cash	(04 310)	E1 640	(602 401)	106 570
working capital	(84,318)	51,640	(802,491) 	190,579
	(809,588)	(1,258,030)	(3,528,076)	(4,234,811)
Investing activities				
Purchase of marketable				
securities	(1,171,489)	(247,638)	(4,726,771)	(247,638)
Maturity or sale of marketable securities	1 705 925	198 508	7 180 865	4 569 918
Purchase of property and	1,793,823	490,000	7,100,005	4,303,910
equipment	-	(64,478)	(110,939)	(209,633)
Purchase of technology rights	_	_	_	(15,000)
	624,336	186,392	2,343,155	4,097,647
Financing activities				
Issuance of common shares,				
net of cash issue costs	272,622	-	272,622	160,944
Issuance of common share				
units, net of cash issue costs	_	_	_	_
Issuance of common shares				
on exercise of warrants	-	-	-	523,408
Issuance of common shares				
on exercise of options		97,500	-	115,500
Other financing activities	-	-	-	-
	272,622	97,500	272,622	799,852
Net increase (decrease)				
in cash	87,370	(974,138)	(912,299)	662,688
Cash - beginning of				
period	1,213,107	3,297,420	2,212,776	1,660,594
Cash - end of period		0 000 000	1 200 477	0 000 000

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/For further information: Dr. George Adams, President & Chief Executive Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6959, Fax: (416) 847-6899, george.adams(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 08:00e 11-FEB-09

Attention Business/Medical Editors: Amorfix awarded "Life Science Company of the Year" for moving innovative products into commercialization

TSX: AMF

TORONTO, Jan. 20 /CNW/ - Amorfix Life Sciences Ltd. has been selected as the inaugural recipient of the "Life Science Company of the Year" by The Biotechnology Initiative. Amorfix was selected because of its pioneering approaches to innovative diagnostic and therapeutic products for brain-wasting diseases, including Alzheimer's Disease (AD), Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig's Disease), Parkinson's Disease (PD) and variant Creutzfeldt-Jakob Disease (vCJD) for global markets.

"We are honoured to have been selected by The Biotechnology Initiative, and pleased that Amorfix has been identified for its excellence in taking technologies from the bench to the global market. Our vCJD blood test, uniquely designed for living subjects, will lead to immediate protection of the blood supply, and longer term more effective treatments for these baffling diseases," said Dr. George Adams, President and CEO of Amorfix.

"Ontario is strong when it comes to innovative life sciences companies that are globally competitive. Ontario-based companies like Amorfix are working to quickly move their ideas and world-class research into the global marketplace. That means good jobs for Ontario and hope for people and families suffering from diseases such as Alzheimer's and Parkinson's," said Ontario Minister of Research and Innovation, John Wilkinson. "I commend The Biotechnology Initiative for rewarding research and commercialization excellence - and congratulate Amorfix for winning this year's award."

### Diagnostic Tests

Amorfix's lead product is a blood test for vCJD to screen blood for transfusions. People infected with vCJD, or "carriers", have infectious blood, but may not show symptoms for many years - sometimes as few as 10 years, but perhaps as many as 40 or 50 years. It is important to identify carriers who test positive to ensure that the disease is not spread through donation of blood or organs, or through the re-use of surgical instruments.

Amorfix is clearly in the lead in the race to commercialize a vCJD test. "Our test has been shown to be 100% sensitive and 99.94% specific based on studies of U.K. and France blood donor samples. It must be sensitive to not miss infected donations and it must be specific to minimize false positives," added Dr. Adams.

The same approach used in the vCJD test can be applied to develop diagnostic tests for the other misfolded protein diseases such as AD, PD, and ALS.

### Therapeutic Treatments

Amorfix has successfully demonstrated its treatments for ALS in preclinical models to its partner Biogen Idec, a world leader in biotechnology that has therapies for various diseases already on the market. The same molecule known to misfold in ALS disease was detected in Alzheimer's disease patients and so the therapies Amorfix developed for ALS are now being tested in Alzheimer's animal models. Amorfix and the Canadian Institutes of Health Research are funding the Alzheimer's research in Dr. Neil Cashman's laboratory at the University of British Columbia.

About The Biotechnology Initiative

The Biotechnology Initiative represents and promotes life sciences technologies and encourages their commercial success in Ontario through Government advocacy, stakeholder engagement, mentoring and education and promotion of Ontario's world-class science and industry.

### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting brain-wasting diseases including ALS, Alzheimer's Disease, Parkinson's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample of normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and the ability to identify AMPs and understand their structure and mechanism of folding are the first steps to developing new treatments for these devastating diseases. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

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> << Notes to Editors:

Go to http://ontbi.org/AboutTBI for more information on The Biotechnology Initiative.

Go to www.amorfix.com for more information on Amorfix. >>

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CO: Amorfix Life Sciences Ltd.

CNW 07:00e 20-JAN-09

Attention Business/Medical Editors: Large-scale testing initiated in France with 10,000 blood samples tested for vCJD

<< -- Amorfix Demonstrates vCJD Test Can Be Used Routinely to Test Blood Donations --

TSX: AMF

TORONTO, Jan. 13 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today announced it has tested 10,000 blood donations in France using its EP-vCJD(TM) test as part of a large-scale study to demonstrate the feasibility of routine testing of blood donations for vCJD.

"France has taken a leading role in assessing the feasibility of testing routine blood donations for vCJD by establishing the Amorfix test in a major blood transfusion centre. Based on the 99.94% specificity achieved in this large-scale independent testing of 10,000 samples, and the 100% sensitivity at 1:1,000,000 dilution of vCJD brain in the UK validation panel, the Amorfix test has demonstrated its readiness for use by high-risk nations to conduct prevalence studies to assess the safety of their blood supply," said Dr. George Adams, Chief Executive Officer of Amorfix.

The 10,000 blood samples 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 EP-vCJD(TM) test fits well into the normal pathogen testing program for blood donations. The test was quickly established in our facilities and has demonstrated excellent performance," said Dr. Jean-Pierre Cazenave, Director of the EFS-Alsace Blood Transfusion Center in Strasbourg.

The France feasibility study will now expand to test anonymous blood donations from two other regional centres in France.

### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting brain-wasting diseases including ALS, Alzheimer's Disease, Parkinson's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample of normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and the ability to identify AMPs and understand their structure and mechanism of folding are the first steps to developing new treatments for these devastating diseases. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

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CO: Amorfix Life Sciences Ltd.

CNW 00:02e 13-JAN-09

Attention Business Editors: Blood Test for vCJD Achieves 100% Accuracy << -- Available For Large-scale Testing of Populations to Identify Infected Carriers -->>

TSX: AMF

TORONTO, Dec. 19 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today announced it achieved 100% sensitivity and 100% specificity in a second blinded trial of human blood samples using its EP-vCJD(TM) blood test in collaboration with the National Institute for Biological Standards and Control (NIBSC) in the United Kingdom.

"We have now successfully completed both fresh and frozen human plasma testing, as part of a test validation process facilitated by NIBSC," said Dr. George Adams, Chief Executive Officer of Amorfix. "The company has 50,000 test kits available to begin large-scale testing to determine the fraction of the population infected with vCJD. This information is vital for determining the need for routine testing of blood donations."

The UK Spongiform Encephalopathy Advisory Committee (SEAC) yesterday 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 is consistent with a recent editorial in a leading medical journal, Lancet Neurology, published last week 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. Yesterday's report of vCJD with MV genetics shows we are not out of the woods with this tragic epidemic, and also raises the possibility of ongoing blood-borne transmission of vCJD from silent carriers of the infection," said Dr. Neil Cashman, Chief Science Officer of Amorfix.

In the most recent panel, NIBSC provided Amorfix with 500 frozen blinded human plasma samples which included some samples spiked with vCJD brain prions. The EP-vCJD(TM) 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). The test scored one sample initially positive (initial reactivity of 99.8%) but upon repeat testing correctly identified the sample as negative (specificity of 100%). In the first blinded panel, Amorfix tested 1,000 fresh UK plasma samples with identical perfect results.

### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting brain-wasting diseases including ALS, Alzheimer's Disease, Parkinson's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample of normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and the ability to identify AMPs and understand their structure and mechanism of folding are the first steps to developing new treatments for these devastating diseases. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

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CO: Amorfix Life Sciences Ltd.

CNW 07:36e 19-DEC-08

Attention Business Editors: Amorfix Receives Fourth Biogen Idec Investment

TSX: AMF

- First Patent on DSE Targets Issued by United States Patent Office -

TORONTO, Dec. 11 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, announced today that Biogen Idec (Nasdaq:BIIB) made their fourth investment in Amorfix with the purchase of 254,551 shares for gross proceeds to Amorfix of US\$75,000. With this investment, Biogen Idec maintains its right to license Amorfix's superoxide dismutase-1 (SOD1) targeted therapies for use in ALS until February 10, 2009.

Amorfix has also 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 (DSE) in the SOD1 "Jekyll and Hyde" protein which we have shown is exposed when it misfolds and becomes toxic for nerve cells. Amorfix DSE(TM) 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.

"Obtaining the first issued patent is a major milestone for any life science company. Biogen Idec should be commended for partnering with us on the ALS project so early and providing the resources we needed to validate our approach," said Dr. George Adams, Chief Executive Officer of Amorfix. "We are already applying the now patented approach to other diseases where misfolded proteins are prevalent and seeking partners for these new indications."

Biogen Idec has an option to license the Amorfix technology for ALS and would be responsible for completing preclinical and clinical development, regulatory approvals, manufacturing and commercialization. If the option is exercised, Amorfix will receive an upfront payment and potential milestone payments in excess of US\$25 million under the license agreement. Amorfix will also receive royalties on commercial product sales.

### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting brain-wasting diseases including ALS, Alzheimer's Disease, Parkinson's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample of normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and the ability to identify AMPs and understand their structure and mechanism of folding are the first steps to developing new treatments for these devastating diseases. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

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CO: Amorfix Life Sciences Ltd.

CNW 07:00e 11-DEC-08

Attention Business Editors: Amorfix Successfully Completes ALS Drug Discovery Program

<<

- Amorfix Also Achieves Third and Final Milestone Under Biogen Idec Agreement -

TSX: AMF

TORONTO, Nov. 26 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, announced today that it has achieved the third and final milestone under the 2006 research, investment and option agreement with Biogen Idec (Nasdaq: BIIB) to discover novel treatments for amyotrophic lateral sclerosis (ALS - Lou Gehrig's disease).

"The successful completion of the research alliance with Biogen Idec validates the company's approach to develop treatments for misfolded protein diseases," said Dr. George Adams, Chief Executive Officer of Amorfix. "We are looking forward to passing the baton to Biogen, who have the resources to quickly progress to the clinical evaluation of our ALS therapies."

Biogen Idec has an option to license the Amorfix technology for ALS under already defined terms and would be responsible for completing preclinical and clinical development, regulatory approvals, manufacturing and commercialization. If the option is exercised, Amorfix will receive an upfront cash payment and potential milestone payments in excess of US\$25 million under the license agreement. Amorfix will also receive royalties on commercial product sales. Biogen Idec must make one final small investment in Amorfix by December 10, 2008 to maintain the option to license the therapies for use in ALS, which must be exercised by February 10, 2009 or the rights expire.

Amorfix achieved the first milestone in July 2007 with the creation of Disease Specific Epitope (DSE(TM)) monoclonal antibodies for misfolded superoxide dismutase-1 (SOD1); and the second milestone in October 2008 with the demonstration that DSE(TM) antibody treatments significantly improved survival in an animal model of ALS. The third and final milestone was achieved by submitting to Biogen Idec a comprehensive final report on all the research performed during the program.

### About Amorfix

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CO: Amorfix Life Sciences Ltd.

CNW 07:00e 26-NOV-08

Attention Business Editors: Amorfix Receives Third Biogen Idec Investment

- Biogen Idec Retains Option to License to Amorfix ALS Technology -

TSX: AMF

TORONTO, Nov. 17 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, announced today that Biogen Idec (Nasdaq:BIIB) made their third investment in Amorfix with the purchase of 608,250 shares for gross proceeds to Amorfix of US\$150,000. With this investment, Biogen Idec maintains its right to license Amorfix's superoxide dismutase-1 (SOD1) targeted therapies for use in ALS.

"The continued participation of Biogen in the development of a treatment for ALS validates our approach to misfolded protein diseases and gives us a knowledgeable and strong partner," said Dr. George Adams, Chief Executive Officer of Amorfix. "We look forward to completing the research collaboration and entering into a commercial relationship with Biogen to clinically evaluate the ALS therapies."

Biogen Idec has an option to license the Amorfix technology for ALS and would be responsible for completing preclinical and clinical development, regulatory approvals, manufacturing and commercialization. If the option is exercised, Amorfix will receive an upfront payment and potential milestone payments in excess of US\$25 million under the license agreement. Amorfix will also receive royalties on commercial product sales.

### About Amorfix

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CNW 07:00e 17-NOV-08



NEWS RELEASE FOR IMMEDIATE RELEASE TSX: AMF

## AMORFIX ANNOUNCES FISCAL 2009 SECOND QUARTER RESULTS

**TORONTO, Ontario – November 6, 2008** – Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today announced its operational and financial results for the three and six months ended September 30, 2008.

## Q2-2009 Development and Corporate Highlights

- During the quarter, Amorfix made solid progress in the UK National Institute for Biological Standards and Control (NIBSC) process to verify the performance of an acceptable blood test for vCJD. The NIBSC invited Amorfix to test 1,000 normal and spiked fresh plasma samples from UK blood donors within the NIBSC laboratories. Amorfix completed the testing, subsequent to the quarter end, demonstrating 100% sensitivity for all spiked samples down to a 1 in 100,000 dilution of 10% brain homogenate (1/1,000,000 dilution of vCJD brain). The specificity for all samples was 99.3% on initial testing and 100% on repeat reactive testing.
- On October 20, 2008, Amorfix announced the achievement of the second milestone under the Biogen Idec (Biogen) research and option agreement. The study showed that monoclonal antibody treatments demonstrated statistically significant improvement in survival over controls in a mouse model of Amyotrophic Lateral Sclerosis (ALS). With the achievement of this second milestone, Biogen must invest a further US\$150,000 in Amorfix to maintain its rights to license the antibodies for use in ALS.
- On September 12, 2008, Amorfix reported that its EP-vCJD<sup>™</sup> Blood Screening Assay can detect sporadic Creutzfeldt-Jakob Disease (sCJD) prions using brain material spiked into human plasma at the same sensitivity as vCJD prions. This provides an additional commercial opportunity for the company if this result can be validated using blood from sCJD patients.
- On October 7, 2008, Amorfix attended the EU Commission's vCJD Expert's Group Meeting in Brussels, Belgium held to discuss comments received on the European Diagnostic Manufacturers' Association's June 2008 proposal on standards for vCJD Blood Screening Devices. Reviewer comments will be summarized in a guidance document that will be considered in November 2008 at the next EU In Vitro Diagnostic Technical Group meeting for the drafting of a Common Technical Specification for vCJD tests.

"We are very pleased with the excellent performance of our EP-vCJD<sup>™</sup> Blood Screening Assay in its first beta-site setting. We will continue to move ahead as quickly as possible to reach the final validation step of accessing and testing human vCJD patient samples with our assay." said George Adams, President & Chief Executive Officer of Amorfix. "Having established the proof of concept for our approach of targeting disease-causing misfolded regions of proteins with Disease Specific Antibodies, we are considering other diseases where we can apply our technology and expertise, and we await Biogen's decision to exercise its option and take over our promising ALS therapy program."

### Financial Results

For the three months ended September 30, 2008 the Company reported a net loss of \$1,147,947 (\$0.03 per share) compared to a net loss of \$2,007,422 (\$0.05 per share) for the comparable period last year. For the six months ended September 30, 2008 the Company reported a net loss of \$2,754,131 (\$0.07 per share) compared to a net loss of \$3,792,278 (\$0.09 per share) for the six months ended September 30, 2007.

Research and development expenditures for the three months ended September 30, 2008 were \$890,514 compared to \$1,669,098 for the three months ended September 30, 2007, and for the six months ended September 30, 2008 were \$2,257,681 compared to \$3,201,522 for the comparable period last year. The decrease in both current year periods was due to lower vCJD program expenses associated with scale up and commercialization in fiscal 2008 and lower expenses due to staffing reductions made in June 2008 related to the deferral of commercialization work for vCJD until the UK NIBSC process is complete, and other cash conservation initiatives.

General and administration costs for the three months ended September 30, 2008 were \$253,814 compared to \$423,947 for the three months ended September 30, 2007, and for the six months ended September 30, 2008 were \$517,438 compared to \$785,698 for the comparable period last year. Lower expenses for the three and six months ended September 30, 2008 resulted mainly from lower stock-based compensation expense and lower exchange filing fees. In July 2007, the company graduated to the TSX exchange and incurred significant exchange filing fees associated with that transaction.

Cash burn (cash used in operating activities) was \$1,036,042 for the three months ended September 30, 2008 compared to \$1,484,151 for the three months ended September 30, 2007. For the six months ended September 30, 2008, the company's cash burn was \$2,718,488 as compared with \$2,976,781 in the comparable period last year. The decreased cash burn for the three and six months ended September 30, 2008 from the comparable periods in 2007 was due mostly from lower development and operating costs, offset by a higher amount of accounts payable that was paid out in the current periods ended September 30, 2008.

As at September 30, 2008 Amorfix had working capital of \$5,808,725 compared to \$8,119,896 as at March 31, 2008.

As at September 30, 2008 the Company had 41,678,380 common shares outstanding.

## Outlook

The Company's fiscal 2009 diagnostic priorities are to:

- complete the NIBSC process to verify the performance of the EP-vCJD<sup>™</sup> Blood Screening Assay which would lead to commercialization of the test;
- continue development and complete the assessment of the market opportunity for the EP-TSE<sup>™</sup> sheep scrapie assay and engage a partner to assist in commercializing the test; and
- validate its Alzheimer's diagnostic test using AD blood and spinal fluid.

The Company's 2009 therapeutic priorities are to:

- complete the remaining milestone under the Biogen Idec agreement; and
- initiate preclinical studies for Alzheimer's Disease targeting misfolded SOD1.

Additional information about the Company, including the MD&A and financial results may be found on SEDAR at www.sedar.com.

### About Amorfix

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For more information, please contact		
Dr. George Adams	James Parsons	
President & Chief Executive Officer	Chief Financial Officer	
Amorfix Life Sciences Ltd.	Amorfix Life Sciences Ltd.	
Tel: (416) 847-6959	Tel: (416) 847-6929	
Fax: (416) 847-6899	Fax: (416) 847-6899	
george.adams@amorfix.com	james.parsons@amorfix.com	

Financial results included below :

# Amorfix Life Sciences Ltd.

(a development stage company) Balance Sheets

	September 30, 2008	March 31, 2008
	\$ ( unaudited)	\$
Assets		
Current assets Cash and cash equivalents Marketable securities Amounts receivable Tax credits receivable Prepaid expenses and deposits	1,213,107 4,637,815 92,946 550,082 72,638	2,212,776 6,467,490 198,026 400,082 136,855
Total current assets	6,566,588	9,415,229
Property and equipment, net	572,602	575,053
	7,139,190	9,990,282
Liabilities		
Current liabilities Accounts payable and accrued liabilities	757,863	1,295,333
Total current liabilities	757,863	1,295,333
Shareholders' equity		
Common shares Warrants and options Contributed surplus Accumulated other comprehensive income Deficit	19,194,840 3,222,577 221,464 2,330 (16,259,884)	19,194,840 2,815,838 187,777 2,247 (13,505,753)
	6,381,327	8,694,949
	7,139,190	9,990,282

## Amorfix Life Sciences Ltd.

(a development stage company)

## Statements of Operations and Comprehensive Loss

(Unaudited)

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	Three months ended September 30,		Six months ended September 30,	
	2008	2007	2008	2007
	\$	\$	\$	\$
Revenues				
Interest earned	58,525	124,805	134,378	259,922
Expenses				
Research and development	890,514	1,669,098	2,257,681	3,201,522
General and administrative	253,814	423,947	517,438	785,698
Amortization of property and equipment	62,144	26,462	113,390	44,541
Amortization of technology rights	-	12,720	0	20,439
	1,206,472	2,132,227	2,888,509	4,052,200
Loss before the undernoted	(1,147,947)	(2,007,422)	(2,754,131)	(3,792,278)
Costs related to reverse takeover	<b></b>	-	-	-
Loss for the period	(1,147,947)	(2,007,422)	(2,754,131)	(3,792,278)
Other comprehensive income (loss)				
Unrealized gain (loss) on available-for-sale marketable securities	6,709	23,578	83	(10,079)
Comprehensive loss for the period	(1,141,238)	(1,983,844)	(2,754,048)	(3,802,357)
Basic and diluted loss per common share	(0.03)	(0.05)	(0.07)	(0.09)
Weighted average number of common shares outstanding	41,678,380	41,157,982	41,678,380	41,020,621

## Amorfix Life Sciences Ltd.

(a development stage company) Statements of Cash Flows (Unaudited)

	Three months ended		Six months ended	
	Septembe		Septembe	
	2008	2007	2008	2007
Cash provided by (used in)	\$	\$	\$	\$
Operating activities				
Loss for the period	(1,147,947)	(2,007,422)	(2,754,131)	(3,792,278)
Amortization of property and equipment	62,144	26,462	113,390	44,541
Amortization of technology rights	02,144	12,720	115,590	20,439
Stock-based compensation	219,339	297,595	440,426	605,578
Other non-cash expenses	219,559	291,393	440,420	005,578
Changes in non-cash working capital	(169,578)	186,494	(518,173)	- 144,939
enanges in non cash working capital	(1,036,042)	(1,484,151)	(2,718,488)	(2,976,781)
Investing activities				
Purchase of marketable securities	(1,840,819)	_	(3,555,282)	_
Maturity or sale of marketable securities	3,517,801	3,375,752	5,385,040	4,071,410
Purchase of property and equipment	(22,001)	(34,640)	(110,939)	(145,155)
Purchase of technology rights	(22,001)	(15,000)	(110,555)	(115,000)
	1,654,981	3,326,112	1,718,819	3,911,255
Financing activities				
Issuance of common shares, net of cash issue costs	-	160,944	-	160,944
issuance of common share units, net of cash issue costs	-	-	-	-
ssuance of common shares on exercise of warrants	-	189,895	-	523,408
ssuance of common shares on exercise of options	-	,	-	18,000
Other financing activities	-	-	-	-
		350,839		702,352
Net increase (decrease) in cash	618,939	2,192,800	(999,669)	1,636,826
Cash - beginning of period	594,168	1,104,620	2,212,776	1,660,594
Cash - end of period	1,213,107	3,297,420	1,213,107	3,297,420

Attention Business Editors: Amorfix Is First Company In World To Show Preclinical Efficacy Using Monoclonal Antibodies Targeting Misfolded Regions Of Disease-Causing Proteins

AMALS A-150

- Amorfix Also Achieves Second Milestone Under Biogen Idec Agreement -

TSX: AMF

TORONTO, Oct. 20 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, announced today that its Disease Specific Epitope (DSE) monoclonal antibody treatments demonstrated statistically significant improvement in survival over controls in a mouse model of Amyotrophic Lateral Sclerosis (ALS).

"The potential for Amorfix's novel DSE approach to treating misfolded protein diseases has now taken a huge leap forward with these results," said Dr. Neil Cashman, Chief Scientific Officer of Amorfix. "There are no effective treatments to arrest ALS progression and we believed a new approach was needed. Amorfix's preclinical results give us new hope that we are on the right track to combating this devastating disease."

With these results, Amorfix has achieved the second milestone under the 2006 research, investment and option agreement with Biogen Idec (Nasdaq:BIIB), by demonstrating effectiveness with the antibody treatments. Amorfix achieved the first milestone in July 2007 with the development of monoclonal antibodies that specifically recognize regions on the misfolded superoxide dismutase-1 (SOD1) protein that is widely believed to cause the toxic effects on neurons.

Biogen Idec has an option to license the Amorfix technology for ALS and would be responsible for completing preclinical and clinical development, regulatory approvals, manufacturing and commercialization. If the option is exercised, Amorfix will receive an upfront payment and potential milestone payments in excess of US\$25 million under the license agreement. Amorfix will also receive royalties on commercial product sales. With the achievement of this second milestone, Biogen Idec must invest a further US\$150,000 in Amorfix to maintain its rights to license the antibodies for use in ALS.

"Our company was founded on a belief that antibodies could be used to both diagnose and treat diseases where misfolded proteins were present and it is a major validation to show DSE monoclonal antibodies are therapeutic in preclinical models of ALS," said Dr. George Adams, Chief Executive Officer of Amorfix. "We have initiated our preclinical program for the treatment of Alzheimer's disease using the same DSE approach and are considering other diseases where we can apply our technology and expertise."

One in a thousand people are afflicted with ALS, which belongs to a family of fatal neurodegenerative diseases, which includes Alzheimer's and Parkinson's diseases. These diseases have aggregated misfolded proteins which are thought to be a major pathway in the progressive killing of nerve cells. In ALS, motor neurons are attacked causing neurodegeneration of the brain and spinal chord. Amorfix's therapeutic approach is based on the premise that the misfolding and aggregation of SOD1 is a principal agent in the death of motor neurons in all types of ALS disease. Amorfix believes its antibodies recognize and neutralize the misfolded SOD1 prior to aggregation and thereby inhibit the progression of the disease, while leaving normally-folded SOD1 to perform its anti-oxidant protective function in the body.

### About Amorfix

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### %SEDAR: 00022789E

CO: Amorfix Life Sciences Ltd.

CNW 07:00e 20-OCT-08

Attention Business Editors: Amorfix vCJD assay achieves 100% sensitivity and 100% specificity on 1,000 fresh samples from UK blood donors

TSX: AMF

TORONTO, Oct. 17 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today announced the best sensitivity and specificity ever reported using its EP-vCJDTM Blood Screening Assay to test fresh blood plasma samples from anonymous UK blood donors. Amorfix completed this testing in the laboratories of the National Institute for Biological Standards and Control (NIBSC) in the United Kingdom.

Amorfix tested 1,000 fresh blinded human plasma samples which included samples that were spiked with vCJD brain prions and normal brain. The EPvCJDTM Blood Screening Assay scored 100% sensitivity for all spiked samples down to a 1 in 100,000 dilution of 10% brain homogenate (1/1,000,000 dilution of vCJD brain). The specificity for all samples was 99.3% on initial testing and 100% on repeat reactive testing.

"A major concern for screening human blood donors for vCJD is finding false positives and then erroneously notifying blood donors and excluding them from future donations, "said Dr. George Adams, Chief Executive Officer of Amorfix. "The UK authorities have put forward a 99.9% specificity as an acceptable performance for a vCJD test on blood donor samples and these first results suggest we can meet or exceed this requirement."

NIBSC has asked us 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. The current testing was conducted with kits manufactured over 12 months ago which continue to demonstrate excellent shelf life and stability.

### About Amorfix

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CO: Amorfix Life Sciences Ltd.

CNW 08:10e 17-OCT-08

Attention Business Editors: Amorfix sheep scrapie results from blinded panels presented at international Prion Conference

TSX: AMF

TORONTO, Oct. 8 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today announced that Dr. Neil Cashman, Chief Scientific Officer of Amorfix, will present a poster describing the sheep scrapie results from two blinded sheep scrapie panels using Amorfix's prototype EP-TSE(TM) Blood Screening Assay at the Prion 2008 Conference today in Madrid, Spain. The presentation entitled, "Detection of prions in blood from asymptomatic scrapie sheep using Epitope Protection technology" highlights the sensitivity and specificity of the EP-TSE(TM) sheep scrapie assay.

Dr. Philip Minor, Head of Virology Division of the National Institute for Biological Standards and Control (NIBSC), the UK agency that prepared the blinded panels, will also present blinded panel results for Amorfix's EP-vCJD(TM) Blood Screening Assay and the more recent sheep scrapie results in his presentation entitled "Blood based assays for infection with the agent of vCJD".

"There are approximately 100 million blood donations collected every year and blood transfusion services outside of Europe must reject donors who have traveled in Europe during the BSE outbreak. All countries struggle to collect enough blood and our test for vCJD would allow more people to be blood donors and stabilize the blood system worldwide," said Dr. George Adams, Chief Executive Officer of Amorfix. "We continue to work closely with NIBSC and the UK National Blood Service with the goal of testing human vCJD patient blood samples for final assay validation."

Scrapie is an infectious prion disease in sheep similar to Mad Cow disease (BSE) in cattle but without the known transmission risk to humans of BSE. Amorfix developed its sheep scrapie prion-detection assay to support the commercialization of its leading EP-vCJD(TM) Blood Screening Assay currently in late stage product validation. Due to the low number of blood samples from people who have suffered from vCJD being available for large scale assay validation, the UK government requires manufacturers to demonstrate that their blood screening technology can detect prions in an animal model of the disease. Amorfix tested samples from two NIBSC blinded panels of normal and scrapie sheep that were symptomatic for the disease to show that the test can differentiate between normal sheep and sheep with prion disease.

### About Amorfix

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### **%SEDAR: 00022789E**

/For further information: Dr. George Adams, President & Chief Executive Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6959, Fax: (416) 847-6899, george.adams(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 17:00e 08-OCT-08

Attention Business Editors: Amorfix sets up vCJD blood screening assay in UK and begins to test blood donor samples

TSX: AMF

TORONTO, Sept. 23 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, announced today it has set up the EP-vCJD(TM) assay system in the Prion Laboratory at the British National Institute for Biological Standards and Control (NIBSC) and has begun to test fresh human blood samples as part of the ongoing assay validation process announced earlier this year.

"NIBSC and the UK National Blood Service have been exceedingly helpful in establishing the performance of the EP-vCJD(TM) assay on routine samples from blood donors," said Dr. George Adams, Chief Executive Officer of Amorfix. "We expect to finish this alpha-site testing program in a month and demonstrate the required specificity for the assay."

Experts in the UK believe people may be infected for decades before showing signs of vCJD. The number of people who contracted the disease by consuming BSE-positive products is unknown. To date, four people have been reported to have been infected through blood transfusion from donors who later developed symptoms and died from vCJD. Blood transfusion services in low-risk countries refuse to take blood from people who have lived in or visited high-risk countries, where BSE-positive cattle were prevalent, to slow the potential spread of the disease. A screening test for vCJD would allow more people to be blood donors and increase the safety of the blood transfusion services worldwide.

### About Amorfix

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CO: Amorfix Life Sciences Ltd.

CNW 07:00e 23-SEP-08

Attention Business Editors: Amorfix reports new finding for vCJD blood screening assay and provides corporate update

TSX: AMF

TORONTO, Sept. 12 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today reported that its EP-vCJD(TM) Blood Screening Assay can detect sporadic Creutzfeldt-Jakob Disease (sCJD) prions using brain material spiked into human plasma at the same sensitivity.

"sCJD is the most common form of this brain wasting disease and has a profound impact on health care because of its potential for patient to patient transmission," noted Dr. Neil Cashman, Chief Scientific Officer of Amorfix. "An antemortem diagnostic test for sCJD would be an important step forward in managing the risk from this disease in health care settings."

This finding supports Amorfix's platform technology for detecting aggregated misfolded proteins and expands the potential use of the assay to sCJD. The company is seeking to acquire blood and spinal fluid from sCJD patients to assess whether the assay can be used for antemortem diagnosis of this disease. Sporadic CJD occurs spontaneously in the worldwide population with an estimated 6,000 new cases per year and there are only post-mortem diagnostic tests available.

The company also reported that, other than as a result of generally adverse market conditions, the company is not aware of any reason for the recent decline in its share price. The company continues to advance its business plan for both diagnostic and therapeutic products as outlined in previous announcements.

### About Amorfix

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/For further information: Dr. George Adams, President & Chief Executive

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CO: Amorfix Life Sciences Ltd.

CNW 12:00e 12-SEP-08

Attention Business Editors: Amorfix provides corporate update on regulatory processes and manufacturing for vCJD diagnostic

TSX: AMF

TORONTO, Sept. 9 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today announced an update on the regulatory process in the European Union (EU) and manufacturing for vCJD blood screening tests.

The EU Commission's In Vitro Diagnostics Technical Group and government representatives from EU member countries met in Brussels earlier this summer to consider expert scientific information in determining the process for regulating vCJD tests. Amorfix attended as an industry expert and presented the European Diagnostic Manufacturer's Association's (EDMA) position on the standards that should be established for a first blood screening test for vCJD. The EDMA proposal was broadly circulated for comments to be reviewed at the next Commission meeting planned for early October.

"Amorfix and EDMA are taking a leadership role in advising on the scientific and practical considerations involved in regulating vCJD diagnostic blood screening assays," said Dr. George Adams, President & CEO, Amorfix. "We are encouraged by the broad EU member state support for the establishment of regulations for this test."

Amorfix has now established ISO 13485:2003 certification at its facility in Mississauga, Ontario and in its new Prion Containment Laboratory which has also been certified by the Canadian Food Inspection Agency and the Public Health Agency of Canada. This laboratory is required for the development of prion-related assays and for the quality control and release of test kits. Real-time testing of the EP-vCJD(TM) Blood Screening Assay diagnostic kit has now confirmed a shelf life of 12 months for all critical reagents.

"Amorfix's ISO quality systems have been established for manufacturing and distribution of the vCJD blood screening test," said Milan Striez, Director of Operations at Amorfix. "The on-going shelf-life testing continues to demonstrate stability of the test kits and we are confident that the stability will meet the standards of our prospective customers."

### About Amorfix

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### **%SEDAR: 00022789E**

/For further information: Dr. George Adams, President & Chief Executive Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6959, Fax: (416) 847-6899, george.adams(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 09-SEP-08

Attention Business Editors: Amorfix to set up vCJD assay in UK to continue validation process

TSX: AMF

TORONTO, Aug. 19 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, announced today that it will set up the EP-vCJD(TM) assay system in the Prion Laboratory at the British National Institute for Biological Standards and Controls (NIBSC) outside London and begin to test fresh human blood samples as part of the ongoing assay validation process announced earlier this year. Based on the performance of its EP-vCJD(TM) assay, Amorfix received and accepted an invitation from the British government to further qualify the specificity of the assay using British blood donor samples to be supplied by the National Blood Service.

"We welcome the continued assistance of the UK government to validate our test for vCJD," said Dr. George Adams, Chief Executive Officer of Amorfix. "The establishment of the test system in the UK will facilitate the testing of fresh blood donor samples as we continue to verify that the assay is suitable for prevalence studies and routine testing of donor blood."

Recent evidence has suggested that people may be infected for decades before showing signs of vCJD. The number of people who contracted the disease by consuming BSE-positive products is unknown. To date, four people have been reported to have been infected through blood transfusion from donors who later developed symptoms and died from vCJD. Blood transfusion services in low-risk countries refuse to take blood from people who have lived in or visited high-risk countries, where BSE-positive cattle were prevalent, to slow the potential spread of the disease. A screening test for vCJD would allow more people to be blood donors and assure the safety of the blood transfusion services worldwide.

### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting brain-wasting diseases including ALS, Alzheimer's Disease, Parkinson's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample of normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and the ability to identify AMPs and understand their structure and mechanism of folding are the first steps to developing new treatments for these devastating diseases. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

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CO: Amorfix Life Sciences Ltd.

CNW 07:00e 19-AUG-08

Attention Business/Financial Editors: Amorfix announces fiscal 2009 first quarter results

TSX: AMF

TORONTO, Aug. 7 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today announced its operational and financial results for the three months ended June 30, 2008.

<< Q1-2009 Development and Corporate Highlights

- Amorfix has entered the UK National Institute for Biological Standards and Control (NIBSC) process to verify the performance of an acceptable blood test for vCJD. The NIBSC will provide blood samples from scrapie-infected sheep, normal human controls and patients with vCJD. Amorfix submitted the first blinded panel of sheep scrapie and normal sheep plasma samples for evaluation and is waiting for confirmation to progress to test a large number of normal human plasma samples to demonstrate the specificity of Amorfix's EP-vCJD(TM) Blood Screening Assay.
- Amorfix attended the EU Commission's In Vitro Diagnostic Technical Group meeting in Brussels, Belgium on June 12, 2008 as a representative of the European Diagnostic Manufacturer's Association (EDMA). The meeting was attended by representatives of many of the EU member country Competent Authorities to address regulatory issues including establishing a Common Technical Specification (CTS) for an in vitro diagnostic test for vCJD.
- Using our EP-TSE(TM) sheep scrapie assay and testing a third-party supplied blinded panel, endogenous scrapie prions were detected in blood plasma from asymptomatic sheep as young as 17 months of age. Scrapie, a disease in sheep similar to mad cow disease, is infectious and has resisted years of attempts to eradicate the disease amongst the 1 billion sheep in the world. Detection of infected sheep 2 to 3 years prior to symptoms will allow effective removal of infected animals before they have the ability to infect other sheep in the flock. A simple blood test could be used for surveillance as well as eradication and would lead to the identification of infected animals earlier.
- Amorfix's Alzheimer's disease diagnostic test has achieved its target sensitivity and the company is now testing patient samples of blood plasma and cerebral spinal fluid. The test is designed to detect aggregated Abeta proteins, the characteristic feature of Alzheimer's disease.
- The ALS therapeutics program in collaboration with Biogen Idec (NASDAQ: BIIB) is progressing on schedule with completion of antibody infusion studies expected in September with data and final analysis of results expected in the fourth quarter of 2008.
- Subsequent to the quarter end, announced the receipt of a Canadian Institutes of Health Research (CIHR) grant of \$227,500 to support preclinical studies to evaluate Amorfix's Disease Specific Epitope (DSE) antibodies and vaccines for the treatment of Alzheimer's Disease.
- Amorfix presented at the Rodman & Renshaw 5th Annual Global Healthcare Conference in Monte Carlo, Monaco an important conference to connect to life science investors from Europe and North America.

"Amorfix continues to make progress in the validation and regulatory process for the vCJD assay. We are fully engaged with the UK and EU authorities and have confidence we will continue to move ahead in both processes." said George Adams, President & Chief Executive Officer of Amorfix. "With our Alzheimer's disease assay achieving its target sensitivity, we are beginning to test patient samples to look for aggregated A-beta protein as a positive indicator of disease."

### Financial Results

For the three months ended June 30, 2008 the Company reported a net loss from operations of \$1,606,184 (\$0.04 per share) compared to net loss of \$1,784,856 (\$0.04 per share) for the three months ended June 30, 2007.

Research and development (R&D) expenses for the three months ended June 30, 2008 were \$1,367,167 compared with \$1,532,424 for the three months ended June 30, 2007. The decrease was due mainly to lower vCJD program external commercialization expenses compared to the three months ended June 30, 2007, partially offset by salary costs for personnel hired during fiscal 2008 to develop the sheep scrapie assay, to support commercialization of the EP-vCJDTM test, and to carry out the ALS research program in conjunction with Biogen.

General and administrative expenses for the three months ended June 30, 2008 were \$263,624 compared with \$361,751 for the corresponding period in 2007. The decrease was due mainly to lower stock-based compensation expense.

At June 30, 2008, the Company had working capital of \$6,690,481 and 41,678,380 common shares outstanding.

<< Outlook The Company's fiscal 2009 diagnostic priorities are to:

- complete development of its Alzheimer's diagnostic test and validate its utility using AD blood.
- complete the NIBSC process to verify the performance of the EP-vCJD (TM) Blood Screening Assay which would lead to commercialization of the test;
- continue development and complete the assessment of the market opportunity for the EP-TSE(TM) sheep scrapie assay and engage a partner to assist in commercializing the test; and

The Company's 2009 therapeutic priorities are to:

- complete the remaining two milestones under the Biogen Idec agreement and
- initiate preclinical studies for Alzheimer's Disease targeting misfolded SOD1.

Additional information about the Company, including the MD&A and financial results may be found on SEDAR at www.sedar.com.

### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting brain-wasting diseases including ALS, Alzheimer's Disease, Parkinson's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of

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> Financial results included below : << Amorfix Life Sciences Ltd. (a development stage company) Balance Sheets

	June 30, 2008 \$ (unaudited)	March 31, 2008 \$
Assets		
Current assets		
Cash and cash equivalents	594,168	2,212,776
Marketable securities	6,308,088	
Amounts receivable		198,026
Tax credits receivable		400,082
Prepaid expenses and deposits	81,295	136,855
Total current assets Property and equipment, net	7,667,809 612,745 8,280,554	575,053
Liabilities		
Current liabilities Accounts payable and accrued liabilities	977,328	1,295,333
Total current liabilities	977,328	1,295,333

Shareholders' Equity 19,194,840 19,194,840 Common shares 3,012,075 2,815,838 212,627 187,777 (4,379) 2,247 Warrants and options Contributed surplus Accumulated other comprehensive income (loss) (15,111,937) (13,505,753) Deficit \_\_\_\_\_ 7,303,226 8,694,949 9,990,282 8,280,554 \_\_\_\_\_ Amorfix Life Sciences Ltd. (a development stage company) Statements of Operations and Comprehensive Loss (Unaudited) Period from January 23, Three months Three months 2004 ended ended (inception) June 30, June 30, To June 30, 2008 2007 2008 \$ \$ \$ Revenue 75,853 135,117 843,676 Interest earned \_\_\_\_ Expenses 1,367,167 1,532,424 12,182,143 Research and development 361,751 263,624 3,004,118 General and administrative Amortization of property and 51,246 18,079 - 7,719 233,346 equipment 56,313 Amortization of technology rights \_\_\_\_\_\_ 1,682,037 1,919,973 15,475,920 \_\_\_\_\_ Loss before the undernoted (1,606,184) (1,784,856) (14,632,244) Costs related to reverse takeover 479,693 (1,606,184) (1,784,856) (15,111,937) Loss for the period \_\_\_\_\_ Other comprehensive income (loss) Unrealized loss on available-for-(6,626) (33,657) sale marketable securities Comprehensive loss for the period (1,612,810) (1,818,513) \_\_\_\_\_ 

common share	(0.04)	(0.04)
Weighted average number of common shares outstanding	41,678,380	40,881,750

Amorfix Life Sciences Ltd. (a development stage company) Statements of Cash Flows (Unaudited)

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(Unaudited) Cash provided by (used in) Operating activities	Three months ended June 30, 2008 \$	June 30,	Period from January 23, 2004 (inception) To June 30, 2008 \$
Loss for the period Amortization of property and	(1,606,184)	(1,784,856)	(15,111,937)
equipment	51,246	18,079	233,346
Amortization of technology right	.s -	7,719	56,313
Stock-based compensation	221,087	307,983	2,149,625
Other non-cash expenses	-	-	235,115
Changes in non-cash working capital	(348,595)	(41,555)	121,313
	(1,682,446)	(1,492,630)	(12,316,225)
Investing activities Purchase of marketable securities Sale of marketable securities Purchase of property and equipment Purchase of technology rights	(1,714,463) 1,867,239 (88,938) -		(23,388,373) 17,075,906 (846,091) (56,313)
	63,838	585,143	(7,214,871)
Financing activities			
Issuance of common shares, net of cash issue costs	-	-	4,383,129
Issuance of common share units, net of cash issue costs Issuance of common shares on exercise of agent options and warrants	-	-	11,973,069
	-	333,513	2,980,920
Issuance of common shares on		18,000	521,368
exercise of options	-	10,000	266,778
Other financing activities	-	-	200,//0

	-	351,513	20,125,264
Net (decrease) increase in cash and cash equivalents			
during the period	(1,618,608)	(555,974)	594,168
Cash and cash equivalents -			
Beginning of period	2,212,776	1,660,594	-
Cash and cash equivalents -			
End of period	594,168	1,104,620	594,168
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CO: Amorfix Life Sciences Ltd.

CNW 07:00e 07-AUG-08

Attention Business Editors: Amorfix Life Sciences and Dr. Cashman receive Canadian Government grant to develop treatments for Alzheimer's Disease

All and the Arches

TSX: AMF

TORONTO, July 22 /CNW/ - Amorfix Life Sciences (TSX: AMF), a company focused on treatments and diagnostics for brain-wasting diseases and the University of British Columbia (UBC), today announced a research collaboration to develop Alzheimer's treatments based upon the discovery of misfolded superoxide dismutase 1 (SOD1) protein in the brains of people with Alzheimer's Disease. The research will be aimed at preclinical efficacy studies for both antibody treatments and vaccines and will be conducted in Dr. Cashman's laboratory at the Brain Research Center at the UBC in collaboration with Amorfix scientists, and will be supported by a grant from the Canadian Institutes for Health Research (CIHR).

"Amorfix previously reported the discovery of misfolded SOD1 in Alzheimer's patients. This CIHR funding will help initiate an aggressive program to show that our proprietary antibodies and vaccines can be effective in treating Alzheimer's disease," said Dr. Neil Cashman, Chief Scientific Officer of Amorfix and a Professor of Medicine (Neurology) at UBC. "The repeated recent failures of amyloid-removal agents in Alzheimer's clinical trials strongly suggest that other brain-damaging pathways are important and we believe misfolding of SOD1 plays a critical role in this pathway."

"It is reassuring to receive the scientific validation by the CIHR Review Panel of the merits of targeting SOD1 in Alzheimer's disease," said Dr. George Adams, CEO of Amorfix Life Sciences. "We continue to advance our theranostics business plan to develop both diagnostics and therapeutics against Alzheimer's disease."

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. 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.

CIHR will fund \$227,500 in cash over one year with Amorfix contributing the balance of the \$900,000 program.

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting brain-wasting diseases including ALS, Alzheimer's Disease, Parkinson's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample of normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and the ability to identify AMPs and understand their structure and mechanism of folding are the first steps to developing new treatments for these devastating diseases. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

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#### (AMF.)

#### Amorfix Life Sciences Ltd. CO:

CNW 07:00e 22-JUL-08

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Attention Business Editors: Amorfix provides corporate update on ALS therapeutic program

#### TSX: AMF

TORONTO, July 8 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today announced that its therapy program for Amyotrophic Lateral Sclerosis (ALS), commonly referred to as Lou Gehrig's disease, is on schedule for completion of antibody infusion studies this fall.

Amorfix recently hosted a meeting of its Scientific Advisory Board and research collaboration partner Biogen Idec (NASDAQ: BIIB) to review progress and data from this program. All parties were supportive of the program and approved the plan for the final ALS animal treatment study under the research collaboration. This study of antibody injection into ALS mice is expected to be completed in September with data and final analysis of results in the fourth quarter of calendar 2008.

"Our ALS program is on track for results of our antibody approach to treatment of this devastating disease later this year. We are currently testing two candidate antibody therapies at low and high dose regimes to compare their potential efficacy," said Dr. Neil Cashman, Chief Scientific Officer of Amorfix. "We continue to develop an ALS vaccine as an alternate approach."

Biogen Idec has an option to license the exclusive worldwide rights to Amorfix's technology to develop and commercialize biotherapeutics directed against ALS. If Biogen Idec exercises its option, Amorfix will receive an upfront payment and potential milestone payments in excess of US\$25 million under the license agreement. Amorfix will also receive royalties on commercial product sales. If the option is exercised, Biogen Idec will be responsible for completing preclinical and clinical development, regulatory approvals, manufacturing and commercialization.

#### About Amorfix

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(AMF.)

CO: Amorfix Life Sciences Ltd.

CNW 07:00e 08-JUL-08

Attention Business Editors: Amorfix achieves target sensitivity with its Alzheimer's disease diagnostic test

TSX: AMF

TORONTO, June 24 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today announced that its diagnostic test for the presence of aggregated Abeta in Alzheimer's disease is ready to be applied to patient samples. The company has adapted its test to specifically detect aggregated Abeta protein (amyloid) in femtogram quantities (ten parts per trillion) from an Alzheimer's brain when it is spiked into plasma or cerebral spinal fluid (CSF).

"Our AD diagnostic assay is now the most sensitive test available for Abeta protein based on our survey of existing tests. We have achieved the sensitivity required to test human Alzheimer's blood and CSF for aggregated Abeta, a hallmark of Alzheimer's disease," said Dr. Neil Cashman, Chief Scientific Officer of Amorfix. "In addition, we believe we can further improve the assay sensitivity by incorporating technology similar to that developed for our EP-vCJD(TM) Blood Screening Assay."

The company obtained ethical approval to collect and use blood from Alzheimer's patients for assay validation, and has already obtained the necessary blood and CSF samples from Alzheimer's patients and normal controls to begin testing.

Alzheimer's disease is associated with an accumulation of protein aggregates, called amyloid, in the brain. Research has shown that amyloid results from aggregation of misfolded Abeta protein. The Amorfix AD diagnostic test has been developed to detect aggregated Abeta, the characteristic feature of Alzheimer's disease, in a blood sample or CSF whereas existing assays only detect Abeta. The company believes that detection of aggregated Abeta in blood or CSF would represent a significant advancement in the search for a reliable indicator to show evidence of Alzheimer's disease. The company believes that CSF will have a higher concentration of Abeta aggregates because they originate from the brain and are not diluted in the plasma. There are currently no reliable methods for diagnosing this disease prior to death. Amorfix hypothesizes that aggregated Abeta passes from the brain to the CSF and makes its way into the blood system through a known physiological pathway. As there is no test for aggregated Abeta, the presence of or amount of aggregated Abeta in blood or CSF of Alzheimer's patients is not known.

"The Amorfix team has made significant progress in the development of a test to diagnose Alzheimer's disease since our original investment. We continue to be supportive of their efforts to find a diagnostic solution to such a devastating disease," commented Dr. Christian Burks, President & CEO of Ontario Genomics Institute.

#### About Amorfix

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CO: Amorfix Life Sciences Ltd. 

CNW 07:00e 24-JUN-08

Attention Business/Financial Editors: Amorfix announces 2008 year end results

TSX: AMF

TORONTO, June 13 /CNW/ - Amorfix Life Sciences, a company focused on treatments and diagnostics for brain wasting diseases, today announced its operational and financial results for the year ended March 31, 2008, as well as financial results for the fourth quarter.

2008 Development and Corporate Highlights

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- In February 2008, the UK National Institute for Biological Standards and Control (NIBSC) established a process to verify the performance of an acceptable blood test for vCJD. Based on performance of its EPvCJD(TM) Blood Screening Assay in previous tests, Amorfix received and accepted an invitation from the British government to further qualify the assay using British blood samples. The NIBSC will provide blood samples from scrapie-infected sheep, normal human controls and patients with vCJD. Amorfix submitted the first blinded panel of sheep scrapie and normal sheep plasma samples for evaluation subsequent to year end.
- In February 2008, Amorfix received the results of a second blinded panel of spiked human vCJD brain and spleen prions provided by NIBSC which demonstrated a 10-fold improved sensitivity and improved reproducibility than the previous blinded panel results obtained with an earlier version of the assay. The Amorfix EP-vCJD(TM) Blood Screening Assay was able to detect with 100% accuracy spiked blood samples up to a 1:1,000,000 (1:100,000 of 10% homogenate) dilution of vCJD brain in blood.
- Amorfix developed a test that uses larger volumes of blood and can detect a 1:20,000,000 (1:2,000,000 of a 10% homogenate) dilution of brain in blood. This test could be used to verify the initial positive reaction of the screening assay and confirm the results.
- Demonstrated ability to detect endogenous scrapie prions in blood plasma from symptomatic sheep using the EP-TSE(TM) sheep scrapie assay on testing of a blinded panel provided by an independent thirdparty laboratory. Subsequent to year end, the company announced that the EP-TSE(TM) sheep scrapie assay could also detect endogenous prions in the blood plasma of preclinical (asymptomatic) scrapie infected sheep that were as young as 17 months of age.
- Completed the first development milestone of its Amyotrophic Lateral Sclerosis (ALS) program with Biogen Idec and established the proof of concept for both passive and active immunization approaches for the treatment of ALS in pilot animal studies. Amorfix subsequently initiated expanded preclinical animal studies using mouse models of ALS disease. Biogen Idec subscribed for 91,445 shares of Amorfix at a price of Cdn\$1.76 per share for gross proceeds to Amorfix of US\$150,000.
- Announced the discovery of misfolded superoxide dismutase-1 (SOD1) protein in the brain of Alzheimer's Disease patients which suggests that SOD1 is a common link between Alzheimer's and ALS. Based on these findings, Amorfix expanded its research and development program to include a therapy for Alzheimer's Disease.
- Amorfix's ALS technology was published in Nature Medicine in May

2007.

- Achieved ISO 14385:2003 certification in preparation for the commercialization of its EP-vCJD(TM) Blood Screening Assay.
- Graduated to the TSX on July 25, 2007.

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"Amorfix has achieved significant progress in fiscal 2008 in the development and validation of the vCJD assay. The UK process we entered in February 2008 provides a clear path to access human vCJD samples for assay validation. Using our experience gained in vCJD, Amorfix quickly developed a sheep scrapie diagnostic assay that can detect prions in both preclinical and clinical animals opening up a potential additional market opportunity," said George Adams, President & Chief Executive Officer of Amorfix. "We also advanced our therapeutic pipeline by meeting the first Biogen Idec milestone, initiating larger preclinical studies in ALS and using our technology to discover a link between ALS and Alzheimer's Disease that has generated a new therapeutic program."

Financial Results

For the three months ended March 31, 2008 the Company reported a net loss from operations of \$1,920,439 (\$0.05 per share) compared to net loss of \$1,829,533 (\$0.05 per share) for the three months ended March 31, 2007.

For the year ended March 31, 2008 the Company reported a net loss from operations of 7,189,981 (0.17 per share) compared to a net loss of 4,233,754 (0.13 per share) for the year ended March 31, 2007.

Research and development (R&D) expenses for the three months ended March 31, 2008 were \$1,680,454 compared with \$1,429,122 for the three months ended March 31, 2007. The increase was due mainly to additional R&D personnel hired in 2008, partially offset by lower stock-based compensation expenses.

R&D expenses for the year ended March 31, 2008 were \$6,240,108 compared with \$3,407,098 for the corresponding period in 2007. The increase was due mainly to increased R&D staffing, higher expenditures related to scale-up and commercialization of the EP-vCJD(TM) Blood Screening Assay, development of the EP-TSE(TM) sheep scrapie assay, and progress on the ALS therapeutic and AD diagnostic programs.

General and administrative expenses for the three months ended March 31, 2008 were \$283,435 compared with \$457,195 for the corresponding period in 2007. The decrease was due mainly to lower stock-based compensation expenses partially offset by higher personnel costs and professional fees.

General and administrative expenses for the year ended March 31, 2008 were \$1,259,197 compared with \$1,021,478 for the corresponding period in 2007. The increase resulted mainly from additional staffing to support R&D activities, and legal and filing fees associated with graduating to the TSX exchange in July 2007.

At March 31, 2008, the Company had working capital of \$8,119,896 and 41,678,380 common shares outstanding.

Outlook

<< The Company's fiscal 2009 diagnostic priorities are to:

- complete the NIBSC process to verify the performance of the EP-vCJD(TM) Blood Screening Assay which would lead to commercialization of the test;
- continue development and complete the assessment of the market opportunity for the EP-TSE(TM) sheep scrapie assay and engage a partner to assist in commercializing the test; and
- complete development of its Alzheimer's diagnostic test and validate

its utility using AD blood.

The Company's 2009 therapeutic priorities are to:

- complete the remaining two milestones under the Biogen Idec agreement and
- initiate preclinical studies for Alzheimer's Disease targeting misfolded SOD1.
- >>

Additional information about the Company, including the MD&A and financial results may be found on SEDAR at www.sedar.com.

#### About Amorfix

Amorfix Life Sciences Ltd. (TSX:AMF) is a theranostics company developing therapeutic products and diagnostic devices targeting brain-wasting diseases including ALS, Alzheimer's Disease, Parkinson's Disease and variant Creutzfeldt-Jakob Disease (vCJD). Amorfix's proprietary Epitope Protection(TM) (EP) technology enables it to specifically identify very low levels of aggregated misfolded proteins (AMP) in a sample of normal protein. Aggregated misfolded proteins are a common element of many brain wasting diseases and the ability to identify AMPs and understand their structure and mechanism of folding are the first steps to developing new treatments for these devastating diseases. Amorfix's lead programs are a diagnostic blood screening test for vCJD and a therapy for ALS.

> 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.

#### <<

Amorfix Life Sciences Ltd. (a development stage company) Balance Sheets As at March 31

AS at March JI	2008 Ş	2007 \$
Assets		
Current assets		
Cash and cash equivalents	2,212,776	1,660,594
Marketable securities	6,467,490	12,192,600
Amounts receivable	198,026	229,692
Tax credits receivable	400,082	283,527
Prepaid expenses and deposits	136,855	132,312

Total current assets	9,415,229	14,498,725
Property and equipment, net Technology rights, net	575,053 _ 	204,732 30,873
	9,990,282	
Liabilities		
Current liabilities Accounts payable and accrued liabilities	1,295,333	663,482
Total current liabilities		663,482
Shareholders' Equity		
Common shares Warrants and options Contributed surplus Accumulated other comprehensive income Deficit	19,194,840 2,815,838 187,777 2,247 (13,505,753)	2,404,259 4,056 -
		14,070,848
	9,990,282	14,734,330

Amorfix Life Sciences Ltd. (a development stage company) Statements of Operations and Comprehensive Loss

Statements of Operations and	Comprehensive Lo	DSS	
			Period from January 23, 2004
	Year ended	Year ended	(inception)
	March 31,	March 31,	to March 31,
	2008	2007	2008
	\$	\$	\$
Revenue			
Interest earned	477,615	253,701	767,823
Expenses			
Research and development	6,240,108	3,407,098	10,814,976
General and administrative Amortization of property	1,259,197	1,021,478	2,740,494
and equipment	122,418	48,439	182,100
Amortization of technology rights	45,873	10,440	56,313
	7,667,596	4,487,455	13,793,883

Loss before the undernoted	(7,189,981)	(4,233,754)	(13,026,060)
Costs related to reverse takeover			479,693
Loss for the period	(7,189,981)	(4,233,754)	(13,505,753)
Other comprehensive income Unrealized gain on available- for-sale marketable securities	52,247		
Comprehensive loss for the period	(7,137,734)		
Basic and diluted loss per common share		(0.13)	
Weighted average number of common shares outstanding	41,297,742		
Amorfix Life Sciences Ltd. (a development stage company) Statements of Cash Flows			
			Period from January 23, 2004
	Year ended March 31, 2008 \$	Year ended March 31, 2007 \$	(inception) to March 31, 2008 \$
Cash provided by (used in) Operating activities			
Loss for the period Amortization of property	(7,189,981)	(4,233,754)	(13,505,753)
and equipment Amortization of technology	122,418 45,873	48,439 10,440	182,100 56,313
rights Stock-based compensation Other non-cash expenses	916,983	862,586 50,000	1,928,538 235,115
Changes in non-cash working capital	542,419	(133,340)	469,908
	(5,562,288)	(3,395,629)	(10,633,779)
Investing activities Purchase of marketable			
securities Sale of marketable securities	(1,608,840) 7,386,197	(13,715,070) 6,724,405	

.

Purchase of property and equipment Purchase of technology rights 	( <b>492</b> ,739) (15,000)	(168,082) (41,313)	
	5,269,618	(7,200,060)	(7,278,709)
Financing activities Issuance of common shares,			
net of cash issue costs	160,944	422,213	4,383,129
Issuance of common share units, net of cash issue costs Issuance of common shares on	-	9,228,884	11,973,069
exercise of agent options and warrants	568,408	2,126,524	2,980,920
Issuance of common shares on exercise of options Other financing activities	115,500	364,868	521,368 266,778
	844,852	12,142,489	20,125,264
Net increase (decrease) in cash	552,182	1,546,800	2,212,776
Cash - Beginning of period	1,660,594	113,794	-
Cash - End of period	2,212,776	1,660,594	2,212,776

>>

#### %SEDAR: 00022789E

/For further information: Dr. George Adams, President & Chief Executive Officer, Amorfix Life Sciences Ltd., Tel: (416) 847-6959, Fax: (416) 847-6899, george.adams(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 13-JUN-08

Attention Business Editors: Amorfix to webcast presentation at the Rodman & Renshaw 5th Annual Global Healthcare Conference

TSX: AMF

TORONTO, May 16 /CNW/ - Amorfix Life Sciences Ltd. today announced that Dr. George Adams, President and CEO, will present a company overview at the Rodman & Renshaw 5th Annual Global Healthcare Conference in Monte Carlo, Monaco. The presentation will take place at 3:10pm local time (9:10am ET) on Monday, May 19th, 2008.

A live webcast of the presentation can be accessed through the Amorfix website at www.amorfix.com. The presentation will be available for replay following the webcast.

#### About Amorfix

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#### %SEDAR: 00022789E

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CO: Amorfix Life Sciences Ltd.

CNW 07:00e 16-MAY-08

Attention Business Editors: Amorfix detects scrapie prions in blood from asymptomatic sheep

TORONTO, April 29 /CNW/ - Amorfix Life Sciences Ltd. announced today the detection of endogenous prions in the blood plasma of asymptomatic scrapie infected sheep. The company had previously reported detecting symptomatic sheep which was a requirement for testing of human vCJD in the United Kingdom. Scrapie, a disease in sheep similar to mad cow disease, is endemic in almost all the flocks of the 1 billion sheep in the world. Europe and North America have had programs to eradicate scrapie for many years and still have scrapie-infected herds. There were 76 newly-infected flocks identified in the United States in 2007.

"Identification of scrapie sheep prior to symptoms is critical for an effective program to eradicate the disease," said Dr. George Adams, Chief Executive Officer, Amorfix. "For the first time, we have been able to sort scrapie infected and unaffected sheep using a simple blood test."

Scrapie-infected lambs as early as 17 months of age were detected by the Amorfix EP-TSE(TM) 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 will 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, 492 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 (\$60M in 2007) to eradicate scrapie through genetic testing and culling of susceptible sheep.

Current post-mortem testing of scrapie costs \$30 dollars per test and 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. There are 100 million sheep in Europe and 8 million sheep in North America. The testing of all sheep in these continents would eradicate scrapie once and for all. Australia and New Zealand have been scrapie free for decades and enjoy premium prices for their products and exclusive access to markets worldwide for live animals.

Amorfix is in discussions with potential partners to complete product development, regulatory approvals and commercialize the EP-TSE(TM) test. The company continues to validate its EP-CJD(TM) test through the UK process and participate in the development of a common technical specification for a CE mark.

#### About Amorfix

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### %SEDAR: 00022789E

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CO: Amorfix Life Sciences Ltd.

CNW 07:00e 29-APR-08

# AMORFIX LIFE SCIENCES LTD.



# NOTICE OF ANNUAL MEETING OF SHAREHOLDERS

**NOTICE IS HEREBY GIVEN** that the annual meeting (the "**Meeting**") of the shareholders of Amorfix Life Sciences Ltd. (the "**Corporation**") will be held on Wednesday, November 5, 2008 at 3:30 p.m. (Eastern Time) at 3403 American Drive, Mississauga, Ontario, L4V 1T4 for the following purposes:

- 1. receive the audited financial statements of the Corporation for the financial year ended March 31, 2008, together with the report of the auditors thereon (collectively, the "Audited Financial Statements");
- 2. elect six (6) directors;
- 3. appoint auditors and authorize the directors to fix their remuneration;
- 4. to consider and, if deemed advisable, approve the adoption of a deferred share unit plan, including to set the maximum number of common shares of the Corporation issuable thereunder; and
- 5. transact such further or other business as may properly come before the Meeting and any adjournment thereof.

This notice is accompanied by a form of proxy, the Management Proxy Circular and the Audited Financial Statements and the Management's Discussion and Analysis related thereto for the year ended March 31, 2008.

Shareholders who are unable to attend the Meeting in person are requested to complete, date and sign and either deposit the enclosed form of proxy with Olympia Trust Company by mail using the return envelope provided addressed to Olympia Trust Company, 120 Adelaide Street West, Suite 920, Toronto, Ontario, M5H 1T1, or by fax at (416) 364-1827 no later than 5:00 p.m. (EST) on Monday, November 3, 2008 or, if the Meeting is adjourned, at least 48 hours (excluding Saturdays and holidays) before any adjourned Meeting is reconvened.

If you are a non-registered shareholder and have received this notice and accompanying Management Proxy Circular from your broker and or another intermediary, please complete and return the voting instruction or other authorization form provided to you by your broker or other intermediary in accordance with the instructions provided to you.

Dated at Toronto, this 6th day of August, 2008

# BY ORDER OF THE BOARD OF DIRECTORS

Dr. George Adams President and Chief Executive Officer



September 2, 2008

### Filed Via SEDAR

British Columbia Securities Commission Alberta Securities Commission Saskatchewan Securities Commission Manitoba Securities Commission Ontario Securities Commission Autorité des Marchés Financiers Government of New Brunswick, Securities Administration Branch Nova Scotia Securities Commission Securities Commission of Newfoundland & Labrador Prince Edward Island, Dept. of Community Affairs & Attorney General Government of Yukon, Registrar of Securities Government of the Northwest Territories, Registrar of Securities Government of Nunavut, Registrar of Securities Toronto Stock Exchange

Dear Sirs:

# Subject: Amorfix Life Sciences Ltd. (the "Corporation") Notice of Meeting and Record Date

We are pleased to confirm the following information with respect to the Corporation's upcoming Annual Meeting of securityholders:

Meeting Date:	November 5, 2008
Record Date for Notice:	September 29, 2008
Record Date for Voting:	September 29, 2008
Beneficial Ownership Determination Date:	September 29, 2008
Class of Securities Entitled to Receive Notice:	Common
Class of Securities Entitled to Vote:	Common
ISIN Number:	CA0317221012
Meeting Location:	Toronto

In accordance with applicable securities regulations we are filing this information with you in our capacity as agent of the Corporation.

Yours truly,

## OLYMPIA TRANSFER SERVICES INC

signed "Lisa Clarkin"

Lisa Clarkin Account Officer Corporate & Shareholder Services Direct Dial: 416-364-8081x442

cc: CDS & Co.

# FORM 13-502F1 CLASS 1 REPORTING ISSUERS – PARTICIPATION FEE

Reporting Issuer Name:	Amorfix Life Sciences Ltd	-	
Fiscal year end date used to calculate capitalization:	March 31, 2009	-	
Market value of listed or quoted sec			
recent fiscal year end	s or series outstanding as at the issuer's most	42,541,181(i	2
	of that class or series as of the last trading day e clauses 2.11(a)(ii)(A) and (B) of the Rule)	0.62(ii	2
Market value of class or series		(i) X (ii) =	26,375,532(A)
	ach class or series of securities of the reporting a marketplace in Canada or the United States ear)		Nil(B)
Market value of other securities:			
(See paragraph 2.11(b) of the Rule) (Provide details of how value was de			Nil(C)
(Repeat for each class or series of s	securities)		Nil(D)
Capitalization (Add market value of all classes and	d series of securities)	(A) + (B) + (C) + (D) =	26,375,532
<b>Participation Fee</b> (From Appendix A of the Rule, select beside the capitalization calculated beside the capitalization calculated because the cap			\$1,300
New reporting issuer's reduced p (See section 2.6 of the Rule)	articipation fee, if applicable		
Participation fee	X Number of entire months remaining	=	
. <u></u>	in the issuer's fiscal year	-	
	12		
Late Fee, if applicable			

(As determined under section 2.5 of the Rule)

# APPENDIX A – CORPORATE FINANCE PARTICIPATION FEES (effective April 1<sup>st</sup>, 2006)

Capitalization	Participation Fee
under \$25 million	\$600
\$25 million to under \$50 million	\$1,300
\$50 million to under \$100 million	\$3,200
\$100 million to under \$250 million	\$6,700
\$250 million to under \$500 million	\$14,700
\$500 million to under \$1 billion	\$20,500
\$1 billion to under \$5 billion	\$29,700
\$5 billion to under \$10 billion	\$38,300
\$10 billion to under \$25 billion	\$44,700
\$25 billion and over	\$50,300

# FORM 13-502F1 CLASS 1 REPORTING ISSUERS – PARTICIPATION FEE

Reporting Issuer Name:	Amorfix Life Sciences Ltd.	-	
Fiscal year end date used to calculate capitalization:	March 31, 2008	- ,	
Market value of listed or quoted securitie	<u>s:</u>		
Total number of securities of a class or s recent fiscal year end	eries outstanding as at the issuer's most	41,678,380 (i)	
Simple average of the closing price of th of each month of the fiscal year (See cla	at class or series as of the last trading day uses 2.11(a)(ii)(A) and (B) of the Rule)	\$1.225 (ii)	
Market value of class or series		(i) X (ii) =	51,056,016(A)
	lass or series of securities of the reporting rketplace in Canada or the United States		0(B)
Market value of other securities:			
(See paragraph 2.11(b) of the Rule)			
(Provide details of how value was detern	nined)		0(C)
(Repeat for each class or series of secur	rities)		0(D)
Capitalization			
(Add market value of all classes and ser	ies of securities)	(A) + (B) + (C) + (D) =	51,056,016
Participation Fee			
(From Appendix A of the Rule, select the beside the capitalization calculated above	e participation fee re)		\$3,200
<b>New reporting issuer's reduced partic</b> (See section 2.6 of the Rule)	<b>ipation fee</b> , if applicable		
•	umber of entire months remaining		
in	the issuer's fiscal year	= -	
12			
Late Fee, if applicable			

(As determined under section 2.5 of the Rule)

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	\$1 billion to under \$5 billion	\$29,700
	\$5 billion to under \$10 billion	\$38,300
	\$10 billion to under \$25 billion	\$44,700
	\$25 billion and over	\$50,300