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**Akers Biosciences, Inc.**

("ABI" or the "Company")

**Preliminary Results for the Year Ended 31 December 2009**

**Financial Summary**

- Revenue \$1.8 million (2008: \$6.1 million)
- Adjusted Loss Before Tax \$4.6 million (2008: \$1.2 million)
- Basic & diluted loss per share \$0.04 (2008 loss: \$0.01)
- Inventory at year end: \$677k (2008: \$409k)
- Company is debt free with current assets in cash and cash equivalents of \$2.6 million (2008: \$4.3 million)

**Operational Summary**

- 68% increase in unit sales of core PIFA Heparin/PF4 Rapid Assay
- Post year end major distribution deal for PIFA Heparin/PF4 Rapid Assay with Fisher HealthCare
- 100% correlation between Breath Ketone "Check" and whole blood sample testing results in trials – CE-mark obtained for European distribution; FDA submission for marketing clearance in the USA pending
- Breath PulmoHealth "Check" progressing well in extended clinical programme
- 10% increase in Breath Alcohol Detector unit sales – BreathScan PRO product extension launched

**Thomas A. Nicolette, President and CEO, commented,**

"ABI has continued to expand unit sales of its core products and progress new product development. We are very encouraged by the progress of PIFA HPF4 now being represented by both of the USA's largest diagnostic product distributors, the excellent data from Breath Ketone "Check", which we expect to launch later this year, and the clinical programme of Breath PulmoHealth "Check". We believe that the scale of opportunity for our PIFA Heparin/PF4 Rapid Assay, BreathScan PRO, Breath Ketone "Check" and Breath PulmoHealth "Check" will be the transformational, long-term drivers of growth and value."

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## **Chairman's and Chief Executive's Report**

We are pleased to present the annual financial results of ABI for 2009. Whilst business opportunities within a key client segment for ABI, the United States Government, have been in a holding pattern as federal financial resources were diverted to economic recovery, the underlying growth in product sales has been immensely encouraging. ABI recorded a 68% increase in unit sales of the Company's PIFA Heparin/PF4 Rapid Assay and a 10% growth in non-governmental Breath Alcohol Detector unit sales.

### **Financial Review**

The Company continued to adopt a rigorously efficient management of cash reserves, with cash and cash equivalents at 31 December 2009 of approximately \$2.6 million (FY2008: \$4.3 million). The Company is debt free. The reduction in cash reserves against the prior year predominantly reflects our capital investment in our plant, tooling and equipment to scale-up manufacturing capability of the PIFA Heparin/PF4 Rapid Assay and the building of BreathScan inventory. As such the total value of inventory held by the Company at 31 December 2009 was \$677k (2008: \$409k).

Revenue in 2009 was \$1.8 million (FY2008: \$6.1 million), reflecting a much publicised diversion of federal funds to aid economic recovery. With United States Government departments having been an important customer of ABI, the impact of this hiatus in spending was felt in 2009. Accordingly the adjusted loss before tax of \$4.6 million was significantly higher than the prior year \$1.2 million. Basic & diluted loss per share was \$0.04 (2008 loss: \$0.01). Reduced license revenue, timing of revenue recognition and reduced product sales in the period, particularly of the BreathScan product line, resulted in a decrease in aggregate gross margins which stood at 40.3% (2008: 77.4%). We do, however, expect to return to the higher gross margins previously achieved as sales begin to re-accelerate and the benefits of wider distribution of the PIFA Heparin/PF4 Rapid Assay kick in.

### **Product Review**

ABI's major strength lies within the six proprietary platform technologies that have and will continue to be applied to a variety of rapid testing scenarios, of which the main products are reviewed below:

#### **PIFA Heparin/PF4 Rapid Assay (PIFA HPF4)**

PIFA HPF4, one of the Company's flagship products, incorporates ABI's **Particle ImmunoFiltration Assay technology**. This test continued to gain momentum in the clinical laboratory marketplace in 2009, both in the USA and internationally recording a 68% increase in unit sales over 2008. PIFA HPF4 remains the sole FDA-cleared medical device for the rapid detection of antibodies identified as a critical factor in a patient developing an "allergy" to the blood thinner, heparin. This syndrome is referred to as Heparin-Induced Thrombocytopenia (HIT); instead of thinning the blood, heparin, in essence, becomes a clotting agent that can result in limb- and life-threatening complications. The potential for HIT occurring in the more than 25 million patients who consistently receive heparin in the US and EU annually, creates a

medical necessity for the rapid determination of an individual's antibody status. Unlike pre-existing laboratory-based technology for performing the same test, ABI's PIFA HPF4 assay provides healthcare professionals with patient data that can be integrated into time-sensitive clinical decisions.

PIFA HPF4 is on track to dominate ABI's sales over other existing core products. Our strategy to partner with blue-chip distributors, with strong ties to clinical laboratories, has opened healthcare facility doors for the adoption of the PIFA HPF4 test. In the USA our partnership with Cardinal Health, and our collaboration with their sales professionals, resulted in a 35% increase in unit sales over their 2008 activity and accounted for 53% of PIFA revenue. Post year end the growth prospects for PIFA HPF4 were significantly accelerated with the signing of Fisher HealthCare, one of the USA's leading healthcare product channels, as a distributor. The resultant effect is that ABI's core product is now represented by both of the USA's two largest distributors of diagnostic products, with a combined penetration of almost 100% of the 8,800 US hospitals and a near trebling of sales personnel marketing the test.

Outside of the USA other third party distributors' selling initiatives, combined with ABI's marketing and technical support, resulted in product sales that contributed to 31% of the PIFA HPF4 2009 sales revenue. Overseas sales of the product were driven by sales to Germany and increasingly the UK and Netherlands. We continue to seek additional distribution partners in the EU and are confident that this upward trend in sales of HPF4 will continue in the current year.

In addition to augmenting our PIFA HPF4 distribution network, ABI is also working to expand the use of our HIT antibody technology at the Point-of-Care (POC). To accomplish this, our Research and Development team is integrating the Company's FDA-cleared, Blood Cell Separator ("Separator") technology into the PIFA format. The Separator will eliminate the need for healthcare personnel to acquire a whole blood sample through a venous blood draw, and no longer require the use of a centrifuge or calibrated pipette. A simple finger stick blood sample will be introduced into the Separator, and the precise micro-volume of serum will be delivered into a PIFA test cassette for immediate testing. The design of this "closed system" is completed and will be branded as the "PIFA POC" rapid test platform. Since the Company has already obtained marketing clearance from the FDA for both the PIFA test system and Blood Cell Separator technology, the PIFA POC HPF4 rapid test can be introduced into the US market once scale-up activities are concluded.

From a clinical development perspective, we have a number of initiatives underway that support current and future versions of the PIFA HPF4 Rapid Assay. These developments should have both an immediate and long-term positive impact on sales. For example, in Q3 2010, we anticipate the completion of a pivotal study that is underway at the University of Miami and Jackson Memorial Hospital (Miami, Florida USA) in the Medical Intensive Care Unit. The interim data collected within the study protocol was presented by one of the principal investigators at the 30th International Symposium of Intensive Care and Emergency Medicine ("ISICEM") in Brussels, Belgium in March 2010. The authors concluded that a "negative PIFA test can quickly exclude the presence of anti-PF4 antibodies and therefore essentially rule out HIT as the cause of the thrombocytopenia." Since the PIFA test has been shown to be effective as a screening test, its use will prevent patients from receiving unnecessary, expensive, alternative anticoagulation therapy. Importantly, the PIFA test outperformed the standard laboratory test in this study. Because of these extremely positive conclusions, the Company has decided to expand the study to encompass a number of other healthcare facilities in the United States and abroad.

## BreathScan

ABI's BreathScan line incorporates our ***Micro Particle Catalyzed (MPC) Biosensor technology***. The BreathScan disposable breath alcohol detectors experienced close to a 10% growth rate in non-governmental sales in 2009. In the USA, we expanded our wholesale distribution network and signed a private label agreement with a veteran organisation focused solely on the breath alcohol detection market segment. Their contribution to sales was only relevant for the last two months of 2009 and, post year end, have continued to accelerate. In the USA, the Company is aggressively pursuing opportunities to expand the adoption of our BreathScan Privately-Owned Vehicle (POV) Safety Program by government and military personnel. This programme pairs a BreathScan detector with a custom, water-resistant key chain to render the breath alcohol device truly portable and available for use whenever and wherever it is needed.

To help streamline the purchasing process for eligible federal, state, and local contracting officers, ABI applied for, and was awarded, a United States Government Service Administration (GSA) Schedule contract in mid-December 2009. The GSA Schedule is one of the most widely accepted contract vehicles available to procurement officers at all levels of government. These qualified buyers can now contract directly with ABI for BreathScan and other products, and a variety of the Company's other disposable testing solutions. The GSA award provides ABI with a five-year contract listing of the prices the federal government has agreed to pay for the Company's varied product portfolio. The contract may be renewed for three additional five-year periods resulting in a twenty-year contract if all renewals are executed.

In addition to government-related entities, ABI is seeking to expand the use of the BreathScan plus Key Chain safety units to encompass other well-structured, Off-the-Job (OTJ) safety programs in the commercial sector. The US-based National Safety Council (NSC) reports that Off-the-Job injuries result in over \$200 billion in annual costs to society, and represents approximately 29% of all injury-related expenses that employers end up financing. The NSC and other occupational safety experts all agree that any investment in OTJ safety programs would be offset by savings in OTJ injury costs.

Post year end, the Company announced the initiation of production of a BreathScan alcohol detection product line extension that will be branded under the trade name, BreathScan PRO. BreathScan PRO merges the convenience of the Company's proprietary breath alcohol detection technology with the quantitative precision of an electronic analyser. The BreathScan PRO system will utilise a specially formulated disposable alcohol detector to collect a breath sample from each test subject. The used detector is then inserted into the BreathScan PRO digital analyser to obtain a quantitative breath alcohol level for each individual. Initially, the system will be marketed worldwide for forensic use by trained professionals, including those in civil and military law enforcement, human resources, educational supervision and other safety-related occupations. The Company intends to file for FDA and CE mark approvals in the near future. ABI will also seek an Over-the-Counter designation which would further expand the user base of the product in the United States.

From an international perspective, in 2010 ABI signed a licensing agreement with BreathScan International Ltd (BIL) granting them, in return for ABI being issued a 20% equity stake, the exclusive sales, marketing, and distribution rights to the BreathScan product line in the UK and Republic of Ireland for a period of five years. The organisation was also granted the non-exclusive right to develop opportunities internationally, outside of North America. The London-

based BIL will also have access to the BreathScan PRO as it will be CE-marked to facilitate sales in the EU.

### **The Free Radical Enzymatic Device (“FReD”)**

The Free Radical Enzymatic Device, a non-invasive, disposable breath-based test to measure free radical activity in the blood, also employs the Company’s proprietary **Micro Particle Catalyzed (MPC) Biosensor technology** platform. Free radicals are chemically unstable substances implicated in numerous disease processes and are often associated with the consumption of processed foods and alcohol, and the use of tobacco products. Antioxidants, available in many forms including vitamins and liquid supplements, help neutralise these free radicals. ABI, funded by Pulse Health (Pulse), who operate in the antioxidant, “nutraceutical” market in the USA, developed FReD to provide health-conscious consumers with a convenient way to monitor the efficacy of antioxidant therapy. In late 2008, Pulse purchased the rights to the technology pertaining to FReD, and also signed a multi-year supply agreement with ABI to produce the breath tests; ABI will also earn a royalty for every tube produced. In Q1 2010, ABI completed the Pulse-required user studies for the device and we hope to commence manufacturing of the product for our customer in the near future.

### **Battlefield Blood Transfusion Card**

The Battlefield Blood Transfusion Card, a **Particle ImmunoFiltration Assay test system**, has seen an increase in demand from military customers, as the product is featured on ABI’s GSA contract. This rapid blood typing card is used to assess donor-patient blood grouping compatibility in minutes, to help facilitate fresh whole blood transfusions in triage situations. The Battlefield Blood Transfusion Card is designed to enhance combat casualty care, especially when blood requirements outpace blood supplies. The clinical utility of this product can be appreciated with the fact that nearly 50% of blood transfusions in US military personnel are performed by medics under battlefield conditions. Our test is the only American-made blood typing card available for sale.

### **Product pipeline - Breath Ketone “Check” and Breath PulmoHealth “Check”**

ABI has two major tests in development, each of which addresses a vast international market, providing a rapid testing solution that we believe will benefit patients and the medical industry immensely. Clinical development of the Breath Ketone “Check” rapid test, incorporating the **Micro Particle Catalyzed (MPC) Biosensor technology** platform, was completed in Q2 2010, providing the Company with the study data needed for FDA 510(k) and CE-mark approvals, the latter of which has now been obtained. This first-in-class device detects the presence of ketones in a test subject’s breath condensate sample. Ketones are acids that have the potential to build up in the body causing a condition called ketosis, commonly associated with diabetes. An extreme form of this complication is a life-threatening medical emergency called ketoacidosis. At-risk populations for this severe form of ketosis include diabetics and persons who subscribe to restrictive ketogenic diets for epilepsy management or to obtain aggressive weight loss results.

To date the medical industry relies on blood- and urine-based ketone testing methods, both of which are invasive and inconvenient. Blood tests are more clinically relevant as ketones in the blood can be detected earlier than urine levels. ABI has identified that breath and blood ketone levels are closely correlated. As a result, Breath Ketone “Check” was designed to offer healthcare professionals a convenient, accurate way to identify the presence of ketones at the

earliest stages. The product's accuracy was demonstrated during clinical trials in which Breath Ketone "Check" results were compared to a standard laboratory method called gas chromatography/liquid chromatography (GC/LC), a technique that analyses a patient's whole blood sample to obtain a quantitative ketone reading. There was 100% agreement between the testing methodologies.

Given the aforementioned clinical profile and the rapid, non-invasive nature of the test, Breath Ketone "Check" may replace the need for routine blood and urine tests and thereby improve the quality of life for vulnerable populations. In addition, the confirmed accuracy of the test verifies that a Breath Ketone "Check" result will provide healthcare professionals with clinically-relevant data that can be integrated into a patient's treatment plan. The Company intends to begin marketing of the product in the EU where it has obtained a CE-mark and will be positioned as the only disposable ketone breath test in the world. A USA market introduction will be forthcoming pursuant to the necessary clearance from the FDA, for which the Company will soon apply.

The Breath PulmoHealth "Check", incorporating the ***Micro Particle Catalyzed (MPC) Biosensor technology***, continues to make positive progress in development. The disposable device is designed to be a simple, accurate diagnostic tool that medical professionals can use to screen patients demonstrating symptoms of, or at-risk for, lung cancer, or those in remission from the disease. Due to the chemical complexity of the test, the clinical programme was expanded and the Company looks forward to publishing the results of this clinical programme in the future.

## **Board Changes**

In line with the Company's efforts to streamline the board, Dr. Raymond F. Akers Jr., the founder of ABI, was appointed Executive Chairman in December 2009, with Edward Mulhare returning to his position of independent non executive director, chairing both the audit and remuneration committees. Charles Bunker, a non executive director, resigned from the board and we'd like to take this opportunity to thank him again for his service.

## **Outlook**

Notwithstanding the setback from a hiatus in United States Government departmental spending caused by a diversion of resources to aiding economic recovery, ABI has continued to grow unit sales of its core products and progress new product development. We are very encouraged by the progress of PIFA HPF4 now being represented by both of the USA's largest diagnostic product distributors, the excellent data from Breath Ketone "Check", which we expect to launch later this year, and the clinical programme of Breath PulmoHealth "Check". We believe that the scale of opportunity for our PIFA Heparin/PF4 Rapid Assay, BreathScan PRO, Breath Ketone "Check" and Breath PulmoHealth "Check" will be the transformational, long-term drivers of growth and value.

Thomas A. Nicolette, President & Chief Executive Officer  
Raymond F. Akers, Jr. PhD, Chairman  
21 June 2010

**As of 31 December 2009 and 2008**

	<b>2009</b>	<b>2008</b>
	<b>\$</b>	<b>\$</b>
<b>ASSETS</b>		
<b>Non-Current Assets</b>		
Property, plant and equipment, net	320,871	336,013
Intangible assets, net	2,134,617	2,739,943
Long-term Receivables, net of current portion	1,527,183	1,250,000
Other Assets	4,282	12,632
	<hr/>	<hr/>
<b>Total Non-Current Assets</b>	<b>4,341,581</b>	<b>4,338,588</b>
<b>Current Assets</b>		
Inventories (net)	677,352	409,085
Trade and other Receivables (net)	910,084	2,120,397
Cash and Cash Equivalents	2,648,973	4,311,381
Other Assets	105,172	94,812
	<hr/>	<hr/>
<b>Total Current Assets</b>	<b>4,341,581</b>	<b>6,935,675</b>
	<hr/>	<hr/>
<b>Total Assets</b>	<b>8,328,534</b>	<b>11,274,263</b>

	<b>2009</b>	<b>2008</b>
	<b>\$</b>	<b>\$</b>
<b>EQUITY (DEFICIT)</b>		
Share Capital	79,328,108	77,799,990
Accumulated Deficit	(72,149,745)	(67,521,728)
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<b>Total Equity (Deficit)</b>	<b>7,178,363</b>	<b>10,278,262</b>

**LIABILITIES****Current Liabilities**

Trade and Other Payables	1,150,171	906,001
Borrowings, net of discounts	-	90,000
<b>Total Current Liabilities</b>	<u>1,150,171</u>	<u>996,001</u>
<b>Total Liabilities</b>	<u>1,150,171</u>	<u>996,001</u>
<b>Total Equity and Liabilities</b>	<u>8,328,534</u>	<u>11,274,263</u>

**AKERS BIOSCIENCES, INC AND SUBSIDIARIES****Consolidated Statement of Operations****As of 31 December 2009 and 2008**

	<b>2009</b>	<b>2008</b>
	<b>\$</b>	<b>\$</b>
Revenues:		
Product Revenue	1,415,105	2,699,779
License Revenue	429,000	3,378,198
Total Revenue	1,844,105	6,077,977
Cost of Sales:		
Product Cost of Sales	(1,100,646)	(1,370,913)
License Cost of Sales	-	-
Total Cost of Sales	(1,100,646)	(1,370,913)
Gross Profit	743,459	4,707,064
Other Income	47,386	134,005

Administrative Expenses	2,805,513	1,695,642
Research and Development Expenses	662,082	430,782
Non-Cash Share Based Compensation	1,506,613	1,185,571
Amortization of Non-Current Assets	482,201	479,700
Impairment of Non-Current Assets	353,125	-
Income (Loss) from Operations	(5,018,689)	1,049,374
Other Income/Expenses		
Foreign Currency Transaction (Income)/Expense	(300,672)	1,001,788
(Gain)/Loss on Disposal of PP&E	(90,000)	-
Interest Expense	-	85,699
Non-Cash Interest Expense	-	1,196,301
Total Other Expense	(390,672)	2,283,788
Loss Before Income Taxes	(4,628,017)	(1,234,414)
Income Tax Benefit	-	699,612
Net Loss	(4,628,017)	(534,802)
	\$	\$
Basic & diluted loss per share	(0.04)	(0.01)
Weighted average basic & diluted common shares outstanding	113,503,858	92,706,529

**AKERS BIOSCIENCES, INC AND SUBSIDIARIES**  
**Consolidated Statements of Changes in Equity (Deficit)**  
**As of 31 December 2009 and 2008**

	Share Capital \$	Capital Reserves \$	Accumulated Deficit \$	Total Equity \$
<b>Balance at 31 December 2007</b>	66,543,545		(66,986,926)	(443,381)
<b>Changes in Equity (Deficit) for 2008</b>				
Net loss for the year			(534,802)	(534,802)
<b>Total recognized income &amp; expense for the period</b>	66,543,545	-	(67,521,728)	(978,183)
Recognition of share based payments for options & warrants	1,185,571			1,185,571
Issuance of shares for board of director fees	39,375			39,375
Issuance of shares for conversion of debt & accrued interest	5,409,822			5,409,822
Sale of ordinary shares for cash	4,566,710			4,566,710
Exercise of warrants & stock options	36,569			36,569
Issuance of shares for the conversion of accounts payable	18,398			18,398
<b>Balance at 31 December 2008</b>	77,799,990	-	(67,521,728)	10,278,262
<b>Changes in Equity (Deficit) for 2009</b>				
Net loss for the year			(4,628,017)	(4,628,017)
<b>Total recognized income &amp; expense for the period</b>	77,799,990	-	(72,149,745)	5,650,245
Recognition of share based payments for options & warrants	1,506,613			1,506,613
Exercise of warrants & stock options	21,505			21,505
<b>Balance at 31 December 2009</b>				

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79,328,108	-	(72,149,745)	7,178,363
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### **Annual General Meeting**

The Annual General Meeting of the Company will be held at 11.00am on 21 July 2010 at RiverWinds Community Center, 1000 RiverWinds Drive, Thorofare NJ 08086, USA

### **Annual Report and Accounts**

The Annual Report and Accounts will be posted to shareholders on 28 June 2010 and will be available thereafter on the Company's website: [www.akersbiosciences.com](http://www.akersbiosciences.com)