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### 82- SUBMISSIONS FACING SHEET

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REGISTRANT'S NAME

Diamyd Medical AB

\*CURRENT ADDRESS

Linnégatan 89 B

SE-115 23 Stockholm

Sweden

\*\*FORMER NAME

\*\*NEW ADDRESS

PROCESSED

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FISCAL YEAR

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**SCHEDULE I****Diamyd Medical AB  
(the "Company")****List of Documents Being Submitted to the  
Securities and Exchange Commission  
Pursuant to Rule 12g3-2(b)(1)(i)**

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8-31-05

No.	Date of Publication	Title of Document	Press Release	Made Public under Swedish Laws	Filed with SSE
1	01/20/06	Interim Report for Diamyd Medical AB (OPIX: DIAMB) September 1, 2005 - November 30, 2005		x	x
2	12/19/05	Diamyd Medical appoints protein sciences (USA) for production of its lead therapeutic diabetes vaccine for Phase III-trials and to submit an IND to the FDA	x		
3	12/15/05	Diamyd Medical demonstrates safety of new GAD formulation in pre-clinical study	x		
4	12/13/05	Diamyd Medical broadens diabetes pipeline with acquisition of Nurel Therapeutics	x		
5	12/12/05	Press Release from Annual General Meeting of Diamyd Medical (publ)	x	x	
5A	12/04/05	Diamyd Medical Annual Report 2004/05		x	x
6	11/25/05	Earlier reporting of results from Diamyd's diabetes clinical trial in juveniles in August 2006	x		
7	11/22/05	Diamyd Acquires American Biotechnology Company Nurel Therapeutics, Inc.	x	x	
9	10/27/05	Diamyd Medical retains the global consulting group as investor relations counsel	x		
10	10/26/05	Year End Report for Diamyd Medical AB (OMX: DIAMB) September 1 <sup>st</sup> , 2004 - August 31 <sup>st</sup> , 2005		x	x
11	10/07/05	Diamyd <sup>TM</sup> - a novel treatment for 10% of all Type 2 diabetes patients - in a fully recruited Phase II/III trial	x		
12	07/29/05	Nine-Month Report for Diamyd Medical AB (publ) 1 <sup>st</sup> September 2004 - 31 <sup>st</sup> May 2005		x	x
13	06/03/05	Diamyd's Gad Gene is a potential therapeutic for reducing pain associated with diabetes neuropathy and cancer	x		
14	05/13/05	Diamyd was wise to license GAD-technology for neurological therapeutics says UCLA professor.	x		
15	05/10/05	All patients in Diamyd's child clinical trial have	x		

No.	Date of Publication	Title of Document	Press Release	Made Public under Swedish Laws	Filed with SSE
		received full treatment			
16	05/9/05	Explanation	x	x	
17	04/20/05	Six-Month Report for Diamyd Medical AB (publ) September 1, 2004 - February 28, 2005		x	x
18	04/15/05	Patient recruitment completed for clinical trial of Diamyd™ in children	x		
19	04/07/05	Assoc. Prof. Bjorn Nilsson joins the Diamyd Medical Board of Directors	x	x	
20	01/20/05	Three month report for Diamyd Medical AB (publ) 1 <sup>st</sup> September 2004 - 30 <sup>th</sup> November, 2004		x	x
21	12/15/04	Medical Products Agency permit a Phase II clinical trial with the Diabetes vaccine Diamyd™ in children who have recently succumbed to insulin-dependent diabetes	x		
22	12/14/04	Diamyd Medical (O list) announces that more than 2,000 type 2 diabetes patients have expressed an interest in participating in the Company's vaccine study for autoimmune diabetes. Screening to find 160 patients with GAD antibodies is underway and vaccination of the first patients has begun	x		
23	12/10/04	Press Release from the Annual Shareholders Meeting of Diamyd Medical AB (publ)	x	x	
24	10/07/04	Diamyd starts larger trial in type 2 diabetes patients in Sweden	x		

**SCHEDULE II**

**Diamyd Medical AB**

**List Required by Rule 12g3-2(b)(1)(ii)**

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<b>Type of Information or Report</b>	<b>Required Date of Release</b>	<b>Required by</b>	<b>Method of Distribution</b>	
			<b>Publication</b>	<b>SSE</b>
Report of unaudited annual earnings	Immediately	SSE	X	X
Interim report	Quarterly/ Immediately	SSE	X	X
Significant change in reported unaudited annual earnings figures or interim report	Immediately	SSE	X	X
Change in published forecasts	Immediately	SSE	X	X
Notices to attend shareholders meetings	Immediately	SSE	X	X
Resolutions adopted at shareholders meetings in respect of dividends, changes in the board of directors and auditors and other significant information	Immediately	SSE	X	X
Issue of securities by the company or its subsidiaries that have to be approved by a general meeting of shareholders of the parent	Immediately	SSE	X	X
Decisions regarding exchange listing	Immediately	SSE	X	X
Information provided to or received from another marketplace, court or authority	Immediately	SSE	X	X
Changes in management	Immediately	SSE	X	X
Transactions with closely affiliated parties	Immediately	SSE	X	X
Report regarding proposed significant transfer of shares in a subsidiary or a significant transfer of business to an officer of the company	Immediately	SSE	X	X
Report regarding proposed significant acquisition of assets from an officer of the company	Immediately	SSE	X	X
Qualified auditors report			X	X

<b>Type of Information or Report</b>	<b>Required Date of Release</b>	<b>Required by</b>	<b>Method of Distribution</b>	
			<b>Publication</b>	<b>SSE</b>
Adoption of resolutions likely to materially affect the company's situation created by previously filed information or otherwise affect the valuation of company's securities	Immediately	SSE	X	X
Radical changes	Within a reasonable period of time	SSE	X	X
Purchase and sale of the company's own shares	Immediately	SSE	X	X
Criticism by the auditors	Immediately	SSE		X
Public tender offers	Immediately	SSE		X
Notification of an offer to the shareholders of the company by a third party	Immediately	SSE		X
Forecast adjustment	Prior to publication	SSE		X

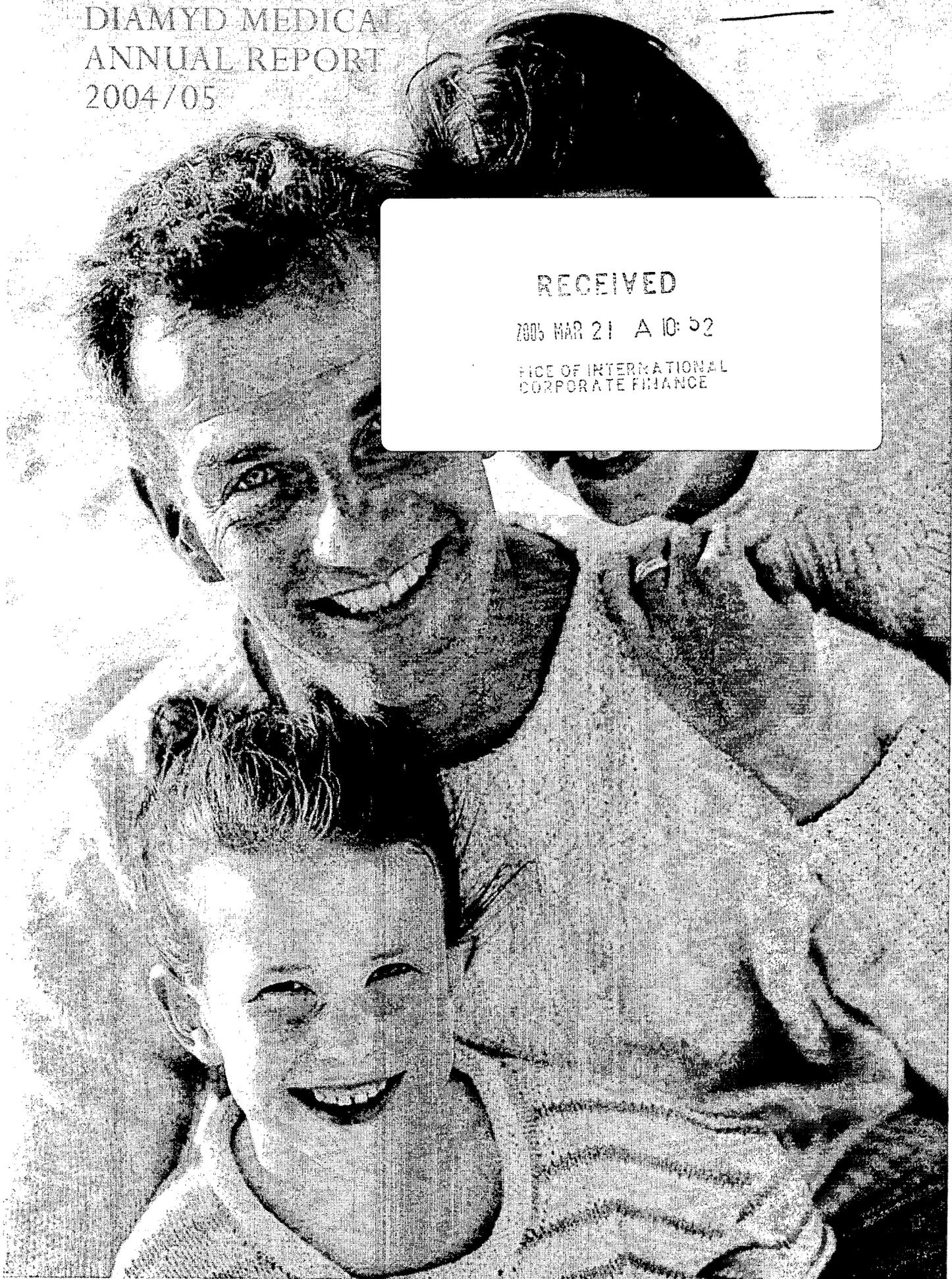
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DIAMYD MEDICAL  
ANNUAL REPORT  
2004/05

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# ABOUT DIAMYD MEDICAL

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Diamyd Medical conducts therapeutic development based on the GAD65 (glutamic acid decarboxylase) technology platform. 10% of all Type 2 diabetes patients have antibodies against GAD and hence a form of autoimmune diabetes (LADA). These patients are easily identified through routine blood sample analysis.

The Company previously reported 24-month result from a Phase II study with its lead candidate Diamyd™. The study was conducted on 47 LADA patients and a wide dose spectrum was examined with regard to safety and efficacy. The results indicated that Diamyd™ is safe to administer and that it also improves the level of insulin production instead of as previously assumed only slow down deterioration. The Company is now looking for a partnership for continued commercialization towards future marketing approval – at the same time – the development of Diamyd™ continues in a pivotal Phase II/III study in 160 patients with Type 2 diabetes. Results from the double-blinded phase is expected in June 2007.

Diamyd Medical also develops Diamyd™, for treatment of Type 1 diabetes. Diamyd™ is currently being tested in 70 juveniles with recent onset of Type 1 diabetes in a randomized, double-blind Phase II clinical trial. The disease develops when the body's immune system attacks the patient's own insulin-producing pancreatic beta cells. At disease onset, the patients generally have about 10% of their beta cells remaining. However, these are incapable of producing enough insulin in order to maintain the normal blood sugar level, and external insulin must be taken. After debut, the autoimmune attack continues against the remaining beta cells, which in time will be completely destroyed. Diamyd™ is intended to prevent the destruction of beta cells and at best to allow regeneration of beta cells without their continued attack by autoreactive immune cells.

The Diamyd Medical group (the Company) consists of the parent company Diamyd Medical AB, Diamyd Therapeutics AB, Diamyd Diagnostics AB and Diamyd, Inc. Diamyd Medical also owns a 19% stake in the biodiagnostic company Mercodia AB, which develops and markets diagnostic products, including those for diabetes. The Company was derived from Synectics Medical AB, which was founded by its CEO, Anders Essen-Möller, in 1976. In conjunction with the acquisition of Synectics Medical AB by Medtronic Inc. (USA) in 1996, shareholders were offered shares in Diamyd Medical.

## **FINANCIAL REPORT CALENDAR**

Annual General Shareholders' Meeting	12th December 2005
3-month report (September-November)	20th January 2006
6-month report	20th April 2006
9-month report	28th July 2006
Year End Report (September-August)	26th October 2006

Financial reports, press releases and other information are available on the Diamyd Medical web site, [www.diamyd.com](http://www.diamyd.com).

## **FOR INFORMATION REGARDING FINANCIAL ISSUES CONTACT:**

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SE-115 23 Stockholm  
Telephone: 08-661 00 26. Fax: 08-661 63 68  
E-mail: [investor.relations@diamyd.com](mailto:investor.relations@diamyd.com)

Diamyd shares have been registered on the Stockholm Stock Exchange O-list since June 2002.

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*This Annual Report is a translation from the Swedish original. No guarantees are made that the translation is free from errors. While the information in this Annual Report is believed to be accurate, no representations or warranties are made as to the accuracy and completeness of the contents and of any statement herein. This Annual Report may not be distributed for fundraising or investment purposes in any country where distribution presumes registration measures or is conflicting with the laws in such country. Any disputes arising out of the contents of this Annual Report shall be settled by Swedish law and by a Swedish court of law, exclusively. It should be noted that development companies in the Biotech area are subject to high risk.*

## PRESIDENT'S STATEMENT

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### **DEAR SHAREHOLDERS,**

Fiscal 2004/2005 was a year of significant accomplishments for Diamyd Medical. We initiated and completed treatment with our lead diabetes drug candidate, Diamyd™, in two clinical trials – one targeting Type 1 diabetes, the other targeting Type 2 diabetes. After more than 10 years of research and development, we are now getting close to a rather binary situation.

Very positive results were published from the first Phase II trial in Type 2 diabetes patients with GAD antibodies in the peer reviewed Journal of Diabetes and Its Complications (Volume 19, Issue 4, July-August, Pages 238-246). These results paved the way for the additional two Phase II studies.

In August 2006, we plan to present results from our Phase II study in 70 juvenile, Type 1 diabetes patients. At that time, we expect to report whether our drug is able to prevent beta cell destruction in patients with recent onset Type 1 diabetes. If “yes”, we also hope to show whether there is a chance that beta cells can regenerate and cure the disease.

In June 2007, we expect to achieve another major milestone in our Company's development – the results from the second Phase II study in 160 Type 2 adult diabetes patients. We hope that this study will be part of the registration filing and therefore are calling it a Phase II/III study. All of the patients in this study have GAD-antibodies that indicate their beta cells are under attack by the immune system, which may eventually lead to insulin dependency. We have completed the recruitment phase and treatment of all 160 patients.

The way towards market approval of Diamyd™ will include Phase III trials in several hundreds of patients in the US and Europe. We have continued discussions with several large pharmaceutical corporations, and these potential partners are waiting with interest for the Phase II study results.

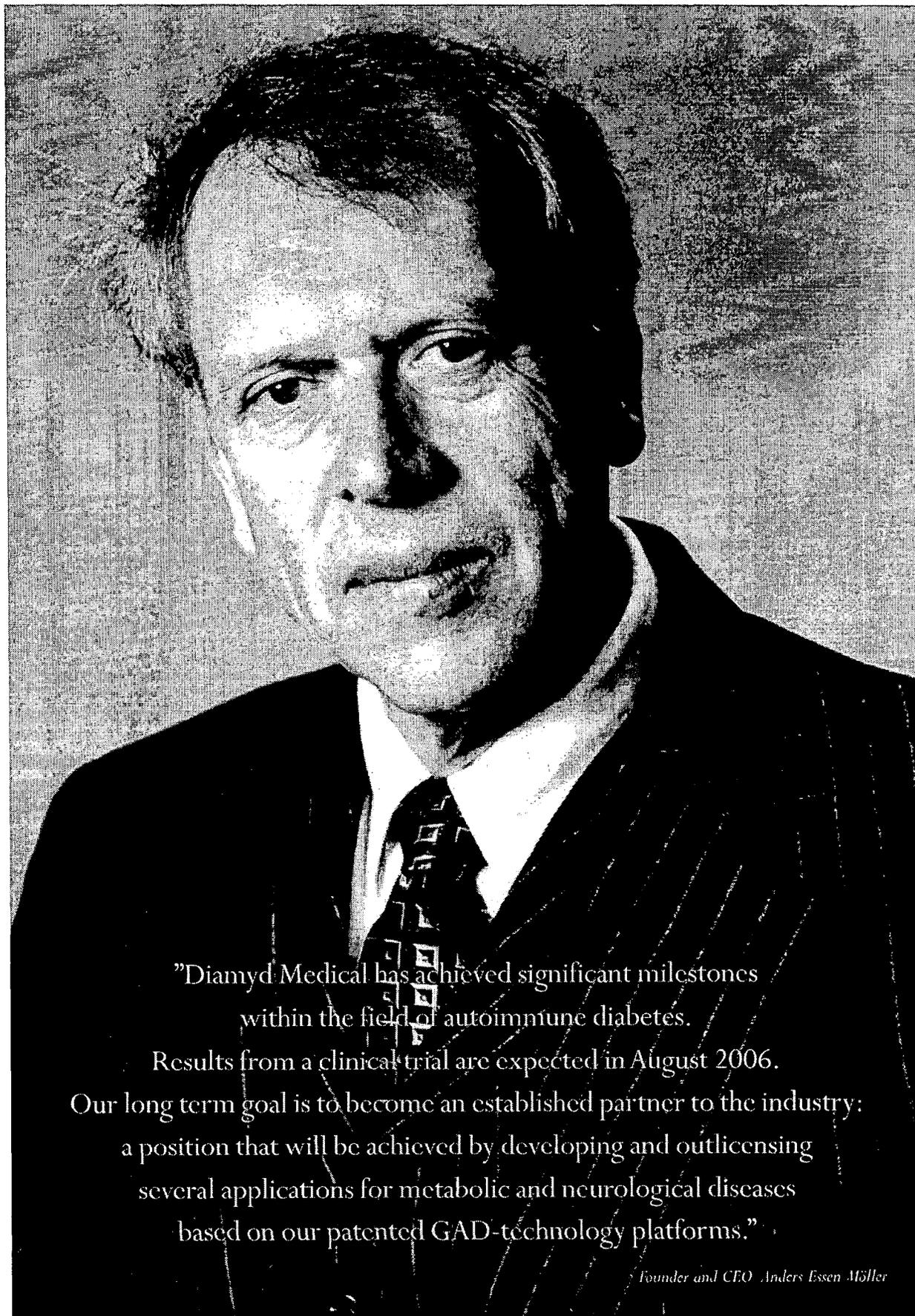
GAD65 is important not only as a potential major antigen in autoimmune diabetes, but also as an enzyme in several neurological diseases. GAD converts the excitatory amino acid Glutamate into the inhibitory transmitter GABA. During the past year, Diamyd has discussed collaboration opportunities with other parties in respect to developing therapies using GAD for certain neurological diseases. I am confident that some of these discussions may materialize within the coming fiscal year.

In response to increasing international interest in Diamyd, the Company has decided to increase its presence and awareness in the US. As a first step, we have elected to initiate a Level 1 ADR program, which will allow US investors to trade Diamyd shares directly in the US. In addition, this program will facilitate Diamyd's efforts to benefit from the world's largest capital market. As part of this initiative, we also appointed a renowned Investor Relations company to assist with our IR-matters in the US and arrange several road shows for us with interested US investors.

In closing, I would like to thank our shareholders for your continued interest and support of Diamyd. In addition, I wish to extend my appreciation to our patients for volunteering in our studies, and to our dedicated personnel for the outstanding contributions they have made this year.

We expect this year to be an equally exciting time.

Yours truly,  
Anders Essen-Möller  
Founder and CEO



"Diamyd Medical has achieved significant milestones within the field of autoimmune diabetes.

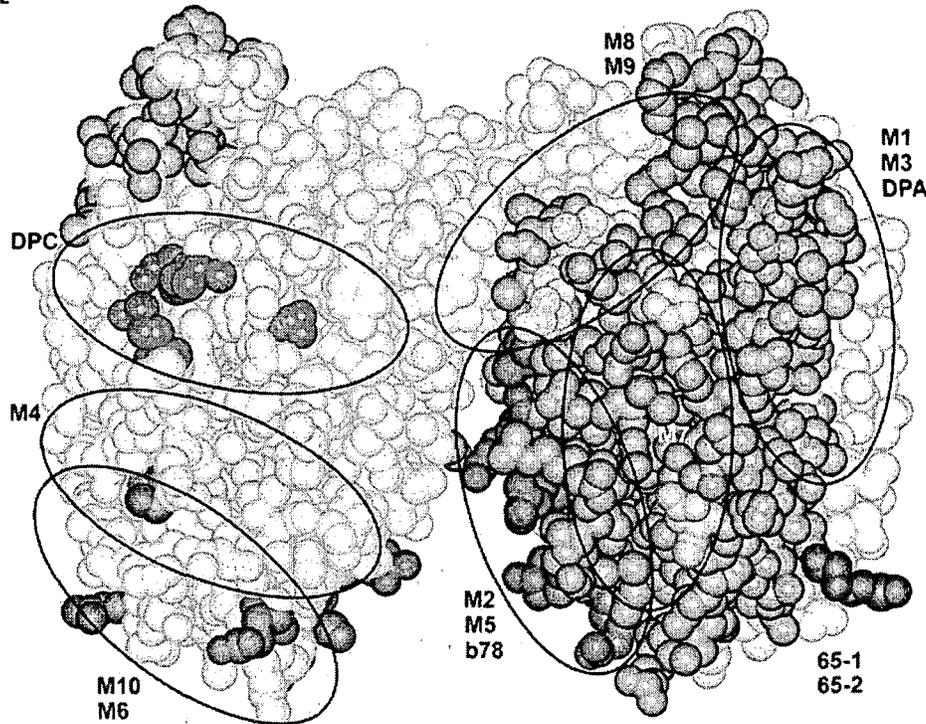
Results from a clinical trial are expected in August 2006.

Our long term goal is to become an established partner to the industry: a position that will be achieved by developing and outlicensing several applications for metabolic and neurological diseases based on our patented GAD-technology platforms."

*Founder and CEO Anders Essen Möller*

# DIAMYD MEDICAL'S TECHNOLOGY PLATFORM

## GAD65-MOLECULE



The figure illustrates the GAD65 molecule and epitopes and is reproduced by permission from Academic Press (*Journal of Molecular Biology* vol. 287, No. 5, April 16, 1999, pp. 983-999, Baekkeskov S, Schwartz HL).

The Diamyd Medical technology platform is based and focuses on GAD65 (glutamic acid decarboxylase) therapies for the treatment of metabolic and neurological diseases. GAD65 is an enzyme that converts the excitatory neurotransmitter glutamate to the inhibitory transmitter GABA. In this context, GAD65 may have an important role in CNS-related disease states. In addition, GAD65 may also target pancreatic beta cell autoantigen in autoimmune diabetes, which leads to the development of insulin-dependence. Diamyd™, the Company's lead diabetes drug candidate, is the furthest developed project. The drug is currently being studied for the treatment of both Type 1 and Type 2 diabetes in three clinical trials.

GAD65 antibodies are a diagnostic and prognostic marker of Type 1 diabetes (T1D), and both preclinical and clinical studies have confirmed that GAD65 is a very important antigen for the prediction and prevention of autoimmune diabetes.

Immunological tolerance is the aim of antigen-specific treat-

ment of autoimmune diseases. This means that an appropriate presentation of the autoantigen to the immune system enables the reprogramming of the antigen-specific immune response. To achieve immune tolerance, the antigen must be applied in the appropriate form, route, adjuvant, quantity and frequency of treatment – variables that impact on the induced effect. Upon achieving immune tolerance to the autoantigen administered, the autoimmune attack and disease onset may be arrested.

Administration of GAD65 may induce immune tolerance and prevent insulin dependence at an early stage of development of T1D. The induced regulation of the autoimmune process may be sufficient to maintain beta cell function, and thus remove the need for administration of exogenous insulin.

GAD65 is also an important candidate drug in several neurological diseases, given that under normal conditions GAD65 catalyzes the conversion of the amino acid glutamate to GABA, a neurotransmitter.



#### **DEVELOPMENT OF DIAMYD™ FOR TYPE 2 DIABETES PATIENTS**

Diamyd Medical is developing a pharmaceutical, Diamyd™, for treatment of autoimmune diabetes. Approximately 10% of all Type 2 diabetes patients have antibodies specific for GAD and therefore have a form of autoimmune diabetes (LADA). These patients are easily identified through routine blood sample analysis.

Diamyd Medical has previously conducted a successful small-scale dose-finding Phase II clinical trial of 47 LADA patients. To confirm the positive results obtained from this trial, a first larger-scale Phase II/III clinical trial intended to be part of registration of Diamyd™ is currently being conducted in 160 LADA patients. This trial is randomized, double-blind and placebo-controlled. The treatment group (80 patients) receives two injections of a 20µg dose of Diamyd™ (GAD65 formulated in alum) within a 30-day interval. The placebo group receives the same formulation without GAD65. The current trial is being conducted at 17 clinics throughout Sweden and is headed

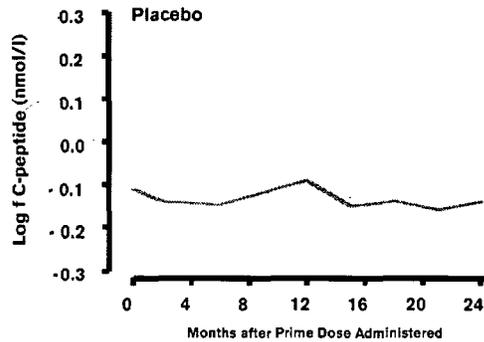
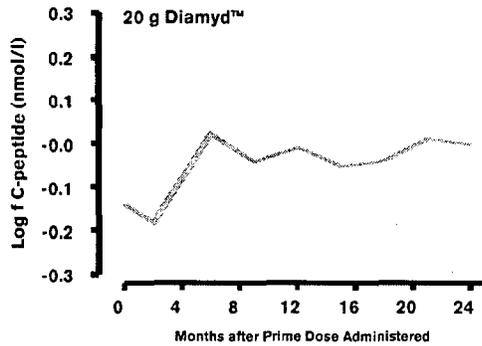
by Professor Carl-David Agardh of the University Hospital MAS in Malmö, Sweden. The Company plans to announce results of the trial in June 2007. Before applying for registration of Diamyd™, at least one additional Phase III clinical trial may be required.

#### **RESULTS FROM A FIRST DOSE-FINDING**

##### **PHASE II CLINICAL TRIAL IN LADA-PATIENTS**

Positive 24-month results from a Phase II clinical dose-finding trial of Diamyd™ were reported in 2004. The trial was conducted in 47 LADA patients and a broad dose range was studied with respect to safety and efficacy. The results indicate that the preparation is safe to administer and that Diamyd™ may even increase insulin (measured as C-peptide) production levels instead of just delaying the decrease, which is ongoing in patients with autoimmune diabetes.

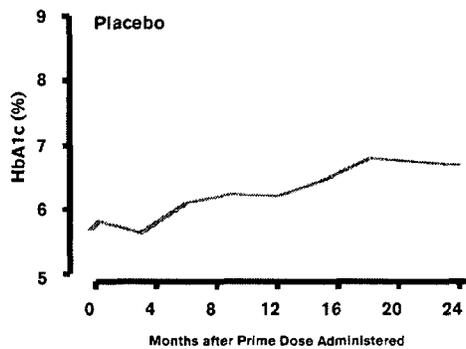
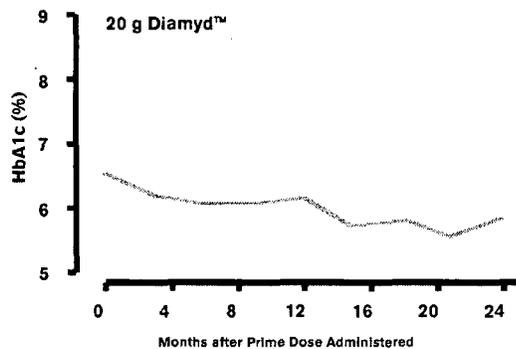
C-peptide levels versus time (months) at dose 2x20µg Diamyd™



It is interesting to note that the statistically positive effect on C-peptide (or insulin) levels observed in the 20 µg dose group was mediated by an elevated number of T cells that can down-regulate an autoimmune attack on islet beta cells. The latter outcome likely enhances beta cell survival and function, and thereby gives rise to improved insulin (C-peptide) production. We reason that both parameters, increased production of C-peptide and number of regulatory T cells, result directly from the Diamyd™ treatment.

Furthermore, these two effects were found to be associated with a decrease in glycated hemoglobin (HbA1c) after treatment with Diamyd™. This finding is exceedingly important because the serum level of HbA1c is widely used in the clinic to evaluate the efficacy of diabetes treatments. Thus, this result is highly compatible with the increase in C-peptide levels observed and the improved status of diabetes occurring in patients receiving 20 µg.

A1c levels versus time (months) at the dose 20µg



**PRICK TEST**

No adverse effects were recorded with a prick test in healthy individuals and patients with T1D, indicating a low risk for allergic reactions following Diamyd™ immunization.

partake in a double-blind, random study in which the GAD protein was injected subcutaneously in 1 to 4 doses with a maximal dose of 500 µg protein per individual.

**PHASE I CLINICAL TRIAL WITH DIAMYD™**

The Phase I clinical trial was designed to ascertain the clinical safety of the GAD protein, which had not previously been injected into people. Twenty-four healthy volunteers were chosen to

**THE RESULTS OF THIS PHASE I TRIAL MAY BE SUMMARIZED AS FOLLOWS:**

- No adverse effects were noted.
- The maximal dose of 500 µg/person was well tolerated.



**DEVELOPMENT OF DIAMYD™ FOR RECENT ONSET TYPE 1 DIABETES**

In addition to the development of Diamyd™ for autoimmune diabetes in Type 2 diabetes patients as described on the previous pages, Diamyd Medical is also developing Diamyd™ for treatment of Type 1 diabetes. Type 1 diabetes develops as the body's immune system attacks the patient's own insulin-producing pancreatic beta cells. At disease onset, the patients generally have about 10% of their beta cells remaining. However, these are incapable of producing enough insulin in order to maintain the normal blood sugar level, and external insulin must be taken. After debut, the autoimmune attack continues against the remaining beta cells, which in time will be completely destroyed. Diamyd™ is intended to prevent the destruction of beta cells and at best to allow regeneration of beta cells.

Diamyd™ is currently being tested in a Phase II trial with 70 juveniles with recent onset of Type 1 diabetes. The trial is randomized, double-blind and placebo controlled. 35 patients are receiving two injections with a 20µg dose of Diamyd™ (GAD65 formulated in aluminum hydroxide) with a 30-day interval, while the placebo group (also 35 patients) is receiving the same formulation without GAD65. The aim of the trial is to investigate whether the positive results obtained from the previous smaller-scale Phase II clinical trial involving Type 2 adult patients with GAD antibodies (LADA patients) can be reproduced in T1D patients. The trial is being conducted at eight clinics in Sweden and is headed by Professor Johnny Ludvigsson of Linköping University, Sweden. Diamyd Medical expects to report the results of the T1D Phase II trial in late August 2006.

# DIABETES – A COMMON CHRONIC DISEASE

The International Diabetes Foundation estimated in their 2003 global report that the number of individuals between 20-79 years of age with diabetes was 194 million. This figure is expected to rise to 333 million by the year 2025.

Similarly, it is estimated that the number of individuals with pre-diabetes, so-called 'Impaired Glucose Tolerance' (IGT) will increase from 314 million to 472 million during the same time period.

Of the people with diabetes or IGT, a significant minority are unaware of their disease. For example, in 2002 11 million Ameri-

cans were reported to be diagnosed with diabetes while 5 million were unaware of their condition (National Institute of Diabetes & Digestive & Kidney Diseases, NIDDK). During 2002, the number of individuals in the USA with Type 1 diabetes (insulin-dependent diabetes, juvenile diabetes) was approximately 1 million. The number of new cases of T1D is estimated at 40,000 per year, and the corresponding figure for Type 2 diabetes (T2D) is 660,000 per year.

According to the ADA, the annual cost for diabetes in the USA totaled more than 100 Bn US dollars in 2002.

**Regional estimates for diabetes and impaired glucose tolerance (20-79 age group), 2003 and 2025**

Region	2003					2025				
	Population (millions)	Diabetes prevalence (millions)	Diabetes prevalence (%)	IGT prevalence (millions)	IGT prevalence (%)	Diabetes prevalence (millions)	Diabetes prevalence (%)	IGT prevalence (millions)	IGT prevalence (%)	
AFR	295	7.1	2.4	21.4	7.3	541	15.0	2.8	39.4	7.3
EMME	276	19.2	7.0	18.7	6.8	494	39.4	8.0	36.5	7.4
EUR	621	48.4	7.8	63.2	10.2	646	58.6	9.1	70.6	10.9
NA	290	23.0	7.9	20.3	7.0	374	36.2	9.7	29.6	7.9
SACA	252	14.2	5.6	18.5	7.3	364	26.2	7.2	29.5	8.1
SEA	705	39.3	5.6	93.4	13.2	1,081	81.6	7.5	146.3	13.5
WP	1,384	43.0	3.1	78.5	5.7	1,751	75.8	4.3	120.2	6.9
<b>Total</b>	<b>3,823</b>	<b>194</b>	<b>5.1</b>	<b>314</b>	<b>8.2</b>	<b>5,251</b>	<b>333</b>	<b>6.3</b>	<b>472</b>	<b>9.0</b>

African Region (AFR)  
 Eastern Mediterranean and Middle East Region (EMME)  
 European Region (EUR)  
 North American Region (NA)  
 South and Central American Region (SACA)  
 South-East Asian Region (SEA)  
 Western Pacific Region (WP)

Source: Diabetes Atlas second edition, ©International Diabetes Federation, 2003

An overview of the completed or ongoing clinical studies with GAD65 is presented below:

STUDY TYPE	CRO, LOCATION	DATES	# OF PATIENTS	ENDPOINTS	OUTCOME
SKIN PRICK-TEST	KAROLINSKA HOSPITAL (SWEDEN)	1985	TYPE 1-DIABETES PATIENTS (7) HEALTHY CONTROLS (8)	DTH (DELAYED TYPE HYPER-SENSITIVITY)	NO DTH-REACTIONS TO GAD NO AES
PHASE I	PHARMACO.-LSR (UK)	1998	HEALTHY VOLUNTEERS (24)	SAFETY/TOLERABILITY	SAFE WELL TOLERATED
PHASE II A	CHILTERN INTERNATIONAL (SWEDEN)	2001-2003	LADA-PATIENTS (47)	SAFETY/EFFICACY	NO AES  IMMUNO-MODULATION DEMONSTRATED
PHASE II/III	CLINICAL DATA CARE (SWEDEN)	2004-	LADA-PATIENTS (180)	SAFETY/EFFICACY	JUNE 2007
PHASE II	CLINICAL DATA CARE (SWEDEN)	2004-	T1D-PATIENTS (70)	SAFETY/EFFICACY	AUGUST 2006

#### BRIEF DESCRIPTION OF DIABETES

In response to the increased level of sugar in the blood following a meal, pancreatic islet beta cells normally increase their production of insulin, which allows the sugar to be transported into fat or muscle cells as nutrients. The blood glucose level is thus reduced.

In conjunction with an unhealthy lifestyle (e.g. too much 'junk food'), a high blood sugar level is maintained which requires an increased production of insulin to downregulate this level. A side effect of this increased insulin production is a decrease in its effectiveness, which gives rise to insulin insensitivity. When insulin can no longer regulate the blood sugar level, then the condition termed Type 2 diabetes (T2D) or insulin-independent diabetes develops. About 10% of these individuals also develop an autoimmune disease in which the highly stressed pancreatic islet beta cells die and are exposed to the immune system. Cells of the immune system may recognize previously "sequestered" beta cell proteins, induce immune

responses directed at other beta cells, elicit beta cell destruction and thus reduce the body's ability to produce insulin. Such a condition is termed Type 1 diabetes (T1D). Individuals afflicted by T2D and then T1D are termed LADA (latent autoimmune diabetes in adults) patients and are identified by the presence of antibodies against GAD, an important autoantigen in diabetes.

Sensitivity to insulin varies among individuals. For example, during short exposures to high altitudes, increased insulin production may be required to maintain blood sugar levels at normal values. Insulin sensitivity also decreases in conjunction with stress or illness. Although stress may be transient, the impact of stress on beta cells can be overwhelming and lead to their demise, thereby exposing their normally sequestered proteins to the immune system, and in genetically predisposed individuals, initiate an autoimmune response that may promote the onset of T1D.

# SCIENTIFIC AND MEDICAL ADVISORY BOARD

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The Company has appointed a Scientific and Medical Advisory Board consisting of highly regarded researchers from the US, England and Sweden. The following individuals comprise the advisory board:

**PROFESSOR MARK ATKINSON, USA**, Ph.D., born 1958, is Professor in diabetes and Director of the Center for Immunology and Transplantation at the University of Florida. Atkinson was amongst the first group of researchers to identify the value of measuring immune responses against GAD, and to describe the white blood cell response against this protein in persons with the disease. Atkinson holds positions on a number of scientific advisory boards/research panels including the Juvenile Diabetes Research Foundation International (JDFI), the American Diabetes Association (ADA) and the National Institutes of Health (NIH) in the USA. Professor Atkinson's current research extends to understanding the molecular immunological and genetic mechanisms underlying the formation of diabetes, and his primary research goal lies in the development of an effective method for preventing Type 1 diabetes. Professor Atkinson has been a member of the Scientific and Medical Advisory Board since 1997.

**PROFESSOR DANIEL KAUFMAN, USA**, Ph.D., born 1956, is Professor within the Department of Molecular and Medical Pharmacology at the UCLA School of Medicine in Los Angeles, USA. Professor Kaufman's current research is focused on GAD and its relation to diabetes. In a research paper in November 1993, Professor Kaufman demonstrated that the administration of GAD to mice that would otherwise develop Type 1 diabetes prevented the outbreak of this disorder. Professor Kaufman was the first to clone a GAD gene and his lab was the first to demonstrate that a GAD treatment could inhibit diabetes in mice with established autoimmune responses. Professor Kaufman was a member of the group associated with Professor Allan J. Tobin, which was the first to submit a patent application for the full cDNA code for GAD, the patent portfolio that Diamyd Medical licenses. Professor Kaufman has been a member of the Scientific and Medical Advisory Board since 1996.

**PROFESSOR LARS KLAESKOG, SWEDEN**, MD, Ph.D., born 1944, is Professor of Rheumatology and Head of the Rheumatology Research Laboratory at the Center for Molecular Medicine at Karolinska University Hospital/Karolinska Institute, Sweden. Klareskog's research is specifically aimed at the origin and treatment of autoimmune disorders. Professor Klareskog has been a member of the Scientific and Medical Advisory Board since 1996.

**PROFESSOR ÅKE LERNMARK, USA**, MD, Ph.D., born 1945, is the Robert H. Williams Professor of Medicine at the University of

Washington in Seattle. He is also Professor of Experimental Diabetes at Lund University in the Department of Endocrinology at the University Hospital MAS in Malmö, Sweden. Professor Lernmark focused his attention on diabetes and at an early stage identified the antigen that later proved to be GAD. Professor Lernmark was first to demonstrate the presence of antibodies against GAD in cases of Type 1 diabetes, and to define the HLA genes that are necessary, but not sufficient to develop the disorder. Professor Lernmark has been a member of the Scientific and Medical Advisory Board since 1996.

**PROFESSOR DAVID LESLIE, ENGLAND**, MD, Ph.D., born 1949, is Professor of Diabetes and Autoimmunity at the Royal London and St. Bartholomew's School of Medicine, University of London. He has been involved in diabetes research and clinical studies since 1975. Professor Leslie has been Director of the British Diabetic Twin Study since 1982, the world's largest twin study of its type. By studying twins, Professor Leslie has been able to show the possibilities for predicting and preventing diabetes. Professor Leslie has been a member of the Scientific and Medical Advisory Board since 1999.

**PROFESSOR MARCO LONDEI, ENGLAND**, MD, Ph.D., born 1956, is professor at the Institute of Child Health, University College London. Professor Londei's research has been concentrated on T cells in autoimmunity. The original studies that Londei performed provided evidence that human self-reactive T cells are cloned from the site of autoimmune lesion (in Grave's Thyroiditis). This knowledge can be of importance in the diagnosis and risk for insulin-dependent diabetes – in which self-reactive T cells escape central tolerance (thymus-based) and are activated in the periphery, initiating autoimmune diseases. Professor Londei has been a member of the Scientific and Medical Advisory Board since 2000.

**PROFESSOR ALLAN J. TOBIN, USA**, Ph.D., born 1941, is Managing Director of MRSSI Inc., which advises the High Q Foundation and CHDI, organizations dedicated to finding therapeutics for Huntington's disease. Previously, Professor Tobin was Eleanor Leslie Chair of Neuroscience and Director of the Brain Research Institute at UCLA, Los Angeles, USA. Professor Tobin is also Scientific Director Emeritus of the Hereditary Disease Foundation, which organized the identification of the gene that causes Huntington's disease. Professor Tobin has specialized in the use of molecular methods for synthesis, function and breaking down of GABA, which serves as the major inhibitory signal in the brain and the pancreas. Professor Tobin has been a member of the Scientific and Medical Advisory Board since 1996.

## COMPANY OVERVIEW 2004/05

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### SIGNIFICANT EVENTS IN DIAMYD MEDICAL 2004/05

- Initiation of a Phase II/III clinical trial study in 160 Type 2 diabetes patients.
- Initiation of a Phase II clinical trial study in 70 juveniles with recent onset of Type 1 diabetes.
- Associate Professor Björn O. Nilsson joined the Diamyd Medical board of directors. Nilsson is Chairman of the SwedenBio organization, and was former CEO of KaroBio.

### IMPORTANT EVENTS AFTER THE REPORT PERIOD

- All 160 patients in the ongoing Phase II/III clinical trial study were recruited and treated. Patients were easily identified through routine blood sample analysis.
- Joseph Janes, 40, Juris Doctor, was proposed and elected as a new Diamyd Medical Board director at the Annual Shareholders Meeting in December, 2005. Janes has more than 15 years of experience in corporate law, having worked with leading law firms and American Fortune 500 companies.

### FUTURE PROSPECTS

The positive results regarding clinical safety from the first Phase II clinical trial have fostered and intensified the development of Diamyd™. Negotiations are being held with established biotech companies in order to further develop Diamyd™ into a marketable product.

The Company has made good progress in the treatment of autoimmune diabetes, as demonstrated by the results achieved in the early Phase II trial for LADA patients. Diamyd Medical is focusing its resources on nurturing the value of this project, preparing the production technology to take the drug to market, analyzing achieved results and continuing significant clinical development. Diamyd Medical intends to secure a collaborative agreement with an established pharmaceutical company, by which Diamyd Medical would retain royalty payments based on future sales of the diabetes therapeutic Diamyd™.

With the aim of maximizing the use of the Company's patent portfolio, other potential applications such as metabolic and neurological diseases are being investigated. In addition to developing Diamyd™ as a significant treatment in the fight against diabetes, Diamyd Medical also has set long-term goals of forming relationships with established partners and out-licensing a number of applications from the GAD-platform.

## GROUP'S FINANCIAL OVERVIEW 2004/05

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■ Liquid assets amount to MSEK 115.5 (MSEK 151.3) as of August, 2005 and are estimated to last until 31st December 2007.

■ The Group's costs were MSEK 40.8 (MSEK 19.5).

■ The year's loss was MSEK -36.6 (MSEK -16.0).

■ Earnings per share was SEK -4.4 (SEK -3.0).

■ The costs for Research and Development amounted to MSEK 24.7 (MSEK 4.2).

The costs have increased as the Company runs 3 clinical trials at 25 different clinics all over Sweden. Other increasing costs are employee related.

■ Sales amounted to MSEK 0.9 (MSEK 1.7). Of these sales MSEK 0.3 were from the Company's subsidiary in the US.

■ As of August 31, 2005, the number of outstanding shares was 8,418,043 (8,345,480) of which 471,200 (471,200) were A-shares and 7,946,843 (7,874,280) were B-shares.

■ The Company also has a Warrant program consisting of 917,655 warrants and an option program 2004/07 consisting of 200,000 subscription options. The maximum dilution from these two programs is 13.3%.

■ During the fiscal year the share price changed by 15.6% (-33.1%) compared with the SX All-Share Index which during the same period rose by 26.5% (14.4%).

# A SUMMARY OF FINANCIAL DEVELOPMENTS

<b>Key Ratios in Summary</b>	<b>04/05</b>	<b>03/04</b>	<b>02/03</b>	<b>01/02</b>	<b>00/01</b>
Earnings per Share, SEK	-4.4	-3.0	-3.7	-4.6	-3.4
Earnings per Share after dilution, SEK	-4.4	-3.0	-3.7	-4.6	-3.4
Number of Outstanding Shares	8,418,043	8,345,480	4,615,471	4,603,239	3,841,025
Return on Equity, %	-27.4%	-18.2%	-53.0%	-53.3%	-34.9%
Return on Total Capital, %	-25.8%	-16.9%	-44.0%	-45.8%	-29.7%
Solidity, %	92.0%	96.1%	76.5%	87.3%	84.1%
Return on the Diamyd Share, %	15.60%	-33.10%	110.60%	-13.20%	-52.50%
Equity per Share, SEK	13.7	18.2	5.2	8.9	8.1
Market Cap., MSEK	450.4	388.1	320.8	151.9	146.0
<b>Summary of Statement of Earnings, kSEK</b>	<b>04/05</b>	<b>03/04</b>	<b>02/03</b>	<b>01/02</b>	<b>00/01</b>
Operating Income	931	2,603	2,342	3,082	997
Operating Expense	-40,821	-19,540	-20,628	-23,987	-15,398
Operating Loss	-39,890	-16,936	-18,286	-20,905	-14,401
Financial Income and Expense	3,321	947	1,082	1,702	1,317
Total Loss after Financial Income	-36,569	-15,990	-17,204	-19,203	-13,084
<b>Net Loss for the Year</b>	<b>-36,632</b>	<b>-15,990</b>	<b>-17,204</b>	<b>-19,203</b>	<b>-13,044</b>
<b>Summary of Operating Costs, kSEK</b>	<b>04/05</b>	<b>03/04</b>	<b>02/03</b>	<b>01/02</b>	<b>00/01</b>
Raw Materials and Supplies	-775	-795	-1,415	-279	-307
R&D Costs	-24,676	-4,165	-9,372	-11,223	-5,891
Patent Costs	-1,719	-1,369	-1,356	-1,387	-1,482
Staff Costs	-8,698	-6,077	-5,256	-4,541	-3,283
Other External Costs	-4,052	-6,224	-2,236	-4,139	-2,650
Depreciation	-901	-883	-993	-2,418	-1,785
<b>Total Operating Costs</b>	<b>-40,821</b>	<b>-19,540</b>	<b>-20,628</b>	<b>-23,987</b>	<b>-15,398</b>
<b>Summary of the Balance Sheet (Group)</b>	<b>Aug 31</b>				
	<b>2005</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>
<b>Fixed Assets</b>					
Tangible Assets	220	337	251	382	246
Intangible Fixed Assets	1,309	2,060	2,820	2,240	3,020
Financial Assets	800	800	800	800	400
<b>Total Fixed Assets</b>	<b>2,329</b>	<b>3,197</b>	<b>3,871</b>	<b>3,422</b>	<b>3,666</b>
<b>Current Assets</b>	<b>04/05</b>	<b>03/04</b>	<b>02/03</b>	<b>01/02</b>	<b>00/01</b>
Inventory	8	90	125	775	-
Trade & Other Receivables	7,601	3,086	2,525	3,121	1,574
Short term Investments	91,374	89,608	9,398	34,245	23,201
Cash and Bank Balances	24,161	61,730	15,284	5,505	8,348
Total Current Assets	123,144	154,514	27,332	43,646	33,123
<b>Total Assets</b>	<b>125,473</b>	<b>157,711</b>	<b>31,203</b>	<b>47,068</b>	<b>36,789</b>
<b>Shareholders' Equity &amp; Liabilities</b>	<b>04/05</b>	<b>03/04</b>	<b>02/03</b>	<b>01/02</b>	<b>00/01</b>
Shareholders' Equity	115,468	151,598	23,867	41,084	30,926
Long term Liabilities	-	768	768	768	768
Current Liabilities	10,005	5,345	6,568	5,216	5,095
<b>Total Liabilities and Shareholders' Equity</b>	<b>125,473</b>	<b>157,711</b>	<b>31,203</b>	<b>47,068</b>	<b>36,789</b>
<b>Summary of Cash Flow</b>	<b>04/05</b>	<b>03/04</b>	<b>02/03</b>	<b>01/02</b>	<b>00/01</b>
Cash Flow Before Changes in Working Capital	-35,790	-14,910	-15,842	-15,335	-11,342
Changes in Working Capital	-481	-1,875	2,243	-3,654	-1,448
Cash Flow from Current Operations	-36,271	-16,785	-13,599	-18,989	-12,790
Cash Flow from Investment Business	-30	-210	-1,445	-2,174	-112
Cash Flow from Financial Operations	500	143,680	-	29,363	156
Cash Flow for the Period	-35,801	126,685	-15,044	8,201	-12,746
<b>Liquid Assets at the End of the Period</b>	<b>115,535</b>	<b>151,338</b>	<b>24,682</b>	<b>34,750</b>	<b>31,549</b>

# DIAMYD MEDICAL'S OPERATIONS

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## **BUSINESS CONCEPT**

The goal for Diamyd™, which is being developed for autoimmune diabetes is to eliminate or reduce the need for insulin treatment. The Diamyd Medical business plan is to use its competence and contact network in immunology, biotechnology and business development to identify and develop pharmaceutical projects through clinical trials. Thereafter, partnering will be sought with established pharmaceutical companies for further commercialization.

Development and marketing of related diagnostic tests and reagents may be undertaken to promote contact with researchers and to prepare the market for subsequent pharmaceutical product launches.

The Company's long-term aim, in addition to that of Diamyd™ in the treatment and prevention of diabetes, is to become a recognized partner with established pharmaceutical companies, a position that will be achieved by developing further applications of the GAD technology platform.

## **COMPANY STRUCTURE**

Presently, the organization consists of the parent company, Diamyd Medical AB (publ) with the fully owned subsidiaries Diamyd Therapeutics AB, Diamyd Diagnostics AB and the affiliated company Diamyd, Inc., USA. The administrative head office is based in the city of Stockholm.

Diamyd Therapeutics focuses on the development of pharmaceuticals. Diamyd Diagnostics AB develops and markets related diagnostic products. Diamyd, Inc., markets the Company's own products and acts as agents for products within the diagnostics field.

In addition, Diamyd Medical owns 19% of the Uppsala-based company Mercodia AB, which is specialized in the development and marketing of diagnostic products within the diabetes and cardio-vascular areas.

## **RESEARCH AND DEVELOPMENT**

Since the establishment of Diamyd Medical in 1996, the Company has adhered to the practice of strategic outsourcing for all R&D operations, which provides access to experts and facilities as well as the possibility of maintaining a high rate of development. Diamyd™ activities accounts for approximately 20 outsourced tasks.

The infrastructure established for communication, control and follow-up of outsourced activities, both internally and externally, has enabled the Company to rapidly and effectively advance its first therapeutic project to Phase II/III clinical trials. Large pharmaceutical companies are placing roughly 25% of their research and development activities in contracts primarily due to the fluctuations in current projects. As strategic outsourcing is adapted as an industrial standard, a large amount of companies are now focusing on supplying outsourcing services. For example many companies now are specializing in the identification of developable substances, growth of GLP- and GMP-production processes, formulation of medicines and the perfor-

mance of preclinical trial and clinical trial studies. Furthermore, Contract Research Organizations (CROs') can provide assistance in regulatory queries, design and produce clinical protocols.

The process of developing a therapeutic fundamentally evolves from the identification of a suitable substance, production process, preclinical trials, clinical trial studies (Phase I, II, III) and a registration filing in different countries.

## **THE PROCESS OF DEVELOPING A THERAPEUTIC**

Biologics are often endogenous proteins that are produced via recombinant DNA technology, whereas conventional therapeutic drugs are frequently synthetic molecules that are "foreign" to man. The time from the identification of a candidate therapeutic molecule to market often requires more than 15 years of development.

### *Identification Phase*

First, a candidate therapeutic molecule needs to be identified that can be protected by a patent. Then a full development program must be defined.

### *Pre-clinical Safety Evaluation*

The candidate therapeutic is tested in several non-human systems to assess its safety and efficacy. Such animal studies are a pre-requisite for approval from regulatory agencies prior to testing in man.

### *Clinical Trials*

Candidate therapeutics are then entered into clinical trials in human subjects. These usually consist of three phases:

#### *Phase I*

This involves studies in a small number of healthy volunteers aimed at assessing safety and tolerability.

#### *Phase II*

Phase II involves a small number of patients and aims to confirm safety (i.e., the substance has no side-effects) and to identify suitable dose.

#### *Phase III*

To confirm clinical safety and efficacy, the candidate therapeutic is tested in a larger group of patients. Only after completion and full analysis of the Phase III study will it be apparent if the candidate therapeutic fulfills all the criteria required for marketing approval.

## **ENVIRONMENTAL AND QUALITY CHECK-UP**

Diamyd Medical continuously strives for quality, in all areas of the organization, and the Company's established environmental program is constantly improving. The Company board has accepted an environmental policy where safety, health and environment are essential fundamental requirements for the Company to be



successful. Diamyd Medical, along with its collaborating companies, attempt to minimize the impact on the surrounding environment.

Diamyd Medical shall always publish results, to the extent possible, in order to mediate information regarding important findings to researchers.

During the year, the Company has been present at several international diabetes conferences and presented results from a Diamyd™ Phase II study.

The substances and processes used by Diamyd Medical are not a subject of cloning or genetic manipulation. Animal testing made to guarantee the safety and efficiency of Diamyd™ was performed by professionals.

#### **SALES, CUSTOMERS AND SUPPLIERS**

Diamyd Medical Group has divided sales into three business segments, of which the largest is the out-licensing of the GAD technology, a segment which today only has costs and no income. In addition to this business segment the group has some sales of products related to the GAD technology. The third segment is comprised of other supplemental products.

#### *Out-licensing of Diamyd™*

The main business of Diamyd Medical is the development of a pharmaceutical for diabetes patients who have GAD-antibodies. Currently no out-licensing agreement has been made, but future plans include this.

#### *GAD-related Products*

These products are comprised of the GAD protein (the active ingredient in Diamyd™). The products are sold to researchers and laboratories. The sales are mainly a way to prepare the market for the upcoming product Diamyd™, which is under development.

#### *Other Products*

The Company also markets a number of agency products as a part of its strategy to be a leading company in autoimmune diagnostics.

#### *Suppliers*

The Company's suppliers primarily consist of Contract Research Organizations (CROs) in addition to other consultants and specialists.

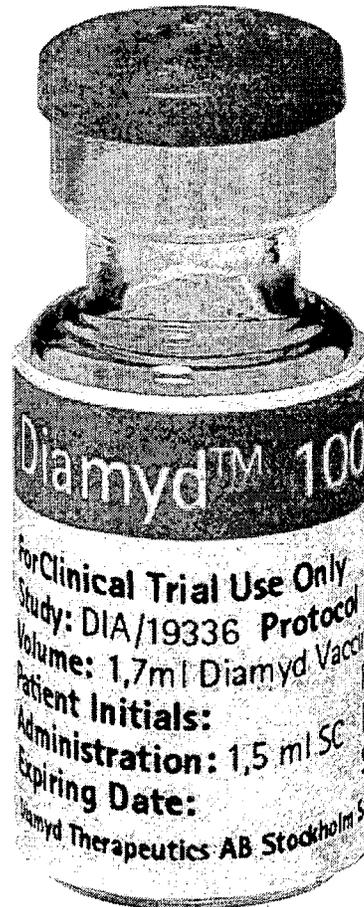
#### **PATENTS AND TRADEMARK**

An important part of the Company's strategy is to protect its projects with its own or licensed patents. The Company has licensed exclusive patent rights for the treatment of diabetes with GAD65 or the GAD65 gene. Of particular interest are the Company's exclusive licenses with the University of California in Los Angeles (UCLA) and the University of Florida in Gainesville (UF). Preservation of patent rights is critical for development of therapeutics, for which the economic investment is considerable.

The GAD65 gene and its protein also have potential for therapeutic applications in other metabolic and neurological diseases such as obesity, Parkinson's disease, epilepsy, SPS and Batten's syndrome and more. The licensed patents protect the Company's use of GAD65 until the year 2021 in the U.S., and to the year 2016 (including extensions) in Europe. In addition to the exclusive rights to therapeutic use of GAD65, the Company licenses UCLA and UF non-exclusive rights to GAD-based diagnostic applications.

In addition, U.S. patent rights covering a method for identifying non-insulin dependent diabetics who are at risk of developing insulin dependent diabetes (LADA-patients) are exclusively licensed from the University of Washington in Seattle.

The Company has been granted its own patent in the U.S. and Europe pertaining to a modified GAD molecule that lacks enzymatic activity but retains the protein's immunological characteristics.



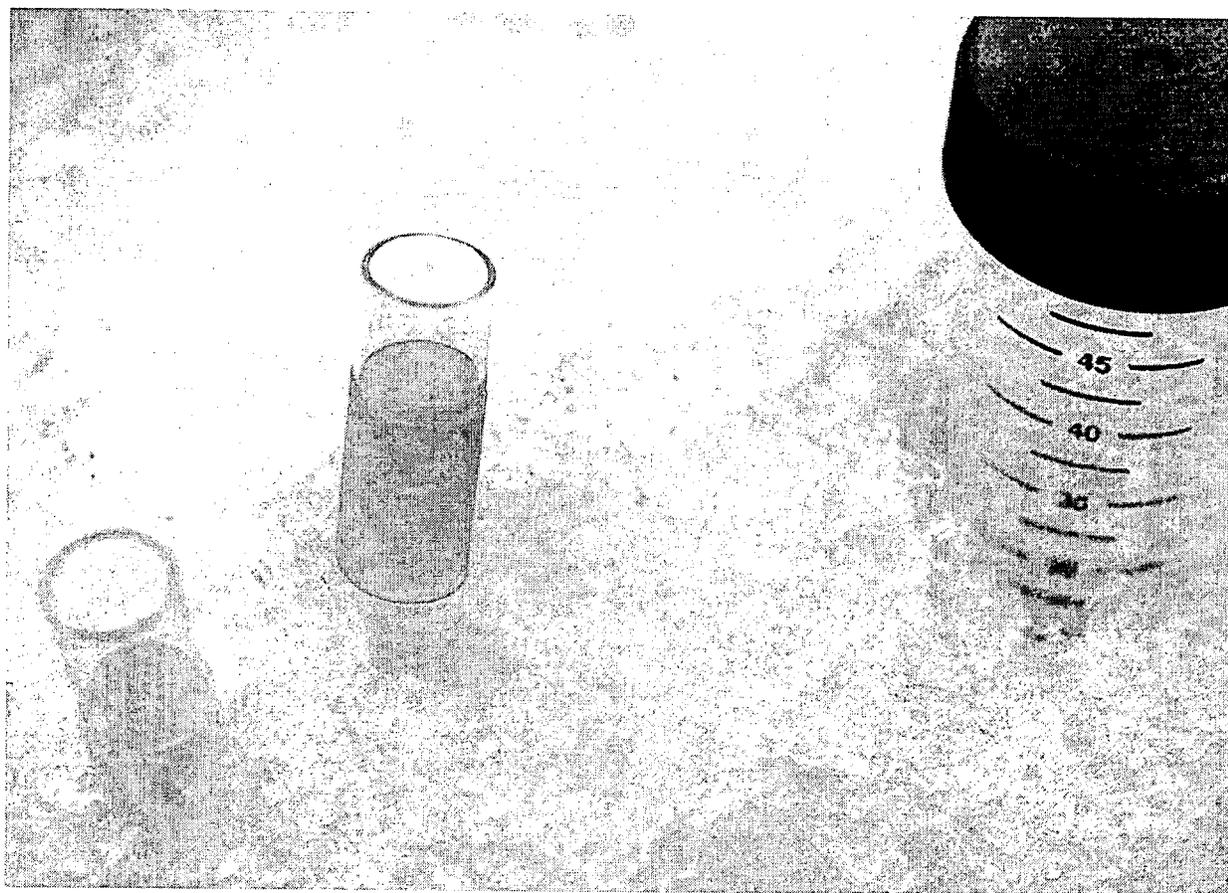
*Diamyd™ currently in three clinical trials.*

#### **GOALS AND STRATEGY**

Diamyd Medical's aim is to cure autoimmune diabetes. The Company's business idea is to use its competence and contact network in immunology, biotechnology and business development to identify and develop pharmaceutical projects through clinical trials. Thereafter, partnering will be sought with larger pharmaceutical companies for further commercialization.

Diamyd Medical's resources are focused on adding value to the project by preparing for production technology in view of market demand, further analyzing the results obtained, and increasing the clinical development. Concomitantly, the Company is seeking to identify a pharmaceutical company that can take Diamyd™ to market.

To maximize the use of the Company's patent rights, research has been initiated to investigate applications in other metabolic diseases and neurological diseases.



## THE COMPETITION

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Diamyd Medical competes generally with other biotechnology companies that, with their own candidate drugs, attempt to partner with established pharmaceutical companies.

Diamyd Medical selected the full-length GAD molecule as the active substance in its diabetes therapeutic. Alternative strategies being tested by competitors are based on molecules other than GAD.

These include oral insulin, insulin peptide ligands, heat shock protein peptide ligands and anti-T cell antibodies, among others. The following section gives an overview of some of these alternative techniques that are being developed for treatment of autoimmune diabetes. Apart from Diamyd Medical, three other biotechnology companies have immunomodulatory substances in Phase II clinical trials:

Roche studies Daclizumab, a monoclonal antibody that is approved as an immunosuppressant in relation to kidney transplantation in Type 1 diabetics. During 2003, interim results were presented from their clinical trial, which indicated that Daclizumab is well-tolerated and imparts a preserved endogenous insulin production compared to intensive insulin therapy.

Neurocrine has developed a modified insulin peptide. A Phase II clinical trial with Type 1 diabetics is in progress.

Neurocrine and Taisho began a collaboration in 2000, which gave Taisho exclusive rights to develop and commercialize the product. Taisho retracted this agreement during 2003 without explanation.

Peptor and Aventis agreed on a collaboration in July 2002 regarding the peptide AVE-277. This agreement was terminated in 2004 and AVE-277 was returned to Peptor, who has now joined forces with the German company Develogen. Develogen is conducting Phase II clinical trials in both LADA- and Type 1 patients.

The Company's understanding is that Diamyd™ has a significant advantage compared to other therapies in that it is aimed specifically at the self-reactive T cells that attack the islet beta cells.

This enhances the likelihood of both a positive outcome as well as reduced side effects with Diamyd™ treatment. If any of the above-mentioned, or any other un-named alternative strategy, should be shown to be successful, this does not mean that GAD administration would be excluded.

Rather, it could be an attractive complement in a combination therapy in which the different treatment strategies confront various pathways of the disease process.

# BOARD, KEY EXECUTIVES AND ACCOUNTANTS

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## THE BOARD

**LEIF EK**, born 1940, Stockholm, Dr. hc, M.Sc. in Economics, M.Sc. in Engineering, has been a Board member of Diamyd Medical since December 2001. Other assignments: Ek is board member of Boule Diagnostics AB. Ek was previously President of Nobelpharma AB, Pharmacia Diagnostics AB and Skandigen AB. Holdings: 5, 000 subscription options 2004/07.

**ANDERS ESSEN-MÖLLER**, born 1941, Stockholm, M.Sc. in Engineering, is founder and CEO of Diamyd Medical AB and member of the Board since 1996. Essen-Möller was also founder of Synectics Medical AB, which was sold to Medtronic, Inc., in 1996. Other assignments: Chairman of Armea AB. Holdings: 471,200 A-shares, 193,551 B-shares and 89,304 options TO1A and 34,033 options TO1B and 30, 000 subscription options 2004/07.

**TORD LENDAU**, born 1957, Stockholm, is CEO of Artimpant AB and a Board member of Diamyd Medical AB since 1996. 2004 Lendau was elected Chairman of the Board. Lendau participated in 1994 as president in Synectics Medical AB in the initiation of Diamyd Medical AB. Other assignments: Lendau is a Board member of ArthroCare, Inc. Previously, he was the President of Noster System AB and before that General Manager of Medtronic Synectics AB. Holdings: 500 B shares and 5, 000 subscription options 2004/07.

**PETER ROTHSCHILD**, born 1950, Stockholm, M.Sc. in Engineering, CEO of BioGaia AB and a Board member of Diamyd Medical AB since 2001. Other assignments: Rothschild is also a Board member of Perlan Dialog och Ledarskap AB. Holdings: 5, 000 subscription options 2004/07.

## KEY EXECUTIVES

**CEO IS ANDERS ESSEN-MÖLLER.** (See the Board).

**MEDICAL DIRECTOR IS ANN-SOPHIE BENNET**, MD, born 1950. Bennet has extensive experience in the pharmaceutical industry. Bennet has a specialist competence in both internal medicine and gene-

ral medicine and worked most recently for Schering-Plough AB as Medical Director. Holdings: None.

**CHIEF FINANCIAL OFFICER IS MAGNUS THOLÉN SVENSSON**, born 1972, M.Sc. in Economics and Business Administration from the Stockholm School of Economics. Tholén Svensson has worked for the Company since 2002. Holdings: 15, 000 subscription options 2004/07.

**DIRECTOR OF R&D IS JOHN ROBERTSON**, Ph.D., born 1952, Stockholm. Robertson has worked for the Company since 1996. Robertson has an international background with experience in biotechnology and toxicology, both from institutes (Karolinska Institute and Novum Research Park, Stockholm, The Pasteur Institute in Paris and the NIH in Washington) and businesses (Inveresk Research International, United Kingdom and Schering Agrochemicals, U.K.). Holdings: 26,652 B shares and 15, 000 subscription options 2004/07.

**CHIEF INFORMATION OFFICER IS JOHANNES FALK**, MFA, born 1967. Falk has worked for the Company since 1999. Holdings: 9,768 B shares and 15, 000 subscription options 2004/07.

**FINANCIAL CONTROLLER IS KARIN ALMQVIST**, born 1980, M.Sc in Information Technology and B.Sc in Business Administration from the University of Stockholm and the University of Kalmar. Almqvist has worked for the Company since 2004. Holdings: 15,000 subscription options 2004/07.

## ACCOUNTANTS

**ERNST & YOUNG, WITH OLA WAHLQUIST** as the main Company accountant since 2002.

**GÖRAN WIMAN, AUTHORISED ACCOUNTANT**, Focus Revision AB, ordinary accountant since 2002.

**MARTIN HAMMARE, AUTHORISED ACCOUNTANT**, Focus Revision AB, deputy accountant since 2002.

## FACTS FROM THE CORPORATE BYLAWS

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### **COMPANY FIRM**

The Company's firm is Diamyd Medical Aktiebolag (publ).

### **BOARD HEADQUARTERS**

The Board shall have its headquarters in Stockholm.

### **OPERATIONS**

The Company shall, directly or indirectly, develop, produce and market products intended for diagnosis and treatment of autoimmune diseases and cancer and compatible projects. The Company shall even own, administer and sell shares in companies within the medicine and healthcare industries.

### **SHARE CAPITAL**

The share capital comprises at lowest MSEK 3 and at highest MSEK 12.

### **BOARD AND ACCOUNTANTS**

The Board consists of 3-5 members with 0-3 deputies. Each is chosen annually at the Annual General Meeting for a 1 year period. One-to-two accountants with/without deputies are chosen at the Annual General Meeting for a 4 year financial year period.

### **INVITATION TO THE ANNUAL GENERAL MEETING**

Invitation to the AGM will be made at least six and at latest four weeks prior to the event. The announcement will be made publicly in the national newspapers Svenska Dagbladet and Dagens Nyheter as well as in the Post & Inrikestidningar.

### **VOTING RIGHT**

Everyone who is entitled to vote may do so at the AGM.

### **FINANCIAL YEAR**

The Company's financial year is from September 1 - August 31.

# LEGAL ISSUES, POLICIES AND OTHER INFORMATION

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## **DISPUTES**

Not involved in any known disputes.

## **INSURANCE**

The Company's insurance coverage is believed to be adequate and related to the nature and scope of the business.

## **ENVIRONMENTAL POLICY**

The Board has adopted an environmental policy. Security, health and environmental considerations are fundamental requirements for Diamyd Medical to be a successful company.

## **INFORMATION MANAGEMENT**

The Board of Diamyd Medical has adopted an information policy with the ambition to meet the requirements of a publicly traded company.

## **POLICY FOR THE MANAGEMENT OF LIQUID FUNDS**

The main policy is that liquid funds are invested in different lots with a maximum size of MEK16 of the Company's total liquid

funds. The need for liquid funds is calculated in co-operation between the CFO and the CEO and remaining funds are placed in short-term funds with a bank guarantee.

## **POLICY FOR CURRENCY**

The Company shall try to minimize currency exposure by balancing income and expenses. The Company has the policy not to hedge foreign currency in regard to agreed assignments but instead to let the course of the day at the time of payment decide the final cost or profit.

## **CORPORATE ID**

The registration number of Diamyd Medical AB (publ) is SE-556530-1420. The Company changed its name to Diamyd Medical AB (publ), formerly Biosyn Holding AB on January 13th, 1999. Diamyd Medical AB has been registered with the VPC since 22nd March 1996. The Company has been in action since registration. The Company's form of association is regulated by the Swedish Companies Act (1975:1385). The Company has its registered head office in Stockholm, Sweden.

# SHARES, SHARE CAPITAL AND OWNERSHIP STRUCTURE

The Diamyd Medical B-share has been traded on the O-list on the Stockholm Stock Exchange since 30th May 2002. The B-share was earlier traded on the NGM-list since 1997. Diamyd Medical has appointed Remium Securities AB as market maker for Diamyd shares. The aim is to improve the liquidity of the shares within the framework of the Stockholm Stock Exchange's system for market makers.

## SHARE PRICE DEVELOPMENT

During the financial year, the share price changed by 15.6% compared to -33.1% for the prior year, and compared with the SX All-Share Index which rose 26.5% compared to 14.4% for the prior year during the same period. The highest quoted price during the year was SEK 70.00 compared to 92.00 for the prior year and the lowest was SEK 36.20 compared to 40.20 for the prior year. The average share price for the year was SEK 47.61 compared to 63.69 for the prior year. The total market capitalization of Diamyd Medical was SEK 450.4 million at the end of the fiscal year, compared to SEK 388.1 million at the

end of the previous year. When the Company was first listed on the OMXS on May 30, 2002, the market cap was SEK 210 .1 million. During the year Diamyd shares were traded at a value of SEK 123.3 million compared to SEK 133.8 million for the prior year. This represents a turnover of 29.8% compared to 37.1% for the prior year.

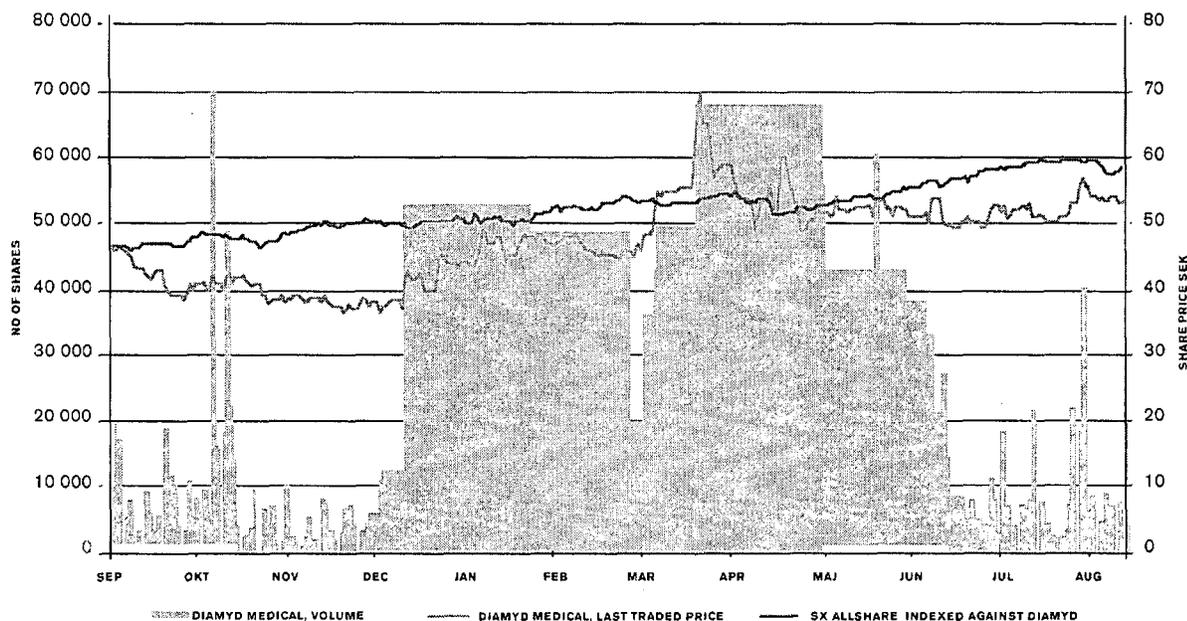
## DIVIDEND POLICY

Diamyd Medical has not paid out dividends since the Company was founded in 1996. The Board has no current intention of proposing such payment until the Company has achieved significant royalty income or has generated good profits and cash flow through other means.

## SHARE CAPITAL

Diamyd Medical's share capital amounted to SEK 8,418,043 distributed over 471,200 class A-shares each conferring one vote and 7,946,843 class B-shares, each conferring one tenth of a vote. The nominal share value is SEK 1.

DIAMYD MEDICAL SHARE PRICE DEVELOPMENT 2004-2005



Year	Event	Conditions	Increase in Equity, SEK	Increase in No. A Shares	Increase in No. B Shares	Number of Shares
1996	Company formed*		126,288	150,000	102,575	252,575
1996	Preferential rights issue**		512,500	-	512,500	765,075
1997	Preferential rights issue		771,335	785	770,550	1,536,410
	Preferential rights issue		1,536,410	150,785	1,385,625	3,072,820
2000	Preferential rights issue		768,205	75,392	692,813	3,841,025
2002	Redemption of options	1:1, SEK 40	762,214	471,200	4,132,039	4,603,239
	Redemption of options	1:1, SEK 22,10	12,232	-	12,232	4,615,471
2003	Redemption of options	1:1, SEK 21,79	10,921	-	-	-
	Redemption of options	1:1, SEK 56	2,185	-	13,106	4,628,577
2004	Redemption of options	1:1, SEK 21,79	5,616	-	-	-
	Redemption of options	1:1, SEK 56,00	2,185	-	7,801	4,636,378
	Preferential rights issue	2:1, SEK 40	2,318,189	-	2,318,189	6,954,567
	Directed placement	SEK 40	1,390,913	-	1,390,913	8,345,480
	Redemption of options	1:1, SEK 18,36	72,563	-	72,563	8,418,043

\* Nominal share value SEK 0.50.

\*\* Nominal share value SEK 1.

#### SHARE OPTION PLANS

99/2006

In connection with a new issue in December 1999, the Company also issued 768,205 stock options to shareholders, divided into 75,392 series A-Shares (TO1A) and 692,813 series B-shares (TO1B), which were registered with the Swedish Securities Register Center (VPC). Each option entitled the holder to subscribe to one share of the relevant series at a price of SEK 65 and subscription may take place during the period May 1 to August 31st 2006. The number of shares that can be subscribed under this program has been recomputed to 917,655 (with the relationship between series A and B intact) as a result of the new issues in 2001 and 2004 and the exercise price has been readjusted to SEK 54.42. The maximum increase in share capital supported by these stock options is SEK 917,655.

At full conversion this program leads to a dilution of 11%. Since the principal owners Mr. Bertil Lindqvist and Mr. Anders Essen-Möller have participated fully in the above mentioned warrant issue, the dilution effect does not imply a significant restructuring in the ownership of Diamyd Medical.

2004/07

In December 2004 the Company issued 200,000 promissory notes combined with detachable warrants to employees, colla-

borators and others associated with Diamyd Medical. The subscription price when subscribing to shares using the warrants will be SEK 50 and the program expires on December 31, 2007. Conveyance of the options shall be estimated to market price, based on the Black-Scholes valuation formula.

The maximum increase in share capital supported by these stock options is SEK 200,000. Employees and members of the Board held 52.5% of these options on August 31, 2005.

#### SHARE HOLDERS

As of August 31st, 2005, the number of shareholders was 2,799 (2,557 as of August 31st 2004). The Company's largest investor, Bertil Lindqvist, owns 39.3% of the capital and 26.1% of the votes. The ten largest shareholders in Diamyd Medical have shares corresponding to 68.5% of the capital and 79.0% of the votes.

#### SHARE OWNERSHIP AGREEMENT AND FIRST REFUSAL

According to an agreement between the main owners Mr. Lindqvist and Mr. Essen-Möller, as owner of class A-shares, Mr. Essen-Möller has undertaken not to transfer class A-shares to any third party (excepting inheritance), unless such a party simultaneously offers to redeem all class B-shares on the same terms. Owners of class A-shares have the right to transform these to class B-shares.

**OWNERSHIP STRUCTURE AS OF 2005-08-31**

Holdings	#of shareholders	A-shares	B-shares	Capital (%)	Votes (%)
1 - 500	1,895	-	368,931	4.38%	2.91%
501 - 1000	475	-	376,394	4.47%	2.97%
1001 - 5000	348	-	744,594	8.85%	5.88%
5001 - 10000	32	-	226,322	2.69%	1.79%
10001 - 15000	13	-	163,645	1.94%	1.29%
15001 - 20000	8	-	141,147	1.68%	1.12%
20001 -	28	471,200	5,925,810	75.99%	84.03%
<b>Total</b>	<b>2,799</b>	<b>471,200</b>	<b>7,946,843</b>	<b>100.0%</b>	<b>100.0%</b>

**THE TEN LARGEST SHAREHOLDERS AS OF AUGUST 2005-08-31**

Name	A-shares	B-shares	Capital, %	Votes, %
Lindkvist, Bertil	-	3,309,534	39.31	26.14
Essen-Möller, Anders	471,200	193,551	7.90	38.75
Östersjöstiftelsen	-	648,608	7.70	5.12
Fonden Pecunia	-	300,500	3.57	2.37
Fonden Edge	-	173,000	2.06	1.37
SEB Sverige småbolagsfond	-	167,850	1.99	1.33
Gälöstiftelsen	-	164,100	1.95	1.30
Stockholms sjukhem	-	153,000	1.82	1.21
Synectics Medical AB	-	113,000	1.34	0.89
Bear & Stearns & CO	-	67,500	0.80	0.53
Others		2,656,200	31.55	20.98
<b>Total</b>	<b>471,200</b>	<b>7,946,843</b>	<b>100.00%</b>	<b>100.00%</b>

**DIAMYD SHARES MAY BE TRADED ON THE US MARKET THROUGH A LEVEL 1 AMERICAN DEPOSITORY RECEIPT (ADR) PROGRAM**

The program is planned to start during the Spring of 2006. The Company and the Bank of New York have agreed on seeking to establish a Level 1 American Depository Receipt (ADR) program on the OTC market. The trade in Diamyd shares will be simplified for American investors.

ADRs are commonly used to facilitate the holding and tra-

ding by US investors of securities in foreign companies not listed in the United States. An ADR is created when a broker purchases a company's shares on the home stock market and delivers those to the depositary's local custodian bank, which then instructs the depositary bank, The Bank of New York, to issue Depository Receipts.

Depository receipts may trade freely, just like any other security, in the over-the-counter (OTC) market.

# ADMINISTRATION REPORT 2004/2005

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The Board and managing director for Diamyd Medical AB (publ), organization number 556530-1420, with headquarters in Stockholm hereby presents its Annual Report for the Company and the affiliated companies for the financial year beginning 1st September 2004 and ending 31st August 2005.

## **OPERATIONS**

The Company shall, directly or indirectly, run research, production and marketing of products designed for the diagnosis and treatment of autoimmune diseases and cancer as well as business consistent with this. The Company shall also own, manage and sell shares in companies that operate in the medical and health care industries.

## **DEVELOPMENT OF A PRODUCT FOR RECENT ONSET TYPE 1 DIABETES**

Diamyd Medical develops a product, Diamyd™, for treatment of Type 1 diabetes. The disease develops when the body's immune system attacks the patient's own insulin-producing pancreatic beta cells. At disease onset, the patients generally have about 10% of their beta cells remaining. However, these are incapable of producing enough insulin in order to maintain the normal blood sugar level, and external insulin must be taken. After debut, the autoimmune attack continues against the remaining beta cells, which in time will be completely destroyed.

Diamyd™ is intended to prevent the destruction of beta cells and at best to allow regeneration of beta cells without their continued attack by autoreactive immune cells.

Diamyd™ is currently being tested in 70 juveniles with recent onset of Type 1 diabetes in a randomised, double-blind Phase II clinical trial. The treatment group (35 patients) receives two injections with a 20µg dose of Diamyd™ (GAD65 formulated in aluminium hydroxide) within a 30-day interval. The placebo group (35 patients) receives the same formulation without GAD65. The aim of the trial is to investigate whether the positive results obtained during a previous smaller-scale Phase II clinical trial involving Type 2 adult patients with GAD antibodies (LADA patients) can be reproduced in Type 1 diabetes patients. The trial is being conducted at 8 clinics in Sweden and

is headed by Professor Johnny Ludvigsson of Linköping University. All patients have been included in the trial and the results are expected to be reported in late August 2006.

## **DEVELOPMENT OF PRODUCT**

### **FOR 10% OF ALL TYPE 2 DIABETES PATIENTS**

Diamyd Medical develops a pharmaceutical, Diamyd™, for treatment of autoimmune diabetes. Approximately 10% of all Type 2 diabetes patients have antibodies specific for GAD and therefore have a form of autoimmune diabetes (LADA). These patients are easily identified through routine blood sample analysis.

Diamyd Medical has previously conducted a successful small-scale Phase II clinical trial of 47 LADA patients. The first large-scale Phase II/III clinical trial intended to enable registration of the drug is currently being conducted with 160 LADA patients. The trial is randomized, double-blind and placebo-controlled. The treatment group (80 patients) receives two injections of a 20µg dose of Diamyd™ (GAD65 formulated in alum) with a 30 day interval. The placebo group receives the same formulation without GAD65. The aim of the trial is to confirm the positive results obtained during the previous Phase II clinical trial (see below). The current trial is being conducted at 17 clinics throughout Sweden and is headed by Professor Carl-David Agardh of Universitetssjukhuset MAS in Malmö. The results of the trial are expected during the second quarter of 2007. Before applying for registration of Diamyd™ an additional Phase III clinical trial is required. The Company intends to collaborate with an established pharmaceutical company until market approval.

### **RESULTS FROM PHASE II CLINICAL TRIAL WITH TYPE 2 DIABETICS**

Positive 6- and 24-month results from a Phase II clinical trial with Diamyd™ were reported in 2003. The trial was conducted with 47 LADA patients and a broad dose range was studied with respect to safety and efficacy. The results indicate that the preparation is safe to administer and, better than expected, that Diamyd™ increases insulin production levels instead of only slowing the ongoing pancreatic deterioration.

**GAD SHOWS POTENTIAL IN TREATMENT PARKINSON'S DISEASE**

Neurologix Research Inc is nearing completion of a Phase I safety trial in 12 Parkinson patients using GAD-gene therapy and is expected to report its results. Diamyd Medical and Neurologix are at present time discussing a presumptive collaboration for GAD-genetherapy to treat Parkinson's disease whereas Diamyd Medical obtains the exclusive rights for the GAD technology.

**TRANSITION TO IFRS**

As of January 1st 2005 all listed companies within the EU are obligated to emit financial reports in accordance with International Financial Reporting Standards (IFRS). Diamyd Medical adheres to the demand to use IFRS accounting in the accounting procedure for the Group. When Diamyd Medical has closed its financial year, the demand for a report according to IFRS will be conducted during the first quarter 2005/06. The Company's IFRS starting balance will be based on the final accounts that are reported now. Diamyd Medical initiated a project in the beginning of 2005, which was designed to identify the significant differences between IFRS and the accounting procedures which have been used in accounts for the Company according to good accounting practice in Sweden. Diamyd Medical's preliminary evaluation based on the IFRS/IAS recommendations which are now 'endorsed' by the EU are that these differences will not have a significant effect on the Company other than regarding form, key ratios as well as supplementary disclosures. The Company will attain these standards as of 2005-09-01 hereby implement IFRS in the quarterly report 1 2005/06 (Sep – Dec 2005). Comparable numbers for 2004/05 are to be calculated in accordance with IFRS.

**MARKET VALUE AND SHARE CAPITAL**

The total market value of Diamyd Medical was SEK 450.4 million compared to SEK 388 million at the end of the fiscal year. As of August 31st 2005 the number of outstanding shares was 8,418,043. 471,200 were A-shares and 7,946,843 were B-shares. During the financial year, the share price changed by 15.6% compared to -33.1 for the prior year and compared to the SX All-Share Index which changed by 26.5% compared to 14.4% for the prior year. The highest paid price during the year SEK 70.0 compared to SEK 92.00 for the prior year and the lowest was SEK 36.20 compared to SEK 40.20 for the prior year.

**PARENT COMPANY**

The company's turnover was SEK 0 compared to SEK 0 for the prior year as all sales is managed by the affiliated company. The years' balance before final accounting and taxes was SEK -34,950,000 compared to SEK -17,045,000 for the prior year. Investments for the year were SEK 0 compared to SEK 0 for the prior year. Change in liquid assets was SEK -27.2 million compared to SEK 117.9 million for the prior year.

**SALES**

Sales amounted to kSEK 883 (kSEK 1,730) and consisted of Diamyd related- and agency products. Of these sales kSEK 263 were from the Company's subsidiary in the USA. The sale of

Diamyd Diagnostic's products fluctuates due to the present clientele that mainly consists of researchers who purchase the products in connection with ongoing studies.

**DIAMYD DIAGNOSTICS**

Diamyd Diagnostics sells the GAD protein in addition to certain licensed products as part of the Group's strategy to retain contact with the academic research world. Diamyd Medical's year end results are not significantly affected by sales of these licensed products.

**OPERATING COST**

The Group's running costs were SEK 40.8 million compared to SEK 19.5 million for the prior year.

**STAFF**

The Company had a staff of seven people as of August 31st 2005, of which four were men and three were women, compared to six for the prior year. The seven members of staff are employed by Diamyd Therapeutics AB. Diamyd Inc. has no personnel but is run by a consultant with support from personnel in Sweden. Employee costs were SEK 8.7 million compared to 6.2 million for the prior year.

**RESEARCH AND DEVELOPMENT**

The cost for Research and Development (R & D) was SEK 24.7 million compared to SEK 4.2 million for the prior year. R & D costs decreased as the Phase II clinical trial has now entered a follow-up stage in which costs are considerably lower compared to the active stage.

FOU costs during the period 96/97 to 04/05 have been 22%, 16%, 48%, 61%, 62%, 38%, 46%, 45%, and 61% respectively, of the Group's total costs. These costs have been mostly of R & D character and in accordance with good accounting practice are still accounted as current costs as Diamyd™ is still in a development phase and hence the project is still risk-associated, and Diamyd Medical can therefore not guarantee that the product will reach the commercial market.

**PROFIT/LOSS**

The Group's net loss after net interest income/expense was SEK -36.6 million compared to -16.0 for the prior year.

**CASH FLOW**

The Company's cost structure is dominated by costs for research and development which as well as low sales has led to a negative cash flow for the Group since the start.

**INVESTMENTS**

No investments have been made during the year.

**FINANCIAL STATUS AND LIQUIDITY**

The Group's liquid assets, including short-term placements, amounted to SEK 115.5 million as of 31st August 2005 compared to 24.7 million for the prior year. With planned activities these liquid assets are estimated to last up to and including December 2007. During the period 1996-2004 the Company

has generated SEK 284 million through stock issues.

#### **CHANGES IN SHAREHOLDER'S EQUITY**

The shareholder's equity for the Group as of August 31ST 2005 was SEK 115.5 million compared to 151.6 million for the prior year, giving an equity ratio of 92% compared to 96.1% for the prior year.

#### **DIAMYD INC.**

The company's turnover was SEK 0.3 million compared to 0.5 million for the prior year with a balance of SEK -0.1 million compared to -0.9 million for the prior year.

#### **BALANCE OF OTHER SHARES**

Diamyd Medical even owns 19% of the Uppsala-based company Mercodia AB, which specializes in development and marketing of diagnostic products. The turnover of Mercodia during 2004 was SEK 39.2 million compared to 32 million for the prior year, with a booked profit of SEK 3.6 million compared to 1.9 million for the prior year. Diamyd Medical has received a dividend of SEK 152,000 (SEK 95,000) from Mercodia AB during 2005.

#### **BOARD ACTIVITIES**

The Board works according to an established work scheme, which controls the frequency and agenda of Board meetings, distribution of material to attending members as well as the tasks presented to the Board for information purposes or for decision-making. Part of the work scheme controls the division of labor between the Board, the Chairman of the Board and the CEO, as well as defining the CEO's authority and salary. The Chairman of the Board prepares Board meetings together with the CEO. Apart from deciding on the Company's strategy, business ideas and academic and financial plans, the Board also monitors the Company's operations and development. The CEO and management team report on operations at the Board meetings, including development and progress within research and business areas as well as presenting financial reports. The Board makes decisions regarding important issues such as significant contracts, budgets, financial policy and large investments. According to the work scheme, Diamyd Medical will stage at least four Board meetings per calendar year apart from extraordinary Board meetings. The Board held 12 minutes-recorded meetings during the year. All members of the Board and management executives completed an obligatory education in the Stockholm Stock Exchange during the year.

The Company's appointed accountants report their accounting directly to the Board. Questions arising from accounting are considered to be of sufficient importance to warrant handling by the Board and not by a separate accounting committee.

The Company has neither a nomination committee nor a dividends committee, but such issues are dealt with by the Board in conjunction with the Company's main owner.

Payment to the Board during the year amounted to SEK 328,000 of which SEK 130,000 was for the Chairman of the Board in accordance with the Shareholders meeting motion.

Payment to the accountants was according to a fixed retaining fee and is described in note 7.

#### **ANNUAL GENERAL MEETING FOR SHAREHOLDERS**

The AGM will take place in the Olympia room, Sahlénhuset, Norrlandsgatan 15, Stockholm on December 12th 2005 at 15.00. The Board proposes that no dividend be paid.

In order to save money and to be environmentally aware, only the English translation will be printed and can be obtained from the Company on request.

#### **PROPOSAL FOR THE TREATMENT OF THIS YEAR'S LOSS**

The Company and CEO propose that SEK 34,950,277 (SEK 16,853,812 previous year) is transferred from the parent company's premium fund in order to cover the parent company's loss of SEK 34,950,277 (SEK 17,045,322 previous year).

The Group's accumulated loss was SEK 34.5 (14.7) million and no transfer of bound funds is required.

#### **THE GROUP'S FUTURE PROSPECTS**

Diamyd Medical intends to secure a collaborative agreement with an established pharmaceutical company by which the Company would retain approximately 10% royalty payments based on a future sale of the diabetes therapeutic Diamyd™. The Group's liquid assets are expected to last until December 2007.

#### **IMPORTANT EVENTS AFTER THE END OF THE REPORTING PERIOD**

Subsequent to closure of the report period, the MPA in Uppsala and the regional ethics committee at Lund University have agreed to a broad efficacy clinical trial of the diabetes therapeutic Diamyd™ in 160 patients with GAD-specific antibodies (LADA patients). The study will be randomized, double-blind and placebo-controlled. The active group will receive two injections of 20 µg (GAD65 formulated in alum) during a 30 day interval. Eighteen months after the last patient has been injected, the code will be broken and the results analyzed.

The aim is to demonstrate that Diamyd™ has the capacity to stop the autoimmune attack that leads to death of the insulin-producing beta cells.

The trial will be conducted in conjunction with Clinical Data Care AB under supervision of Professor Carl-David Agardh at Malmö University Hospital (UMAS). Samples will be collected from a number of clinics throughout Sweden

#### **LEVEL 1 ADR**

Diamyd Medical has accepted a proposal from The Bank of New York to establish a Level 1 American Depository Receipt (ADR) program. ADRs are commonly used to facilitate the holding and trading by US investors of securities in foreign companies not listed in the United States. An ADR is created when a broker purchases a company's shares on the home stock market and delivers those to the depository's local custodian bank, which then instructs the depository bank, The Bank of New York, to issue Depository Receipts. Depository receipts may trade freely, just like any other security, in the over-the-counter (OTC) market.

# RISK FACTORS

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This section aims to illustrate the main factors that affect the operations of Diamyd Medical from a risk perspective. The concept of risk comprises both internal and external factors in the development of a potential pharmaceutical until it is launched on the market. The development of a pharmaceutical is an industrial process with clearly defined regulatory requirements, among others regarding safety and efficacy. The development of pharmaceuticals entails big risks. Investment in a company such as Diamyd Medical is associated with a high risk. Below, some parameters that are important for evaluating the risk of an investment in Diamyd Medical are listed. The list is not complete nor ranked.

## **RISKS CONCERNING THE SUITABILITY OF DIAMYD™**

Intermediate results indicate that GAD is safe for use in humans. In addition, pre-clinical results show good tolerability in animals. There remains a risk, however, that Diamyd™ is toxic, induces disease or for other reasons is not suitable for administration to humans.

## **PRODUCTION RISKS**

There is a risk that the Company will not manage to produce Diamyd™ in time, in necessary quantities or at a quality sufficient for the clinical trials.

## **PATENT RISKS**

The Company's key executives believe that sufficient and necessary intellectual rights have been licensed to give the Company's diabetes project adequate protection. Since biotechnology is an area characterized by a high number of patents there is a risk that the Company's licensed patent rights may

prove to be insufficient or not give adequate protection to the Company's GAD-based technology platform. The patent portfolio is assessed continually in order to support the Company's strategies and operations.

## **COMPETITION**

Diamyd Medical has chosen to use the whole GAD molecule as the active substance in the therapeutic that is being developed. Several other diabetes preventing strategies that use other molecules and technologies are being developed.

## **PARTNERSHIP RISKS**

Partnership is a key to risk reduction and financing and, in a later phase, marketing and royalties. There is a risk that Diamyd Medical will not manage to ally itself with a suitable partner or build the organizational structure needed to effectively distribute Diamyd™ on the market. There is also a risk that a partnership agreement cannot be concluded on terms beneficial to the Company.

## **AGREEMENT RISKS**

Partly due to its outsourcing strategy, Diamyd Medical has concluded agreements with a number of parties and further agreements are in the pipeline. There is a risk that the Company will not manage to conclude sufficiently good agreements or protect itself adequately against breaches of contract. The Company's intellectual rights concerning diabetes treatment have been licensed from Universities in the U.S. These agreements contain clauses on milestone payments, royalties and timetables. There is a risk that these agreements may be terminated if the Company does not perform according to its undertakings.

#### **FINANCIAL RISKS AND POLICIES**

There is a financial risk that the Company does not succeed to secure the adequate financial resources. A continual inspection of financial requirements is conducted in concert with capital share market development in order to judge financial strategies.

##### *Currency risks*

The Company is affected by changes in currency exchange rates since the development, in large part, is outsourced to companies in foreign countries. The effect of currency fluctuations are not hedged, and therefore, there is risk that exchange rate changes might affect the company's ability to carry on its development according to plan. As of August 31st 2004 there were no significant influence of currency effects on the Company's operations.

##### *Transactions risks*

Changes in exchange rates can affect both the income statement and the balance sheet. These can be affected when income and costs comprise different currencies. This effect is marginal by today's reckoning.

##### *Conversion risks*

The balance sheet may be affected when assets and debts comprise different currencies. This effect is marginal in principle when all assets and debts are expressed in SEK. The balance sheet is affected when Diamyd Inc.'s balance is converted to Swedish kronor. There is a similar affect on the capital assets of Diamyd Inc. when the financials are converted to Swedish kronor. Considering the scale of operations in the USA at the present time this risk is insignificant.

##### *Liquidity risks*

The risk of liquidity concerns Diamyd Medical not having sufficient funds to pay known or unforeseen short-term expenses. The risk is associated with short-term investments and the risk that there is no market for a specific instrument the market is intending to sell. Diamyd Medical's liquidity risk is dealt with through specifying invoice dates based on cash-flow prognoses and through the Company's investment policy. The current liquidity risk is principally nonexistent.

#### **INSURANCE RISK**

Diamyd Medical's insurance policies currently cover the following areas: property, operation breakdown, personal and possession damage, legal protection, operational liabilities, clinical trials, business trips, CEO and Board liabilities, product liabilities (co-protected by Mercodia's AB regarding certain products –Vendors Endorsement).

#### **MARKET DEVELOPMENT**

Investment in Diamyd incurs a risk that the share market course is dependent on research results arising from the project as well as the market's belief in the biotechnology industry.

#### **KEY PERSONNEL**

The Company's operations necessitate extensive documentation, which reduces the dependence on any particular person. The Company's Board of Directors and management group have sufficient knowledge and experience should a situation arise in which a person would be unable to perform their duties.

# CONSOLIDATED INCOME STATEMENT

kSEK

		<b>Sep-Aug 2004-2005</b>	<b>Sep-Aug 2003-2004</b>	<b>Sep-Aug 2002-2003</b>
<b>Operating Income</b>				
Net sales	note 1	883	1,730	2,246
Other operating income		48	873	96
<b>Total Operating Income</b>		<b>931</b>	<b>2,603</b>	<b>2,342</b>
<b>Operating Costs</b>				
Cost of products sold		-775	-795	-1,415
Research and development expense	note 2, 33	-24,676	-4,165	-9,372
Patents	note 2	-1,719	-1,396	-1,356
Personnel costs	note 4, 5	-8,698	-6,077	-5,256
Other external costs	note 7, 19, 24, 28	-4,052	-6,224	-2,236
Depreciation patents	note 8	-751	-760	-827
Depreciation equipment	note 9	-150	-123	-166
<b>Total Operating Costs</b>		<b>-40,821</b>	<b>-19,540</b>	<b>-20,628</b>
<b>Operating Loss</b>		<b>-39,890</b>	<b>-16,937</b>	<b>-18,286</b>
<b>Financial Income and Expense</b>				
Other financial income	note 11	152	95	76
Interest income	note 32	3,195	860	1,028
Interest expense		-26	-8	-22
<b>Total Financial Income and Expense</b>		<b>3,321</b>	<b>947</b>	<b>1,082</b>
<b>Loss before Taxes</b>		<b>-36,569</b>	<b>-15,990</b>	<b>-17,204</b>
Income tax	note 20	-63	-	-
<b>Net Loss for the Year</b>		<b>-36,632</b>	<b>-15,990</b>	<b>-17,204</b>
Earnings per share, SEK		-4.4	-3.0	-3.7
Earnings per share, diluted, SEK		-4.4	-3.0	-3.7
Number of shares		8,418,043	8,345,480	4,615,471
Average number of shares		8,410,787	5,337,188	4,614,112
Number of shares, diluted		8,442,800	5,606,850	4,684,362

# CONSOLIDATED BALANCE SHEET

kSEK

		Aug 31 2005	Aug 31 2004	Aug 31 2003
<b>Assets</b>				
Subscribed for but not paid share capital	note 3	-	475	-
<b>Non-Current Assets</b>				
Intangible assets	note 8	1,309	2,060	2,820
Equipment	note 9	220	337	251
Financial assets	note 10	800	800	800
<b>Total Non-Current Assets</b>		<b>2,329</b>	<b>3,197</b>	<b>3,871</b>
<b>Current Assets</b>				
Inventory	note 12	8	90	125
<b>Trade and Other Receivables</b>				
Trade receivables	note 13	450	501	296
Other receivables		1,536	846	592
Prepaid tax		168	112	309
Prepaid expenses and accrued income	note 14	5,447	1,152	1,328
<b>Total Trade and Other Receivables</b>		<b>7,601</b>	<b>2,611</b>	<b>2,525</b>
Short-term investments	note 15, 34	91,374	89,608	9,398
Cash and bank balances		24,161	61,730	15,284
<b>Total Liquid Funds</b>		<b>115,535</b>	<b>151,338</b>	<b>24,682</b>
<b>Total Current Assets</b>		<b>123,144</b>	<b>154,514</b>	<b>27,332</b>
<b>Total Assets</b>		<b>125,473</b>	<b>157,711</b>	<b>31,203</b>
<b>Shareholders' Equity and Liabilities</b>				
<b>Shareholder's Equity</b>				
Issued capital	note 26, 35	8,418	8,345	4,615
Not registered share capital	note 6, 16	360	1,194	-
Share premium and other restricted reserves		141,193	156,785	131,316
Retained earnings		2,129	1,264	-94,860
Loss for the year		-36,632	-15,990	-17,204
<b>Total Shareholder's Equity</b>		<b>115,468</b>	<b>151,598</b>	<b>23,867</b>
<b>Non-Current Liabilities</b>	note 17, 30	-	768	768
<b>Current Liabilities</b>				
Trade payables		2,508	1,973	4,231
Other payables		1,745	586	499
Accrued expenses	note 18	5,752	2,786	1,838
<b>Total Current Liabilities</b>		<b>10,005</b>	<b>5,345</b>	<b>6,568</b>
<b>Total Shareholder's Equity and Liabilities</b>		<b>125,473</b>	<b>157,711</b>	<b>31,203</b>

# PARENT COMPANY'S INCOME STATEMENT

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kSEK

		<b>SEP-AUG 2004-2005</b>	<b>SEP-AUG 2003-2004</b>	<b>SEP-AUG 2002-2003</b>
<b>Operating Costs</b>				
Employee costs	note 4	-522	-	-
Other external costs	note 7, 19, 24, 28	-394	-3,730	-2,381
<b>Total Operating Costs</b>		<b>-916</b>	<b>-3,730</b>	<b>-2,381</b>
<b>Operating Loss</b>		<b>-916</b>	<b>-3,730</b>	<b>-2,381</b>
<b>Financial Income and Expense</b>				
Amortization in the Group companies/shareholders' contribution	note 31	-37,287	-14,305	-17,942
Other financial income	note 11	152	95	76
Interest income	note 32	3,114	821	981
Interest expense		-13	-	-
<b>Total Financial Income and Expense</b>		<b>-34,034</b>	<b>-13,389</b>	<b>-16,885</b>
<b>Loss before Taxes</b>		<b>-34,950</b>	<b>-17,119</b>	<b>-19,266</b>
Income tax	note 20	-	74	49
<b>Net Loss for the Year</b>		<b>-34,950</b>	<b>-17,045</b>	<b>-19,217</b>

# PARENT COMPANY'S BALANCE SHEET

kSEK

		AUG 31 2005	AUG 31 2004	AUG 31 2003
<b>Assets</b>				
Subscribed for but not paid share capital	note 3	-	475	-
<b>Non-Current Assets</b>				
Shares in Swedish subsidiaries	note 21, 26	1,200	1,200	1,200
Shares in foreign subsidiaries	note 21	9	9	9
Financial assets	note 10	800	800	800
Long-term receivables from group companies	note 22	1,563	9,430	1,307
<b>Total Non-Current Assets</b>		<b>3,572</b>	<b>11,439</b>	<b>3,316</b>
<b>Current Assets</b>				
<b>Trade and Other Receivables</b>				
Other receivables		345	478	345
Prepaid expenses and accrued income	note 23	4,115	636	315
<b>Total Trade and Other Receivables</b>		<b>4,460</b>	<b>1,114</b>	<b>660</b>
Short-term investments	note 15, 34	91,374	89,608	9,398
Cash and bank balances		21,022	49,975	12,274
<b>Total Liquid Funds</b>		<b>112,396</b>	<b>139,583</b>	<b>21,672</b>
<b>Total Current Assets</b>		<b>116,856</b>	<b>140,697</b>	<b>22,332</b>
<b>Total Assets</b>		<b>120,428</b>	<b>152,611</b>	<b>25,648</b>
<b>Equity and Liabilities</b>				
<b>Shareholder's Equity</b>				
Issued capital	note 27, 35	8,418	8,345	4,615
Not registered share capital	note 6, 16	360	1,194	-
Share premium and other restricted reserves		141,073	156,665	131,196
Retained earnings		-	192	-94,070
Loss for the year		-34,950	-17,045	-19,217
<b>Total Shareholder's Equity</b>		<b>114,901</b>	<b>149,351</b>	<b>22,524</b>
<b>Non-Current Liabilities</b>	note 17, 30	-	768	768
<b>Current Liabilities</b>				
Trade payables		40	539	136
Short-term liabilities	note 25	4,149	132	1,711
Other payables		839	-	-
Accrued expenses	note 18	499	1,821	509
<b>Total Current Liabilities</b>		<b>5,527</b>	<b>2,492</b>	<b>2,356</b>
<b>Total Liabilities and Shareholder's Equity</b>		<b>120,428</b>	<b>152,611</b>	<b>25,648</b>

# CHANGE IN SHAREHOLDERS' EQUITY (GROUP)

kSEK

	Share Capital	Restricted Reserves	Non-restricted Reserves	Total Shareholders' Equity
Opening Balance September 1, 1996	765	10,030	6	10,801
New share issue	771	10,027	-	10,798
Realignment betw. non-restricted/restricted reserves	-	-84	84	-
Net loss	-	-	-6,068	-6,068
<b>Closing Balance August 31, 1997</b>	<b>1,536</b>	<b>19,973</b>	<b>-5,978</b>	<b>15,531</b>
New share issue	1,536	52,386	-	53,923
Realignment betw. non-restricted/restricted reserves	-	157	-157	-
Realignment betw. non-restricted/restricted reserves	-	80	-80	-
Net loss	-	-	-17,813	-17,813
<b>Closing Balance August 31, 1998</b>	<b>3,073</b>	<b>72,597</b>	<b>-24,028</b>	<b>51,642</b>
Realignment betw. non-restricted/restricted reserves	-	-33	33	-
Net loss	-	-	-15,628	-15,628
<b>Closing Balance August 31, 1999</b>	<b>3,073</b>	<b>72,564</b>	<b>-39,623</b>	<b>36,014</b>
New share issue	768	29,960	-	30,728
Realignment betw. non-restricted/restricted reserves	-	4	-4	-
Not registered share capital	-	132	-	132
Net loss	-	-	-23,059	-23,059
<b>Closing Balance August 31, 2000</b>	<b>3,841</b>	<b>102,660</b>	<b>-62,686</b>	<b>43,815</b>
Net loss	-	-	-13,044	-13,044
Realignment betw. non-restricted/restricted reserves	-	-104	104	-
Not registered share capital	-	153	-	153
<b>Closing Balance August 31, 2001</b>	<b>3,841</b>	<b>102,709</b>	<b>-75,626</b>	<b>30,924</b>
New share issue	762	28,601	-	29,368
Net loss	-	-	-19,203	-19,203
<b>Closing Balance August 31, 2002</b>	<b>4,603</b>	<b>131,310</b>	<b>-94,829</b>	<b>41,084</b>
New share issue	12	-12	-	-
Allocation	-	16	-16	-
Realignment betw. non-restricted/restricted reserves	-	2	-2	-
Translation loss*	-	-	-13	-13
Net loss	-	-	-17,204	-17,204
<b>Closing Balance August 31, 2003</b>	<b>4,615</b>	<b>131,316</b>	<b>-112,064</b>	<b>23,867</b>
New share issue	13	347	-	360
New share issue	8	237	-	245
New share issue	2,318	90,409	-	92,727
New share issue	1,391	47,763	-	49,154
Non registered share capital	-	1,194	-	1,194
Realignment betw. non-restricted/restricted reserves	-	-113,287	113,287	-
Translation gain*	-	-	41	41
Net loss	-	-	-15,990	-15,990
<b>Closing Balance August 31, 2004</b>	<b>8,345</b>	<b>157,979</b>	<b>-14,726</b>	<b>151,598</b>
New share issue	64	-64	-	-
New share issue	9	131	-	140
Option premiums	-	360	-	360
Realignment betw. non-restricted/restricted reserves	-	-16,853	16,853	-
Net loss	-	-	-36,632	-36,632
Translation gains*	-	-	2	2
<b>Closing Balance August 31, 2005</b>	<b>8,418**</b>	<b>141,553</b>	<b>-34,503</b>	<b>115,468</b>

\* This year's translation loss on consolidation includes transition gains on consolidation of the net profit for the year -6, translation gains on consolidation in the loss brought forward -3, translations losses consolidation in share capital 0, translation losses on consolidation on capital contribution 11.

\*\* 8,418,043 shares with a nominal value of SEK 1, which of 471,200 are series A and 7,946,843 series B.

# CHANGE IN SHAREHOLDERS' EQUITY (PARENT COMPANY)

kSEK

	Share Capital	Restricted Reserves	Non-restricted Reserves	Total Shareholders' Equity
Opening Balance September 1, 1996	765	9,946	-33	10,678
New share issue	771	10,027	-	10,798
Group contribution	-	-	-4,000	-4,000
Taxes on group contribution	-	-	1,120	1,120
Net loss	-	-	-5,211	-5,211
<b>Closing Balance August 31, 1997</b>	<b>1,536</b>	<b>19,973</b>	<b>-8,124</b>	<b>13,385</b>
New share issue	1,536	52,386	-	53,922
Group contribution	-	-	-15,765	-15,765
Taxes on group contribution	-	-	4,414	4,414
Net loss	-	-	-6,458	-6,458
<b>Closing Balance August 31, 1998</b>	<b>3,073</b>	<b>72,360</b>	<b>-25,933</b>	<b>49,500</b>
Group contribution	-	-	-16,339	-16,339
Taxes on group contribution	-	-	4,575	4,575
Net loss	-	-	-3,299	-3,299
<b>Closing Balance August 31, 1999</b>	<b>3,073</b>	<b>72,360</b>	<b>-40,996</b>	<b>34,437</b>
New share issue	768	29,960	-	30,728
Not registered share capital	-	132	-	132
Group contribution	-	-	-21,670	-21,670
Taxes on group contribution	-	-	6,068	6,068
Net loss	-	-	-6,573	-6,573
<b>Closing Balance August 31, 2000</b>	<b>3,841</b>	<b>102,452</b>	<b>-63,171</b>	<b>43,122</b>
Net loss	-	-	-13,512	-13,512
Not registered share capital	-	156	-	156
<b>Closing Balance August 31, 2001</b>	<b>3,841</b>	<b>102,608</b>	<b>-76,683</b>	<b>29,766</b>
New share issue	762	28,601	-	29,363
Group contribution	-	-	945	945
Net loss	-	-	-18,458	-18,458
<b>Closing Balance August 31, 2002</b>	<b>4,603</b>	<b>131,209</b>	<b>-94,196</b>	<b>41,616</b>
New share issue	12	-12	-	-
Group contribution	-	-	175	175
Tax on Group contribution	-	-	-49	-49
Net loss	-	-	-19,217	-19,217
<b>Closing Balance August 31, 2003</b>	<b>4,615</b>	<b>131,197</b>	<b>-113,287</b>	<b>22,524</b>
New share issue	13	347	-	360
New share issue	8	237	-	245
New share issue	2,318	90,409	-	92,727
New share issue	1,391	47,763	-	49,154
Not registered share capital	-	1,194	-	1,194
Allocation	-	-113,287	113,287	-
Group contribution	-	-	266	266
Taxes on group contribution	-	-	-74	-74
Net loss	-	-	-17,045	-17,045
<b>Closing Balance August 31, 2004</b>	<b>8,345</b>	<b>157,860</b>	<b>-16,853</b>	<b>149,351</b>
New share issue	64	-64	-	-
New share issue	9	131	-	140
New share issue	-	360	-	360
Option premiums	-	-16,853	16,853	-
Net loss	-	-	-34,950	-34,950
<b>Closing Balance August 31, 2005</b>	<b>8,418*</b>	<b>141,433</b>	<b>-34,950</b>	<b>114,901</b>

\* 8,418,04 shares nominal value SEK 1, of which 471,200 shares of series A and 7,946,843 of series B.

# CASH FLOW STATEMENT

kSEK

	Group			Parent company		
	Sep-Aug 2004-2005	Sep-Aug 2003-2004	Sep-Aug 2002-2003	Sep-Aug 2004-2005	Sep-Aug 2003-2004	Sep-Aug 2002-2003
<b>Cash Flows from Operations before Changes in Working Capital</b>						
Operating loss	-39,890	-16,937	-18,286	-916	-3,730	-2,381
Interest received	4,162	565	1,918	4,113	821	1,875
Interest paid	-2,744	-8	-22	-2,730	-	-
Paid premiums	-4,216	-	-	-4,216	-	-
Dividend received (note 11)	152	95	76	152	95	76
<i>Non-cash flow items</i>						
Depreciation (note 8, 9)	898	883	1,483	-	-	942
Change in accrued interest	3,693	295	-890	3,660	-	-894
Amortizations of premiums in short term investments	2,274	-	-	2,274	-	-
Income tax paid	-119	197	-121	-	-	-3
<b>Net Cash Flow from Operating Activities before Changes in Working Capital</b>	<b>-35,790</b>	<b>-14,910</b>	<b>-15,842</b>	<b>2,337</b>	<b>-2,814</b>	<b>-385</b>
Increase (-) decrease (+) inventory	82	23	118	-	-	-
Increase (-) decrease (+) receivables	-4,455	-769	706	-2,871	-930	826
Increase (+) decrease (-) liabilities	3,892	-1,129	1,419	2,268	137	216
<b>Net Cash Flow from Operating Activities</b>	<b>-36,271</b>	<b>-16,785</b>	<b>-13,599</b>	<b>1,734</b>	<b>-3,607</b>	<b>657</b>
<b>Cash Flow from Investing Activities</b>						
Group contribution/Shareholders' contribution (note 26)	-	-	-	-37,287	-14,305	-17,767
Purchase of intangible assets	-	-	-1,407	-	-	-
Purchase of property, plant and equipment	-30	-210	-38	-	-	-
<b>Net Cash Flow from Investing Activities</b>	<b>-30</b>	<b>-210</b>	<b>-1,445</b>	<b>-37,287</b>	<b>-14,305</b>	<b>-17,767</b>
<b>Cash Flow from Financing Activities</b>						
Change in long-term receivables, subsidiaries	-	-	-	7,866	-8,123	811
Change in long-term liabilities	-	-	-	-	266	-
New share issue (note 6)	500	142,486	-	140	142,486	-
Option premiums	-	-	-	360	-	-
Not registered share capital	-	1,194	-	-	1,194	-
<b>Net Cash Flow from Financing Activities</b>	<b>500</b>	<b>143,680</b>	<b>-</b>	<b>8,366</b>	<b>135,823</b>	<b>811</b>
<b>Net Increase in Cash and Cash Equivalents</b>	<b>-35,801</b>	<b>126,685</b>	<b>-15,044</b>	<b>-27,187</b>	<b>117,911</b>	<b>-16,299</b>
Cash and cash equivalents at September 1	151,338	24,682	39,750	139,583	21,672	37,995
Net foreign exchange difference	-2	-29	-24	-	-	-24
<b>Cash and Cash Equivalents at Aug 31 (note 29)</b>	<b>115,535</b>	<b>151,338</b>	<b>24,682</b>	<b>112,396</b>	<b>139,583</b>	<b>21,672</b>

\*The parent company manages the main share of the Company's liquid funds. Continuous transfers of money are made through out the year to the subsidiaries when needed and settles at the end of the year through shareholder contributions.

# KEY RATIOS

	Aug 31 04/05	Aug 31 03/04	Aug 31 02/03
Earnings per share, SEK	-4.4	-3.0	-3.7
Earnings per share, diluted, SEK	-4.4	-3.0	-3.7
Shareholders' equity per share, SEK	13.7	18.2	5.2
Shareholders' equity per share, diluted, SEK	13.7	27	4.9
Cash flow per share, SKE	-4.3	23.7	-3.3
Dividends	.	.	.
Share price, SEK	53.5	46.5	69.5
Share price/Equity per share, SEK	3.9	2.6	13.4
P/e-ratio	Neg	Neg	Neg
Opening margin, %	Neg	Neg	Neg
Return on equity,%	-27.4	-18.2	-53
Return on capital employed,%	-27.3	-18.2	-51.8
Return on total assets, %	-25.8	-16.9	-44
Risk-bearing capital,%	92	96.1	76.5
Debt/equity ratio	0.1	0.1	0.2
Interest coverage ratio	-1,405.50	-1,997.60	-782.0
Solidity, %	92.0	96.1	76.5
Average number of employees	6.3	4.5	5.0
Research and development costs, kSEK	24,676	4,165	9,372
Investment in fixed assets, kSEK	33	209	1,470
Number of shares	8,418,043	8,345,480	4,615,471
Numbers of shares, average	8,410,787	5,337,188	4,614,112
Numbers of shares, diluted	8,442,800	5,606,850	4,648,362

## **KEY RATIO DEFINITIONS**

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### **AVERAGE NUMBER OF SHARES**

The weighted number of shares during the year, taking into account new capital share issues during the period.

### **THE NUMBER OF SHARES AFTER FULL DILUTION**

The average number of shares, taking into account the dilution effect of outstanding options.

### **EARNINGS PER SHARE**

The earnings for the year divided by the average number of shares.

### **EARNINGS PER SHARE AFTER DILUTION**

The year's earnings divided by the number of shares after dilution. As the Company is in a loss-making situation the average number of shares is used as no improvement of earnings per share is allowed according to RR 18.

### **SHAREHOLDER'S EQUITY PER SHARE**

The shareholder's equity divided by the number of shares at the year-end.

### **SHAREHOLDER'S EQUITY PER SHARE AFTER DILUTION**

The shareholder's equity divided by the number of shares after dilution.

### **CASH FLOW PER SHARE**

The cash flow divided by the average number of shares.

### **STOCK EXCHANGE PRICE**

The closing price as of the year-end on August 31 st.

### **PRICE/SHAREHOLDER'S EQUITY PER SHARE**

The quoted price divided by the shareholder's equity per share.

### **P/E NUMBER**

The quoted price in relation to the profit per share.

### **OPERATING MARGIN**

The operating profit/loss after write-offs as a percentage of the earnings.

### **RETURN ON EQUITY**

The year's earnings in relation to the average shareholder's equity.

### **RETURN ON CAPITAL EMPLOYED**

The year's earnings after financial income and expenses in relation to the average capital employed.

### **CAPITAL EMPLOYED**

The average balance sheet total with allowance for the average liabilities not charging interest.

### **RETURN ON ASSETS**

The year's earnings after financial income and expenses in relation to the average balance sheet total.

### **SHARE OF RISK-BEARING ASSETS**

The sum of the shareholder's equity and latent tax liabilities divided by the balance sheet total.

### **DEBT-EQUITY RATIO**

The ratio of the average of all liabilities and the average of the shareholder's equity.

### **INTEREST COVERAGE RATIO**

The earnings after financial income and expenses divided by the financial expenses.

### **EQUITY RATIO**

The shareholder's equity divided by the total balance sheet total, expressed in percent.

### **SHARE PROFIT**

Diamyd Medical's profit is defined as the share development based on the most recent share price at the end of the financial year (August 31st) divided by the share price at the start of the financial year (September 1st) expressed in percent minus 1. The Company does not pay out any premium, which is why this measure is the same as the total share profit.

## **ACCOUNTING PRINCIPLES**

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The Group's accounting methods conform *Årsredovisningslagen (ÅRL)* and the recommendations and statements of the Swedish Financial Accounting Standards Council.

### **CONSOLIDATION PRINCIPLES**

Companies where there is a holding of more than 50% of the votes or in which the parent company in other ways has a controlling interest have been included in the consolidated accounts. The consolidated accounts have been drawn up according to recommendation RR 1:00 of the Swedish Financial Accounting Standards Council using the purchase method. This means that assets and liabilities in the acquired companies are valued at the time of acquisition to establish consolidated acquisition values. If the Group's acquisition values for shares exceeds or is less than the consolidated acquisition values for the subsidiary's assets and liabilities at the time of acquisition the difference is accounted for as goodwill or negative goodwill.

### **INCOME TAXES**

The Company accounts for deferred recoverable income taxes pertaining to deductible deficiencies to the extent that it is likely that the deduction can be settled. Deferred tax liabilities are calculated and shown in the balance sheet for such assets and liabilities, the tax value of which differs from the value shown and where the difference forms a taxable temporary difference. Deferred recoverable income tax is calculated in a similar way as for deductible temporary differences and is only shown in the balance sheet in the respect that the right to deduction is assessed to be able to be utilized in the future. The current tax and changes in the deferred tax liability/receivable are shown in the statement of operations under the heading 'tax on the year's earnings.'

### **RECEIVABLES AND LIABILITIES**

Receivables are booked at the value with which they are expected to be received. Receivables and liabilities in foreign currencies are valued at closing rate of exchange at the accounting year-end. Gains or losses for receivables and liabilities of an operating nature are shown among the business's other costs.

### **MATERIAL FIXED ASSETS**

Material fixed assets are valued at the acquisition value with the deduction of accumulated depreciation. Depreciation "according to plan" is calculated using the straight line depreciation method starting with the acquisition value and the estimated economic life.

### **INTANGIBLE ASSETS**

Expenses for acquiring patent licenses is shown as an asset if the patent is the basis for a product and if the license is judged to have a market value equivalent to the value shown. Straight-line depreciation is used for the licenses during the estimated life; this is assessed to be five years. Patent maintenance costs are continually accounted.

### **RESEARCH AND DEVELOPMENT COSTS**

Research and development costs are shown according to the recommendations of the Swedish Financial Accounting Standards Council for intangible assets (RR15). Expenses that arise after the Company has been able to determine that a final commercial product is achieved are activated.

### **INVENTORY**

Inventory (RR2:02) is valued according to the lowest of the reacquisition value and the net realizable value.

### **CASH FLOW ANALYSIS**

The cash flow analysis shows payments to and from the company and is drawn up according to the indirect method. Apart from cash and bank deposits, short-term investments that are partly exposed to insignificant risk for fluctuations in value as well as partly traded in a market to a known value or have a term that is shorter than three months from the date of acquisition are classified as liquid assets.

### **ALLOCATIONS**

For legal or informal undertakings entered into, allocations are made continually based on an assessment of the value of the undertaking. In cases where it has not been possible to make a reliable assessment or there is uncertainty about the undertaking the undertaking/relationship is shown as a contingent liability.

### **FOREIGN CURRENCY TRANSLATION**

#### *Parent Company*

Transactions in foreign currencies are recorded at the rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated at the rate of exchange ruling at the balance sheet date. All differences are debited in the balance.

#### *Group*

The Company's foreign subsidiary is considered to be self-sufficient. The assets and liabilities of foreign subsidiaries are translated at the rate of exchange ruling at the balance sheet date. The income statements of overseas subsidiaries are translated at weighted average exchange rates for the year. The exchange differences arising on the retranslation are taken directly to equity.

### **EVENTS AFTER THE CLOSING DAY**

Any events after the accounting year-end that confirm commitments for the Company on the closing day are shown in the balance sheet. Information about other happenings significant to the Company is recorded.

### **ACCOUNTING FOR NEW SHARE ISSUE COSTS AND BUY BACK OF OWN CAPITAL INSTRUMENTS**

The amount provided to the shareholder's equity is equivalent to the new share issue funds less the direct costs of the new share issue. No buy-back of shares has been executed or is planned.

#### **FINANCIAL INSTRUMENTS**

Financial assets, liabilities and instruments are classified according to their economic significance. The Company's agreements with clients and suppliers do not comprise currency clauses. Financial instruments are considered to have historical write-off value.

#### **LIQUID ASSETS**

Included in liquid asset classification, apart from cash and bank balance, are even short-term financial investments that are in part exposed to insignificant risks to fluctuations in value as well as in part traded on a market to an established value or with a duration period shorter than 3 months.

#### **LEASING AGREEMENTS**

No significant leasing agreements exist in the Group except office leasing. The leasing contract for the office is of an operational nature. The Company has moved to a suitable office location at Linnegatan 89B in Stockholm. The contract is up to and including 31st August 2007. Breaking of the contract should occur at least 9 months before expiry, otherwise the contract will be prolonged for 3 years on each occasion. Remaining payments on the contracts amount to SEK 869,700.

#### **INFORMATION ABOUT SHARE OPTION PLANS IN DIAMYD MEDICAL**

The Company has not issued any share related compensations to its employees. The share option plan is classified as marketable securities. This is of such a nature that it incurs cost for the Company. The only effect of the share option plans on the accounts is with respect to received funds for execution of options as well as conversion to share capital. The calculated dilution effect is presented in the 'share value' section. The appointed market value was calculated in accordance with the Black-Scholes valuation model. Received revenues, net after direct transaction expenses, is accounted for in the shareholders equity (nominal value) and share premium reserve.

#### **REVENUES**

Revenue is recognized to the extent that it is probable that the economic benefits will flow to the group and the revenue can be reliably measured. The following specific recognition criteria must also be met before revenue is recognized:

##### *Sale of Goods*

Revenue is recognized when the significant risks and rewards of ownership of the goods have passed to the buyer and the amount of revenue can be measured reliably.

##### *Interest*

Revenue is recognized as the interest accrues (taking into account the effective yield on the asset).

#### **PENSIONS**

All Company employees are provided with individual pension schemes which are chargeable and for which the Company has an agreement with an insurance company to administer these schemes.

#### **REMUNERATION TO THE BOARD AND EMPLOYEES**

The CEO and Board members are paid a remuneration agreed at the annual general meeting. The CEO and other key executives are paid a basic salary, extra benefits and a pension. The Company does not provide variable remuneration, bonuses, severance payments or pension benefits at the current time. No financial instruments are paid as remuneration for work done. It is the duty of the Chairman of the Board to set the payment level for the CEO. Other employees (management team) negotiate their salary, benefits and bonus with the CEO.

#### **DEFINITION OF BUSINESS AREA, GEOGRAPHIC REGION AND PRINCIPLES OF COST DISTRIBUTION BETWEEN AREAS**

The management of the Diamyd Medical Group has divided sales into three business segments (lines of business), of which the largest is the out-licensing of the GAD technology, a segment which today only has costs and no income. In addition to this business segment the group has some sales of products related to the technology (GAD-related products). The third segment is comprised of other supplemental products.

#### **GEOGRAPHIC MARKETS**

GAD-related products and subsidiary products are mainly sold in Scandinavia, Europe and the USA, and to a lesser degree in the rest of the world. The geographic market encompasses the geographical region in which the Company partakes in the market for products and services, in which the basis for competition is on equal terms and uniform, as well as that the circumstances for competition can deviate from adjoining markets where the circumstances for competition are very different. The basis for competition need not be totally uniform; it is enough if they are similar or appreciably uniform. Even if one considers the established players in the local region, or national players with differential power in different regions, this does not limit a niche in the market on a national scale.

#### **COST BREAKDOWN**

The cost breakdown for the segment GAD-related products and subsidiary products is based on sales for the different segments. Additional costs are considered to be 100% due to licensing of the GAD technology as this is the Company's main operation.

## Note 1. Sales

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Net sales are divided as follows:

### kSEK

	04/05	03/04	02/03
Sales of GAD-protein and diagnostic kits	569	1,183	1,175
Sales in Diamyd, Inc.	263	475	1,009
Invoiced freight	42	72	62
Other operating income	9	-	-
<b>Total</b>	<b>883</b>	<b>1,730</b>	<b>2,246</b>

The management of the Diamyd Medical Group have divided sales into three business segments (lines of business), of which the largest is the out-licensing of the GAD technology, a segment which today only has costs and no income. In addition to this business segment the group has some sales of products related to the technology (GAD-related products). The third segment is comprised of other supplemental products.

All sales are made from the subsidiaries Diamyd Diagnostics and Diamyd Inc. The group usually accounts for all sales and transfers between segments as if the sales took place to a third party at current market prices. The principle for transfer prices to Diamyd Inc., however, is that the margin for Diamyd Inc. should be 50% towards customers. The income is assigned to geographical regions depending on to which region sales have been made.

#### *Out-licensing of Diamyd™*

The main business of Diamyd Medical is the development of a pharmaceutical for diabetes patients who have GAD-antibodies. Currently no outlicensing agreement has been made, but future plans include this.

#### *GAD-related Products*

These products are comprised of the GAD protein (the active ingredient in Diamyd™) and Diamyd anti-GAD RIA-kits (a diagnostic kit that can measure the presence of GAD antibodies in diabetes patients). The products are sold to researchers and laboratories. The sales are mainly a way to prepare the market for the upcoming product Diamyd™, which is under development.

#### *Other Products*

The Company also markets a number of agency products as a part of the company's strategy to be a leading company in autoimmune diagnostics. Currently these products come from Mercodia AB and consist of about ten diagnostic kits for diabetes and cardiovascular diseases.

## Business Segments

The following summary shows the income and balance as well as assets and liabilities for business segments during the financial years 2004/05 and 2003/2004:

### Sales and Net Income

KSEK	GAD-related products		Other products		Out-licensing of Diamyd™		Eliminations		Total	
	04/05	03/04	04/05	03/04	04/05	03/04	04/05	03/04	04/05	03/04
External sales	511	1,137	321	520	-	-	-	-	832	1,657
Internal sales	-	113	-	-	-	-	-	-113	-	-
Invoiced freight	27	53	15	20	-	-	-	-	42	73
Other operating income	48	-	9	873	-	-	-	-	57	873
<b>Total</b>	<b>586</b>	<b>1,303</b>	<b>345</b>	<b>1,413</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-113</b>	<b>931</b>	<b>2,603</b>
Raw materials and supplies	-565	-688	-210	-220	-	-	-	113	-775	-795
<b>Operating income/ loss per business segment</b>	<b>21</b>	<b>615</b>	<b>135</b>	<b>1,193</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>156</b>	<b>1,808</b>
Other costs per business segment, incl. staff in Diamyd, Inc.	-233	-289	-135	-238	-38,776	-17,222	-	-	-39,144	-17,749
Depreciations	-2	-1	-1	-2	-898	-880	-	-	-901	-883
<b>Operating income/loss</b>	<b>-214</b>	<b>325</b>	<b>-1</b>	<b>953</b>	<b>-39,674</b>	<b>-18,102</b>	<b>-</b>	<b>-113</b>	<b>-39,889</b>	<b>-16,937</b>
Interest expense	-	-	-	-	-26	-8	-	-	-26	-8
Interest income	-	2	-	3	3,195	855	-	-	3,195	860
Other financial items	-	-	-	-	152	95	-	-	152	95
<b>Net loss after financial income</b>	<b>-214</b>	<b>327</b>	<b>-1</b>	<b>956</b>	<b>-36,353</b>	<b>-17,160</b>	<b>0</b>	<b>-113</b>	<b>-36,569</b>	<b>-15,990</b>
<b>Other Information</b>										
Assets	1,448	1,355	1,292	1,470	121,765	179,892	968	-25,006	125,473	157,711
Liabilities	1,604	1,255	1,348	1,415	5,650	27,991	1,403	-24,548	10,005	6,113
<b>Investments per segment</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>33</b>	<b>210</b>	<b>-</b>	<b>-</b>	<b>33</b>	<b>210</b>

The principle for allocation of costs to the segments is based on sales for each segment. Other costs are considered to be 100% related to the out-licensing of Diamyd™.

### Geographic Markets

The table below shows turnover in each geographic market in which customers are located.

#### Sales per territory:

	2004		2003		2002	
	GAD-related products	Other products	GAD-related products	Övriga products	GAD-related products	Övriga products
Nordic countries	261	208	456	192	537	36
Europe (exl. Scandinavia)	76	-	390	26	548	7
USA	139	86	197	289	255	736
Other countries	36	-	95	23	65	-
<b>Total</b>	<b>512</b>	<b>294</b>	<b>1,138</b>	<b>530</b>	<b>1,405</b>	<b>779</b>

Assets and liabilities have not been allocated by geographical market as all significant assets and liabilities are in Sweden.

**Note 2.**

The Company uses an income statement classified according to type of cost of which two of the most important costs of the Company are research and development and patents which, because of their importance and significance to the Company are published in the statements of operations. Costs classified as research and development are all costs related to the clinical trial studies and the production of the vaccine for the studies.

**Note 3.**

Subscribed but not paid capital as of August 31, 2004 consisted of 11,882 B shares from the capital issue in June 2004. This capital was paid during the 2004/05 financial year.

**Note 4. Information Regarding Employees, Members of the Board of Directors and Management**

<b>Average Number of Employees</b>	<b>04/05</b>	<b>03/04</b>	<b>02/03</b>
Women	2	1	1
Men	4	4	4
<b>Total</b>	<b>6*</b>	<b>5</b>	<b>5</b>

\* The average number of employees during the year amounts to 6,25 people whereas a recruitment took place in November 29, 2004.

<b>Salaries, Pensions and Other Post-employment Benefits, kSEK</b>	<b>04/05</b>	<b>03/04</b>	<b>02/03</b>
CEO	1,240	1,125	990
Other employees	3,961	2,405	2,590
<b>Total Salaries and Remuneration</b>	<b>5,201</b>	<b>3,530</b>	<b>3,580</b>
Social security costs	1,688	1,246	1,084
Pension costs, CEO	432	364	254
Pension costs, Other key executives	1,006	539	192
Other personnel expenses	371	398	146
<b>Total costs*</b>	<b>8,698</b>	<b>6,077</b>	<b>5,256</b>

\* Employee costs that relates to persons involved in the clinical trial studies amount to 381 kSEK and is accounted for in the Consolidated Income Statement as research and development costs.

	<b>Salary/Board- members Fee</b>	<b>Variable Compensation</b>	<b>Other Benefits</b>	<b>Pension Cost</b>	<b>Financial* Instruments</b>	<b>Other</b>	<b>Total</b>
Chairman of the board**	130	-	-	-	-	-	130
Board members **	198	-	-	-	-	-	264
<b>Total</b>	<b>328</b>	-	-	-	-	-	<b>394</b>

\* Options held by board members and employees have been bought from the company to market price and are not considered stock-related transactions.

\*\* Excluding social security costs.

**Principles**

The chairman and members of the Board are remunerated according to the decision of the Annual General Meeting. The remuneration of the CEO and other key executives is in the form of a fixed basic salary, other benefits and pension. At present the Company does not operate variable remuneration, bonus salaries, severance pay and pensions. No financial instruments are paid as remuneration for work done. It is the duty of the chairman of the Board of Diamyd Medical to determine the remuneration paid to the CEO. Employees negotiate individually for salary increases and any benefits with the CEO. Other leading key executives, refers to people who are part of the management.

**Payments Made to Members of the Board**

The annual general meeting on December 10th 2004 approved a fixed fee of SEK 75 thousand to be paid to the members of the Board and SEK 150 thousand to the chairman of the board for the period ending with the annual general meeting for 2004.

**Payments and Pensions Made to the CEO**

The CEO was paid a fixed salary of SEK 1,240 thousand (SEK 990 thousand) including remuneration SEK 75 thousand for being on the Board during the fiscal year 04/05. The Company pays two occupational pension insurances for the CEO. A fixed annual premium of SEK 50 thousand has been paid to occupational pension insurance #1 since the commencement of the policy on April 9th 1997; the insurance matures when the insured reaches 65. For occupational pension insurance #2, the Company pays a premium of 35% of the annual salary. Commencement of the policy was March 1st 2002. The insurance matures when the insured employee reaches 65 years of age. The total pension costs for the CEO during the current year were SEK 432 thousand (SEK 364 thousand). No stock-related payments were made to the CEO during the current year. During the course of the year, two different companies represented by immediate family to the CEO has been contracted as consultants. The total fees charged during the year were SEK 433 thousand (SEK 115 thousand) and the charges were considered as matching the current market with respect to both conditions and price. Wages paid out to the CEO's immediate family members during the current year were SEK 168 thousand.

**Payments and Pensions Made to Other Key Executives**

Salaries paid to other key executives during the fiscal year amounted to SEK 3.8 million (SEK 2.24 million). Occupational pension premiums for other key executives amounted to SEK 972 thousand (SEK 515 thousand). The Company offers a pension to all employees. The pension agreement is equal to 15-35% of the pension-entitled salary and matures when the insured employee reaches the age of 65. All the pension benefits are transferable, i.e. not conditional on future employment.

**Termination Payments for the CEO and Other Key Executives**

There are no provisions for severance pay. The contract between the Company and the CEO is subject to twelve months' notice by either party. The CEO's employment agreement does not include any provisions for redundancy payments. The contracts between the Company and key executives are subject to between one to three months' notice by either party. Employment agreements currently make no provisions for redundancy payments.

**Board Members**

<b>August 31, 2005</b>		<b>August 31, 2004</b>		<b>August 31, 2003</b>	
Women	Men	Women	Men	Women	Men
0%	100%	20%	80%	20%	80%

**Key Executives**

<b>August 31, 2005</b>		<b>August 31, 2004</b>		<b>August 31, 2003</b>	
Women	Men	Women	Men	Women	Men
33%	67%	0%	100%	0%	100%

**Foreign Subsidiaries**

<b>August 31, 2005</b>		<b>August 31, 2004</b>		<b>August 31, 2003*</b>	
Women	Men	Women	Men	Women	Men
100%	0%	0%	100%	0%	100%

\* Because of conflict with Diarect AG, overseas operations have been reduced.

**Sick Leave**

Men	Women	Total
0.76%	1.57%	1.11%

The given information only relates to employees in Sweden in accordance with legal accounting principles.

**Definition**

The shorter period of a sick leave consists of the first fourteen days of a sick leave and is the period reimbursed by the employer. No employee has been on sick leave for more than 14 days in a row during the fiscal year. Total sick leave for the fiscal year was 1.11% (2.33%), of which 0.76% (1.9%) was attributable to Men and 1.57% (3.89%) to Women. Sick leave is defined as the absence from work divided by the available working time adjusted for leave of absence.

**Note 5. Transactions with Immediate Family Members**

During the course of the year, two different companies represented by immediate family to the CEO were contracted as consultants. The total fees charged during the year were SEK 433 thousand (SEK 115 thousand) excluding VAT. The charges were considered as matching the current market with respect to both conditions and price. Salaries paid to the CEO's significant others during the current year were SEK 168 thousand (SEK 168 thousand). No member of the board or key executive or any of their immediate family have been directly or indirectly involved in any business transaction with the Company that was unusual in its character or terms and conditions and took place during the current year. Neither has the Company given any loans, provided any guarantees or stood surety for or for the benefit of any member of the Board, key executive or accountants in the Company.

**Note 6. Share Option Plans 96/2004, 98/2004 and 04/2007.**

The Company's transferable share option plans 96/2004 and 98/2004 expired on the 31st August 2004. All options arising from the 96/2004 share option plan were exercised. From the 98/2004 share option plan 2,185 options were exercised. A new share option plan was approved by the shareholders at the Company's AGM in 2004. The new share option plan comprises 200,000 options of which 120,000 had been signed by August 31, 2005. The premium per option is SEK 3.

**Note 7. Other External Costs**

During the fiscal year 04/05, auditing costs for the Diamyd Group amounted to kSEK 360 (kSEK 286) and consultancy fees amounted to kSEK 65 (kSEK 60). Auditing costs are part of the total external costs.

kSEK (Group)	04/05	03/04	02/03
<b>Focus Revision AB</b>			
Audit fees	257	157	110
Other services	31	20	7
<b>Total</b>	<b>288</b>	<b>177</b>	<b>117</b>
<b>Ernst &amp; Young AB</b>			
Audit fees	103	129	84
Other services	34	40	6
<b>Total</b>	<b>137</b>	<b>169</b>	<b>90</b>
<b>kSEK (Parent Company)</b>			
<b>Focus Revision AB</b>			
Audit fees	220	88	87
Other services	28	20	7
<b>Total</b>	<b>248</b>	<b>108</b>	<b>94</b>
<b>Ernst &amp; Young AB</b>			
Audit fees	103	129	84
Other services	34	40	6
<b>Total</b>	<b>137</b>	<b>169</b>	<b>90</b>

#### **Note 8. Intangible Assets and Depreciations**

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Intangible assets are patents which are depreciated over 5 years.

kSEK	04/05	03/04	02/03
Purchase value, opening balance	10,200	10,200	10,450
Purchases for the year	-	-	1,407
Disposals	-	-	-1,657
<b>Purchase value, closing balance</b>	<b>10,200</b>	<b>10,200</b>	<b>10,200</b>
Depreciations, opening balance	-8,140	-7,380	-8,210
Disposals	-	-	1,657
Depreciations for the year	-751	-760	-827
<b>Depreciations, closing balance</b>	<b>-8,891</b>	<b>-8,140</b>	<b>-7,380</b>
<b>Net Book Value August 31, 2005</b>	<b>1,309</b>	<b>2,060</b>	<b>2,820</b>

#### **Note 9. Tangible Assets and Depreciations**

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Computers are depreciated over 3 years and machinery and equipment are depreciated over 5 years.

kSEK	04/05	03/04	02/03
Purchase value, opening balance	1,446	1,269	1,234
Purchases for the year	33	209	35
Disposals	-	-32	-
<b>Purchase value, closing balance</b>	<b>1,479</b>	<b>1,446</b>	<b>1,269</b>
Depreciations, opening balance	-1,109	-1,018	-852
Disposals	-	32	-
Depreciations for the year	-150	-123	-166
<b>Depreciations, closing balance</b>	<b>-1,259</b>	<b>-1,109</b>	<b>-1,018</b>
<b>Net Book Value August 31, 2005</b>	<b>220</b>	<b>337</b>	<b>251</b>

**Note 10. Financial Fixed Assets**

kSEK	04/05	03/04	02/03
Acquisition value at the beginning of the year	800	800	800
Investments during the year	-	-	-
<b>Acquisition value at the end of the year</b>	<b>800</b>	<b>800</b>	<b>800</b>
Accumulated amortization at the beginning of the year	-	-	-
The year's amortization	-	-	-
<b>Accumulated amortization at the end of the year</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Net Book Value August 31, 2005</b>	<b>800</b>	<b>800</b>	<b>800</b>

Company	Corporate Identity No	Registered Office	Ownership Share	No. of Shares	Net Book Value
Mercodia AB	556157-5100	Uppsala	19%	1,000	800 kSEK

**Note 11. Financial Income**

The company has received a dividend of SEK 152,000 (SEK 95,000) from Mercodia AB which has been accounted for as a financial income.

**Note 12. Inventories**

The inventory consists of diagnostic kits and is located at the U.S. company Diamyd, Inc.

**Note 13. Accounts Receivables**

The Diamyd Group markets products and agency products related to diabetes in order to promote contacts with researchers and to prepare the market for the impending pharmaceutical. At present the accounts receivables do not amount to a large sum. The accounts receivable for the year are SEK 450,000.

**Note 14. Prepaid Expenses and Accrued Income**

kSEK	Aug 31 2005	Aug 31 2004	Aug 31 2003
Prepaid patent fees	510	466	495
Prepaid insurance premiums	82	144	199
Accrued interest income	4,037	478	178
Other prepaid expenses	818	64	456
Total	5,447	1,152	1,328

The increase in accrued interest income, compared to last year, was generated as a result of the liquid assets, made available from the new share issue in 2004, that have been placed in bonds.

#### Note 15. Short-term Investments

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Short-term investments are valued at acquisition value and are invested in interest bearing bonds in the securities market. A marginal interest risk can result in the value of the Company's financial assets temporarily varying due to changes in market interest rates. All short-term investments are subject to trade and are classified as short-term even if expiry date is longer than one year.

	Aug 31, 2005	Aug 31, 2005
kSEK	Net Book Value	Market Value
Swedish mortgage bonds	15,674	15,552
Banks	14,432	14,892
Other Swedish issuers	61,268	61,809
<b>Total</b>	<b>91,374</b>	<b>92,253</b>

#### Listed short-term investments

kSEK	
Remaining premium	1,942
Remaining discount	.

kSEK	Aug 31, 2005
Duration	Net Book Value
0-1 years	44,544
1-2 years	46,830
<b>Total</b>	<b>91,374</b>

#### Note 16 Ongoing New Share Issue

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The ongoing new share issue consisted of 64,942 options from the 1996 share option plan which were exercised on August 31, 2004. Consequently the equity increased by SEK 64,942 when the new shares were registered and the remaining part of the funds was transferred to the restricted reserves.

#### Note 17. Long-term Liabilities

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In connection with a new share issue in December 1999, 768,205 promissory notes of 1 SEK each were issued with detachable options to subscribe for 75,392 shares of series A (TO1A) and 692,813 shares of series B (TO1B). According to the Swedish Financial Accounting Standards Council Recommendation 27, these promissory notes are not joint instruments. The interest free loan of kSEK 768 will be repaid in conjunction with the exercise of the options and no premature redemption is allowed. The promissory notes are due for payment 2006-08-31 and are therefore classified as a short-term liability as of 2005-08-31.

#### Note 18. Accrued Expenses and Prepaid Income

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kSEK	Aug 31 04/05	Aug 31 03/04	Aug 31 02/03
Accrued vacation pay	59	286	151
Accrued social security costs	170	166	52
Accrued costs, clinical trial studies	3,571	296	371
Other expenses	1,952	2,038	1,264
<b>Total</b>	<b>5,752</b>	<b>2,786</b>	<b>1,838</b>

### Note 19. Operating Costs

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Exchange losses related to sales, cost of materials and other external costs amount to kSEK -125. Exchange gains related to sales, costs of goods sold and external costs amount to kSEK 114. The net loss for the year was affected by a net exchange loss of kSEK 11. The exposure in foreign currency was insignificant at end of the financial year.

### Note 20. Income Tax - 2005

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Non tax-deductible items amount to kSEK 86 (kSEK 68) which should generate a tax cost of kSEK 24 (kSEK 19) if the Company had showed a taxable profit. Tax-deficits are accumulated and may be netted towards future profits. The assessed value for the tax-deficit of the parent company is kSEK 38,019 (kSEK 36,694). For the Group the assessed value for the tax-deficit is kSEK 111,470 (kSEK 76,886) estimated values for accumulated tax-deficits including the financial years 2003/2004 and 2004/2005 are kSEK 44,539 (kSEK 37,841) for the parent company and kSEK 171,091 (kSEK 112,147) for the Group. The tax-deficits are not limited and may be netted towards future profits at any time. No value for income taxes recoverable related to the tax-deficits has been booked. Should the business become profitable in the future, the parent company's income taxes recoverable is going to be worth kSEK 12,471 (kSEK 13,124) at a tax rate of 28%. The equivalent sum for the Group as a whole amounts to kSEK 47,906 (kSEK 37,695).

<b>Group</b>	<b>2004/2005</b>	<b>2003/2004</b>
Loss before taxes	-36,569	-15,990
Taxes according to current tax rates	10,239	4,477
Adjustment for tax rates pertaining to subsidiaries	-3	27
Tax effects in non deductible items	-24	-17
Tax effects in tax free income	1	1
Taxes on last years profit*	-63	-
Non-capitalized deferred income taxes recoverable	-10,213	-6,303
<u>Deductible costs booked directly against shareholders' equity</u>	<u>-</u>	<u>1,815</u>
Effective tax	-63	0

<b>Parent Company</b>	<b>2004/2005</b>	<b>2003/2004</b>
Loss before taxes	-34,950	-17,119
Taxes according to current tax rates	9,786	4,793
Tax effects in non deductible items	-10,441	-4,005
Tax effects in tax free income	1	1
Taxes in group contribution	-	74
Tax effect in non deductible costs accounted for directly against shareholders' equity	-	1,815
Non-capitalized deferred income taxes recoverable	-	-2,604
<u>Used saved deductible deficiency</u>	<u>654</u>	<u>-</u>
Effective tax	0	74

	<b>2005</b>	<b>2004</b>
Sweden	28.00%	28.00%
USA (weighted average - Ohio)	20.10%	25.10%*
Average tax rate for the group	27.99%	28.17%

\* The tax income is higher than the Swedish tax rate of 28% because of the fact that the tax cost in Diamyd, Inc. is lower than 28%.

**Note 21. Shares in Subsidiaries**

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<b>Subsidiary</b>	<b>Corporate Identity No.</b>	<b>Registered Office</b>	<b>Shareholders' Equity kSEK</b>	<b>Earnings kSEK</b>	<b>Ownership Share</b>	<b>No. of Shares</b>	<b>Book Value</b>
Diamyd Therapeutics AB	556242-3797	Stockholm	1,214	-38,697	100%	1,000,000	1,000,000
Diamyd Diagnostics AB	556552-2280	Stockholm	120	-187	100%	100,000	100,000
Diamyd, Inc	01487145	Tom's River, New Jersey	-332	-98	100%	1,000	9,000

**Note 22. Long-term Receivables on the Subsidiaries**

kSEK

Long-term receivables on Diamyd Therapeutics

Long-term receivables on Diamyd Diagnostics 1,563

**Total 1,563****Note 23. Prepaid Expenses and Accrued Income (Parent Company)**

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<b>kSEK</b>	<b>Aug 31 04/05</b>	<b>Aug 31 03/04</b>	<b>Aug 31 02/03</b>
Accrued interest income	3,989	459	148
Other prepaid expenses	126	117	167
<b>Total</b>	<b>4,115</b>	<b>636</b>	<b>315</b>

**Note 24. Currency Clauses in Agreements with Suppliers and Customers**

The Company applies no currency hedging arrangements. There are no currency clauses in agreements with suppliers and customers.

**Note 25. Short-term Liabilities to Subsidiaries**

kSEK

Liabilities, Diamyd Therapeutics AB 3,950

Liabilities, Diamyd, Inc 199

**Total 4,149**

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**Note 26. Deficits in Subsidiaries**

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The parent company has contributed annual capital cover guarantees to the Swedish subsidiaries due to their current deficits.

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**Note 27. The Company's Survival**

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The group is currently generating a negative cash-flow due to the group's core business being to pursue its research and development activities. The Board is convinced that additional financing might be needed in the future in order to accomplish the GAD-project.

The Company has carried out four new share issues. Initially the shareholders placed approximately SEK 21 million in the Company. In a new share issue in September 1997, the Company raised about SEK 54 million. With the earlier new share issue, SEK 74 million had been invested in the Company. A new share issue to the shareholders in January 2000 brought in SEK 30 million before transaction expenses. This brought the investment in Diamyd Medical up to SEK 104 million. A new share issue to the shareholders in March 2002 raised another SEK 30 million before transaction expenses. With prior share issues the Company had now approximately SEK 135 million at its disposal. In May 2004 there was another new share issue of SEK 145 million. Consequently SEK 280 million had been invested in the Company.

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**Note 28. Expenses for the Company's Web Site**

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The Company's web site exists to meet the demands of information in the agreement with the Stockholm Stock Exchange. The web site is thereby at present not classified as an intangible asset as neither cost savings nor income is expected because of the web sites existence. The expenses for the Company's web site are shown in the table below.

kSEK	04/05	03/04	02/03
Maintenance	182.3	67.5	82.5
Translations	29.5	46.8	17.9
Other expenses	3.4	3.1	2.5
<b>Total</b>	<b>215.2</b>	<b>117.4</b>	<b>102.9</b>

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**Note 29. Cash Flow Statement**

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The parent company administers the major part of the Group's funds. Transfers are continually made throughout the year to the subsidiaries as required and settlement is made at the year end, either through a group contribution or a shareholders' contribution. Liquid assets refer to cash and bank deposits as well as short-term investments. As of August 31, 2005 cash and bank deposits amounted to SEK 24,161 and short-term investments SEK 91,374.

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**Note 30. Liabilities**

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All liabilities are non interest bearing.

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**Note 31. Amortization of Shares in the Group Companies/Shareholders' Contributions**

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Amortization of shares in the Group companies/shareholders' contributions refers to amortization of shares that are represented by shareholders' contributions to cover for current net losses in the subsidiaries.

### **Note 32. Interest Received**

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<b>Group</b>	<b>2005</b>
Interest, bank	600
Interest on bonds and commercial papers	2 595
<b>Total</b>	<b>3 195</b>
<b>Parent Company</b>	<b>2005</b>
Interest, bank	519
Interest on bonds and commercial papers	2 595
<b>Total</b>	<b>3 114</b>

### **Note 33. Research and Development Costs**

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Diamyd Medicals AB research and development costs consist of a smaller staff responsible for the ongoing clinical trials. The external costs for clinical trial studies and vaccine production are classified as research and development costs.

### **Note 34. Financial Risk Management Objectives and Policies**

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The main purpose of Diamyd Medicals financial instruments is to maximize income from capital meanwhile maintain a low leveled risk by placing the Company's holdings with known actors such as banks.

#### *Interest Rate Risks*

The interest rate risk emerges primarily when the duration is longer than the expected redemption for the financial instrument. The Company's intention is to invest so that redemptions matches the operations consumption of liquid funds. Hence, the interest rate risk is hereby reduced.

#### *Foreign Currency Risks*

The Company is affected by changes in currency exchange rates since the development to a large extent is outsourced to companies in foreign countries. The effect of currency fluctuations are not hedged and there is therefore a risk that exchange rate changes might affect the company's ability to carry on its development according to plan. As of August 31st 2005 there had been no significant influence of currency effects on the Company's operations.

#### *Credit Risks*

Diamyd Medicals current financial policy allows discount securities, deposits in Swedish banks, bonds with fixed coupons, bonds with variable coupons, zero coupon bonds, etc. Bonds published by companies listed on the Stockholm Stock Exchange A-list are also permissible candidates. The currency permitted is SEK still exceptions can be made if the purpose of the financial investment is to guarantee future commitments in foreign currencies.

#### *Valuation*

Short-term investments are valued to their purchase value. All short-term financial investments are invested in interestbearing papers. The Company's financial instruments can temporarily fluctuate depending on the overall change in market interest rate. Conversely such risk is considered insignificant as the Company's intent is to maintain the financial instruments for the initially planned investment period and accordingly obtain the investments net booked value in addition to accrued interest.

#### *Cash Flow Risks*

The cash flow of the year totals SEK -36.3 million. Total cash flow amount to SEK -35.8 million. As of August 31, 2005 liquid assets amount to SEK 115.5 million. The liquid assets are expected to last until December 2007 without additional paid in capital.

## **Note 35. Transition to IFRS**

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### *Adjustments in Accordance with IFRS 1*

As Diamyd Medical is facing the transition to IFRS numerous adjustments are to be composed in accordance with the recommendations in the IFRS 1. Diamyd Medicals most essential standpoints are summarized below.

### *Definition of Liquid Assets in the Cash Flow Statement*

According to GAAP in Sweden, all investments in short-term financial investments have been included in the definition of liquid assets in the cash flow statement. Financial instruments that expire after a period of three months, counted from the date of the initial investment, are not included in the definition of liquid assets in accordance with IFRS 1.

In the 2004/05 year-end financial instruments equal to a nominal value of SEK 30 million corresponds to the IFRS requirements and are accordingly classified as liquid assets in the cash flow statement. Financial instruments that expire after a period of three months will be accounted for as the change in long-term investment in the cash flow statement in accordance with IFRS. In the balance sheet these assets will all be classified as short-term investments.

### *Investments in Shares in Other Companies*

As of 2005 all investments in companies according to the IAS39, a part of the IFRS, should be booked at market value in the balance sheet, with the exception of investments classified as associated companies. According to GAAP in Sweden such investments are to be valued at purchase value. Diamyd Medical AB owns 19% of Uppsala company Mercodia AB. As of today Mercodias shares are not subject to trade and sufficient information to calculate the company's market value is not obtainable. Due to the uncertainty of the market value Diamyd Medical AB accounts for its holdings in Mercodia at purchase value.

### *Intangible Assets*

According to IAS38 intangible assets are to be valued at market value. If there is uncertainty regarding future income the general principle is to book expenses for intangible assets as cost. Diamyd Medical AB books its expenses for purchases of patents and licenses as fixed assets if they can be defined as a controllable asset that is expected to generate income or to be sold for the booked value. Depreciations are estimated to economic life of five years. Maintenance fees for licenses are booked as costs. Patent rights are not a subject to trade and sufficient information to estimate the patents market value is not obtainable. Hence the Company continues to apply its chosen accounting principle.

Research and development costs are accounted for on a regular basis in accordance with Redovisningsrådets recommendation Intangible Assets (RR15). Expenses for development will be capitalized at the point when a product meets the criteria of generating income.

### *Inventories*

The inventory is valued in accordance with RR 2 at the lower of acquisition- and net sale value. According to IAS2 it is not possible to include the currency translation differences in the purchase value. The effects of this are immaterial and will not be in the opening balance according to IFRS.

The effect of IFRS adjustments on the 2004/05 year end.

kSEK	AUG 31, 2004	AUG 31, 2005
<b>Shareholders' equity according to Swedish GAAP</b>	<b>151,598</b>	<b>115,468</b>
IFRS-adjustments:		
Market value of short-term investments	-	530
Total IFRS-adjustments	-	530
<b>Shareholders' equity according to IFRS</b>	<b>151,598</b>	<b>115,998</b>

# PROPOSAL FOR THE TREATMENT OF THIS YEAR'S LOSS

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The Board proposes that SEK 34,950,277 (SEK 16,853,812) is transferred from the restricted reserves of the parent company to cover this year's loss of the parent company of SEK 34,950,277 (SEK 17,045,322). The Group's accumulated loss amounts to SEK 34.5 million (SEK 14.7 million) and no transfer of restricted funds in the Group is required.

Stockholm  
December 04, 2005

*Tord Lendau, Chairman*

*Anders Essen-Möller, President and CEO*

*Leif Ek*

*Peter Rothschild*

# AUDIT REPORT

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**TO THE GENERAL MEETING OF THE SHAREHOLDERS OF DIAMYD MEDICAL AB (PUBL) CORPORATE IDENTITY NUMBER 556530-1420.**

We have audited the annual accounts, the consolidated accounts, the accounting records and the administration of the board of directors and the managing director of Diamyd Medical AB (publ) for the financial year 2004-09-01—2005-08-31. These accounts and the administration of the company are the responsibility of the board of directors and the managing director. Our responsibility is to express an opinion on the annual accounts, the consolidated accounts and the administration based on our audit.

We conduct our audit in accordance with generally accepted auditing standards in Sweden. Those standards require that we plan and perform the audit to obtain reasonable assurance that the annual accounts and the consolidated accounts are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the accounts for the financial year. An audit also includes assessing the accounting principles used and their application by the board of directors and the managing director, as well as evaluating the overall presentation of information in the annual accounts and the consolidated accounts. As a basis for our opinion concerning discharge from liability, we examined significant decisions, actions taken and circumstances of the company in order to be able to determine the liability, if any, to the company of any board member or the managing director. We also examined whether any board member or the managing director has, in any other way, acted in contravention of the Companies Act, the Annual Account Act or the Articles of Association. We believe that our audit provides a reasonable basis for our opinion set out below.

The annual accounts and the consolidated accounts have been prepared in accordance with the Annual Account Act and, thereby, give a true and fair view of the company's and the group's financial position and results of operations in accordance with generally accepted accounting principles in Sweden.

We recommend to the general meeting of the shareholders that the income statement and the balance sheet of the parent company and the group be adopted, that the loss for the parent company be dealt with in accordance with the proposal in the administration report and that the members of the board of directors and the managing director be discharged from liability for the financial year.

*Stockholm December 04, 2005*

Ola Wahlquist  
Authorized public accountant  
Ernst & Young AB

Göran Wiman  
Authorized public accountant  
Focus Revision AB

# ANNUAL GENERAL SHAREHOLDERS' MEETING

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The Annual General Shareholders' Meeting in Diamyd Medical AB will be held on December 12th 2005 at 3 pm. Location: Salénhuset, room: Aulan, Norrlandsgatan 15, Stockholm. Shareholders who wish to attend the Annual General Meeting must be recorded in the Company's register of shareholders, held by the VPC (the Swedish Securities Register Center) by December 2th 2005, and must notify the Company of their intention to attend no later than 4 pm December 10th 2004. Shareholders whose shares are registered in custodial accounts through the trust department of a bank or a stockbroker must re-register the shares temporarily in the shareholder's own name by November 30th 2004 at the latest.

The shareholder's rights at the Annual General Shareholders' Meeting can be exercised by an agent. If a legal entity is represented by an agent the power of attorney should be signed by the person authorized to sign for the entity and a copy of the current certificate of incorporation shall be enclosed.

#### REGISTRATION TO ATTEND CAN BE MADE:

- by mail to Diamyd Medical AB, Linnegatan 89B, SE-115 23 Stockholm
- by phone +46 (0) 8 661 00 26
- by fax +46 (0)8 661 63 68
- by email to [info@diamyd.com](mailto:info@diamyd.com)
- on the website [www.diamyd.com](http://www.diamyd.com)

#### WHEN REGISTERING THE SHAREHOLDER SHOULD STATE:

- his/her name
- social security number
- address and phone number
- number of shares

