



## **MODEX THERAPEUTICS REPORTS FIRST QUARTER RESULTS**

**Lausanne, Switzerland, May 7, 2001** -- Modex Therapeutics Ltd (SWX New Market: MDXN) today announced its financial results for the first quarter ended March 31, 2001.

### **Income**

Income from operations for the quarter was CHF 325,000. This was an increase of CHF 223,000 compared to the previous year due to income received from the funding of collaboration agreements relating to the BioDelivery technology, together with, for the first time, income from the sale of products in Germany.

### **Operating Expenses**

Total operating expenses for the quarter of CHF 3.9 million increased by CHF 2.2 million over the previous year. This rise relates to the increased development costs for EpiDex™ and the initial selling and marketing expenses related to the sale of the product in Germany along with the preparation for the launch in Europe. For the BioDelivery, higher development costs relating to the Phase I clinical trial also impacted the expenses.

### **Net loss for the quarter**

Net loss for the quarter amounted to CHF 3.0 million compared to CHF 1.6 million for the previous year and is in line with the Company's forecast.

### **Strong Financial Position**

At the end of the quarter the cash and short-term investments amount to CHF 68.5 million which provides Modex with the financial resources to further grow the company in its field of expertise of tissue repair, replacement and regeneration (T3R).

“I am pleased to report strong progress at Modex during Q1 within a number of key areas” commented Dr Jacques Essinger, CEO of Modex. “Several milestones, that were set last year during the IPO in June, have been achieved and we are on track to meet the remainder as follows:

### **1. Successful completion of patient enrollment for the EpiDex™ Phase II trial**

As planned, we successfully completed the enrollment of 80 patients for a Phase II clinical trial of EpiDex™, our skin replacement product.

This clinical trial is the first of its kind. It compares a tissue engineered autologous skin product to the surgical autograft, which is regarded as the gold standard for the treatment of recalcitrant chronic skin ulcers. We expect to announce intermediary results from the first 40 patients in June 2001 and final results from the 80 patients in Q3.

### **2. BioDelivery Phase I trial successfully completed**

We obtained positive results of the Phase I trial conducted for the delivery of Erythropoietin (EPO) using our proprietary encapsulated cell technology BioDelivery. The patients had no complications throughout the eight-week implantation period and did not express an immune response to the human EPO delivered from the implanted devices.

These results confirm and extend the earlier Modex findings that demonstrated excellent cell survival and acceptance of the BioDelivery device in healthy volunteers.

This clinical trial was the first safety demonstration of encapsulated genetically engineered human cells for the delivery of human EPO. Based on this safety data Modex will now advance towards a company sponsored Phase II clinical trial.

### **3. Acquisition of first in-licensing technology since the IPO**

Modex’s development strategy is to grow not only through the development of its existing products but also through the acquisition of technologies or companies in the field of tissue engineering.

During the past quarter we acquired an exclusive license from the Blood Transfusion Center of Lille, France for the use of fibrin glue-keratinocyte combinations for the treatment of wounds. This is the first in-licensed technology since our IPO in June 2000, and falls directly in line with our development strategy.

This technology complements Modex's internal development programs and significantly enhances our product portfolio in wound and skin management.

#### **4. Management team significantly strengthened through three new positions**

We recently strengthened our management team through the appointment of a Head of Tissue Engineering, a Medical Director and a Business Development Director. Each of these individuals has many years of experience in the biotech industry and will bring significant insight and contributions for the future growth of the Company.

#### **Outlook**

During June we expect to announce the intermediate results of the first 40 patients in the EpiDex™ clinical trial. Final results for the 80 patients are expected in Q3. Once we have the final clinical trial results we will be in a position to accelerate our marketing launch of EpiDex™ in the market.

For BioDelivery, we will prepare the launch of the Anemia Phase II clinical trial and further develop other very promising BioDelivery applications.

In terms of Corporate Development, the recent boost to the management team will enable us to accelerate the growth of both our existing products and future acquisitions of products or technologies in the field of tissue engineering. "

***A leader in the field of T3R***

*Modex Therapeutics Ltd is a Swiss biotechnology company, based in Lausanne with a focus on tissue repair, replacement and regeneration (T3R). T3R heralds a new era for healthcare, aiming at regenerating cells for the repair or replacement of deficient tissue. Modex currently focuses its development work on two cell-derived products and technologies:*

***EpiDex™** is a skin equivalent product in Phase II trials that is derived from stem and precursor cells found in the human hair follicle.*

***BioDelivery** proprietary technology uses immortalized fibroblastic cells to continuously deliver therapeutic proteins and has several candidates in various stages of development.*

*The strategy of the company is to in-license advanced and promising T3R technologies, to drive them to a mature stage, and to realize the added value by licensing or selling the developed products to pharmaceutical, biotechnology or medical device companies. Modex Therapeutics (MDXN) has been listed on the SWX New Market since June 2000.*

The full Q1 Report is available on the website [www.mdxn.ch](http://www.mdxn.ch)

Lausanne, May 7, 2001

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# THE MODEX GROUP

## CONSOLIDATED STATEMENT OF INCOME AND EXPENSES

For the quarters ended March 31

	<u>2001</u>	<u>2000</u>
	CHF 000	CHF 000
<b>Income</b>		
Income from research collaborations	224	102
Income from sale of products	101	-
Total Income	<u>325</u>	<u>102</u>
<b>Operating Expenses</b>		
Cost of sales	53	-
Selling and marketing	533	-
Research and development	2,249	1,176
General and administration	742	425
Depreciation and amortization	379	116
Total Operating Expenses	<u>3,956</u>	<u>1,717</u>
<b>Net Operating Loss</b>	(3,631)	(1,615)
Financial income	607	18
<b>Net Loss for the period</b>	<u>(3,024)</u>	<u>(1,597)</u>
<b>Net Loss per share (CHF)</b>		
Basic and diluted loss per share	<u>(2.20)</u>	<u>(52.53)</u>

**THE MODEX GROUP**

CONSOLIDATED BALANCE SHEET

	March, 31 2001	December, 31 2000
	CHF 000	CHF 000
<b><u>Assets</u></b>		
<b>Current Assets</b>		
Cash and cash equivalents	18,541	10,803
Short-term investments	50,000	60,000
Inventories	95	102
Trade accounts receivable	93	363
Other current assets	1,033	851
	69,762	72,119
<b>Long Term Assets</b>		
Property, plant and equipment	2,246	2,226
Intangible assets	1,945	2,139
	73,953	76,484
	73,953	76,484
<b><u>Liabilities and Shareholders' Equity</u></b>		
<b>Current Liabilities</b>		
Trade accounts payable	2,083	747
Accrued payables	471	1,331
	2,554	2,078
<i>Total Current Liabilities</i>	2,554	2,078
Long term liability	972	972
<b>Shareholders' Equity</b>		
Share capital	13,805	13,805
Additional paid in capital	82,892	82,907
Treasury shares	(823)	(855)
Accumulated deficit	(25,447)	(22,423)
	70,427	73,434
<i>Total Shareholders' Equity</i>	70,427	73,434
	73,953	76,484

## THE MODEX GROUP

### CONSOLIDATED STATEMENT OF INCOME AND EXPENSES (IN US\$ 000)

For the quarters ended March 31

	2001	2000
	US\$ 000	US\$ 000
<b>Income</b>		
Income from research collaborations	129	59
Income from sale of products	58	-
Total Income	187	59
<b>Operating Expenses</b>		
Cost of sales	30	-
Selling and marketing	306	-
Research and development	1,292	676
General and administration	426	244
Depreciation and amortization	219	67
Total Operating Expenses	2,273	987
<b>Net Operating Loss</b>	(2,086)	(928)
Financial income	349	10
<b>Net Loss for the period</b>	(1,737)	(918)
<b>Net Loss per share (US\$)</b>		
Basic and diluted loss per share	(1.26)	(30.19)

Exchange rate used for translation to US\$: 1.74

## THE MODEX GROUP

### CONSOLIDATED BALANCE SHEET (IN US\$ 000)

	March, 31 2001	December, 31 2000
	US\$ 000	US\$ 000
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	10,656	6,208
Short-term investments	28,736	34,483
Inventories	55	59
Trade accounts receivable	53	209
Other current assets	594	489
	40,094	41,448
<b>Long Term Assets</b>		
Property, plant and equipment	1,291	1,279
Intangible assets	1,118	1,229
	42,503	43,956
	42,503	43,956
<b>Liabilities and Shareholders' Equity</b>		
<b>Current Liabilities</b>		
Trade accounts payable	1,197	429
Accrued payables	271	765
	1,468	1,194
<i>Total Current Liabilities</i>	1,468	1,194
Long term liability	559	559
<b>Shareholders' Equity</b>		
Share capital	7,934	7,934
Additional paid in capital	47,639	47,647
Treasury shares	(473)	(491)
Accumulated deficit	(14,624)	(12,887)
	40,476	42,203
<i>Total Shareholders' Equity</i>	40,476	42,203
	42,503	43,956
	42,503	43,956

Exchange rate used for translation to US\$: 1.74