

# ValiRx plc

## Interim results

11 September 2008, London. ValiRx plc (AIM: VAL, "ValiRx", "the Company") the cancer therapeutics and diagnostics company, announces its interim results for the six months ended 30 June 2008.

### Highlights

- Secured second patent for GeneICE™ in Australia
- Secured a licensing agreement for a compound with Cancer Research Technology
- Raised approximately £890,000, net of expenses, through a secondary placing
- On course to generate first revenues from Human Papilloma Virus (HPV) Genotype Diagnostic Test Kit in 2009
- Lead pharma compound VAL 101 is on track to enter Phase I trials - first GeneICE™ generated compound to enter human trials
- Acquired outstanding balance of shares in Cronos Therapeutics (July 2008), now trading as ValiPharma, following positive preclinical progress

**Dr Satu Vainikka**, Chief Executive, commented:

*"We have continued to make good progress with our two complementary divisions: ValiBIO and ValiPharma. During the period we strengthened our cash resources and also secured a number of licensing agreements. We were pleased to move our lead compound, VAL 101 into late preclinical development on schedule and are on track to launch our first diagnostic products over the next six months."*

*"We remain confident that we are well positioned to exploit our expertise in epigenetics as healthcare regimes continue to shift towards more personalised approaches to medicine. Our aim is to deliver rapid and accurate diagnostics and targeted and effective therapies in the oncology sector."*

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## **Notes to Editors**

**ValiRx plc** is a biopharmaceutical company developing novel technologies and products in oncology therapeutics and diagnostics. It is headquartered in London and admitted to AIM in October 2006. The Group has a portfolio of innovative epigenetic technologies and products with exclusive worldwide rights and patents.

ValiRx operates through two divisions, ValiPharma, a UK-based epigenetic drug discovery and development business and ValiBIO, a Belgium-based oncology diagnostics and biomarker business.

## Interims statement

### Strategic overview

ValiRx is building a portfolio of complementary cancer-related diagnostic and therapeutic products based on patented and potentially market-changing technologies. It aims to exploit the shift in healthcare towards more personalised approaches to medicine, by being at the forefront of personalising disease management in the oncology arena. Personalised medicine refers to tailoring treatment strategies to work differently in different individuals, dependant upon such factors such as their genetic profile, epigenetic profile, environment and the presence of other diseases in the individual.

The Company's products are rooted in the epigenomic analysis and treatment of cancer. Epigenetics is the emerging science that seeks to understand how, why and when genes are switched on and off.

The Company's business model is executed through two complementary operating divisions: ValiBIO, developing and marketing diagnostics that indicate a patient's individual disease profile; and ValiPharma, developing novel treatment therapies based on its proprietary epigenomics platform.

During the last six months the Company completed a number of important milestones including raising approximately £890,000 net of expenses, securing a second patent for GeneICE™ in Australia securing a licensing agreement for a new compound with Cancer Research Technology ("CRT") and based on its positive preclinical progress with its lead compound VAL 101, ValiRx acquired the outstanding shares in Cronos Therapeutics Limited, which is now trading as ValiPharma.

### Therapeutics

ValiPharma, the therapeutic discovery and development business made good progress in its pre-clinical pipeline in the period. Its business model is to in-license early stage products, develop them through to proof of concept in man, and then seek out-licensing partners for further development and marketing. The Company has secured access to a number of technologies and products, as well as expertise through a number of alliances and partnerships.

GeneICE™ (Gene Inactivation by Chromatin Engineering) is the Company's gene-silencing and discovery platform. Gene silencing ('switching off') potentially represents an innovative and ground breaking new approach to cancer treatment as it allows for the development of targeted, personalised medicine and treatment for patients. GeneICE™ is also applicable to a wide variety of other genetic disorders such as in the fields of neurology and inflammatory diseases. This platform is being applied in both the development of an in-house pipeline of drugs and seeking discovery collaborations with others.

During the period, the Company was pleased to announce promising *in vivo* results for its lead molecule VAL 101, in preclinical xenograph models of pancreatic cancer. Studies showed that tumour growth was less than half the size of that seen in the control group. Based on these results, the Company has now initiated further preclinical studies with the aim of progressing VAL 101 towards Phase I regulatory filing by initiating toxicology studies.

The GeneICE™ technology platform utilises the cells' own inherent gene control machinery to effectively silence genes involved in cancer cell progression, in the case of VAL 101, targeting the cancer cell killing (anti-apoptotic) gene BCL-2. These latest *in vivo* results follow on from studies earlier in the period which provided evidence that GeneICE™ could trigger cell death in ovarian, pancreatic and prostate cancer cells. The application of GeneICE™ technology in both studies targeted the BCL-2 gene, which is often over-expressed in certain types of cancer and may lead to the development of chemotherapeutic cell-death resistance. VAL 101 is on track to enter Phase I ('first in man') clinical trials. This will be the first GeneICE™ generated compound to enter human trials.

The Company has also expanded its product portfolio with the development of a second anti-cancer molecule. In July, the Company announced that it had entered into a licence agreement with CRT to evaluate a novel prostate cancer compound (VAL 201) that has been found *in vivo* (preclinical) to arrest prostate cancer growth. Under the terms of the licence agreement with CRT, ValiRx has a period of 12 months in which to complete the preclinical regulatory development of VAL 201 including toxicology, prior to exercising its option to acquire exclusive worldwide rights to the compound as an anti-cancer agent and subsequently progress to first in man clinical trials early 2009.

The Directors believe that VAL 201 has the potential to add significant value to the Company's pipeline subject to the compound reaching the remaining preclinical and clinical milestones; early studies have thus far indicated that this lead drug candidate may also stop tumour growth in patients who are unresponsive to current treatments.

## **Diagnostics**

ValiBIO, the diagnostic division, continued to make good progress with a number of diagnostic activities in the oncology sector. Its business model is to in-license and develop in-house epigenetic diagnostic platforms and products in the field of oncology. Currently the Company has three product streams: HPV testing, Nucleosomics™ and HyperGenomics™.

In February 2008, the Company broadened its portfolio of screening technologies by signing an agreement with Clarity MD to secure the European distribution rights for its HPV Genotype Diagnostic Test Kit. The test identifies 39 subtypes of HPV and is ready for commercial exploitation with the kits now in production. HPV screening is becoming recognised as a reliable alternative to the current PAP smear test method for identifying cervical pre-cancers; the Company expects to realise revenues from this diagnostic product early in 2009. The Company has already started developing a next generation testing kit in-house.

Nucleosomics™ is a non invasive (blood) epigenomic diagnostic platform that has the potential to screen for early signs of a broad number of cancers using blood samples. The Company is on track to create a high throughput, rapid and affordable testing mechanism for the very early detection of cancer; the Company anticipates that first revenues will be generated from this technology in 2009 with the launch of a research-only-use product.

HyperGenomics™, the Company's third diagnostic product, is at an early stage of development. It is being developed as a high throughput biomarker and diagnostic platform for epigenomic profiling. The Group has filed for patents worldwide and expects to launch the product in 2010.

## **Financials**

The Group's external spend on research & development in the six months to 30 June 2008 was £78,000 (2007: £65,000). Administrative expenses for the first six months were £452,000 (2007: £361,000). The Company reported a loss before tax of £528,341 (2007: £411,073), in line with the Board's expectations and, as at 30 June 2008, had cash reserves of £468,121. The Group generated no revenues in the period (2007: £5,741).

The Company completed an equity financing in May 2008, raising approximately £890,000 net of expenses.

## **Summary**

Overall, the Company has the potential to create new markets in the very early detection of cancer, diagnostics that can drive tailored therapies, and therapeutics that prevent or arrest cancer that offer significantly improved treatments. With the first diagnostic product about to be launched and a range of therapeutic compounds well on the way to the initial trials, ValiRx is making good progress.

**ValiRx Plc**  
**Interim results**  
**For the six months ended 30 June 2008**

**Consolidated income statement**

	<i>Notes</i>	<b>Six months ended 30 June</b>	<b>Six months ended 30 June</b>	<b>Year ended 31 December</b>
		2008	2007	2007
		<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(audited)</i>
		£	£	£
<b>Revenue</b>		-	5,741	42,289
Administrative expenses		<u>(530,066)</u>	<u>(426,385)</u>	<u>(882,957)</u>
<b>Operating loss</b>		(530,066)	(420,644)	(840,668)
Cost of capital reconstruction		<u>-</u>	<u>-</u>	<u>(33,600)</u>
<b>Loss before interest</b>		(530,066)	(420,644)	(874,268)
Finance income		2,210	9,583	13,198
Amounts written off investments		-	-	(428,794)
Finance costs		<u>(485)</u>	<u>(12)</u>	<u>(121)</u>
<b>Loss before taxation</b>		(528,341)	(411,073)	(1,289,985)
Taxation	3	<u>-</u>	<u>-</u>	<u>-</u>
<b>Loss after taxation</b>		(528,341)	(411,073)	(1,289,985)
Minority interest		<u>66,413</u>	<u>60,704</u>	<u>50,444</u>
<b>Loss for the period</b>		<u>(461,928)</u>	<u>(350,369)</u>	<u>(1,239,541)</u>
<b>Loss per share - basic and diluted</b>	4	<u>(1.36)p</u>	<u>(1.19)p</u>	<u>(4.11)p</u>

**Consolidated statement of changes in equity  
For the six months ended 30 June 2008**

	<b>Share capital</b>	<b>Share premium</b>	<b>Retained earnings</b>	<b>Merger reserve</b>	<b>Reverse acquisition reserve</b>	<b>Total</b>
	£	£	£	£	£	£
<i>Unaudited</i>						
Balance at 1 January 2008	1,896,786	145,643	(1,593,692)	637,500	602,413	1,688,650
Loss for the period	-	-	(461,928)	-	-	(461,928)
Issue of shares	893,199	-	-	-	-	893,199
Movement in period	-	(69,164)	-	-	-	(69,164)
Share based payment	-	-	1,325	-	-	1,325
<b>Balance at 30 June 2008</b>	<u><u>2,789,985</u></u>	<u><u>76,479</u></u>	<u><u>(2,054,295)</u></u>	<u><u>637,500</u></u>	<u><u>602,413</u></u>	<u><u>2,052,082</u></u>
<i>Unaudited</i>						
Balance at 1 January 2007	11,153,055	6,979,770	(354,429)	637,500	(15,760,591)	2,655,305
Loss for the period	-	-	(350,369)	-	-	(350,369)
Issue of shares	2,800	-	-	-	-	2,800
Movement in period	-	(28,584)	-	-	-	28,584
<b>Balance at 30 June 2007</b>	<u><u>11,155,855</u></u>	<u><u>6,951,186</u></u>	<u><u>(704,798)</u></u>	<u><u>637,500</u></u>	<u><u>(15,760,591)</u></u>	<u><u>2,279,152</u></u>
<i>Audited</i>						
Balance at 1 January 2007	11,153,055	6,979,770	(354,429)	637,500	(15,760,591)	2,655,305
Loss for the period	-	-	(1,239,541)	-	-	1,239,541
Capital reconstruction	(9,382,672)	(6,979,770)	-	-	16,363,004	562
Issue of shares	126,403	193,721	-	-	-	320,124
Movement in period	-	(48,078)	278	-	-	(47,800)
<b>Balance at 31 December 2007</b>	<u><u>1,896,786</u></u>	<u><u>145,643</u></u>	<u><u>(1,593,692)</u></u>	<u><u>637,500</u></u>	<u><u>602,413</u></u>	<u><u>1,688,650</u></u>

**Consolidated balance sheet  
As at 30 June 2008**

	<b>30 June</b>		<b>31 December</b>
	2008	2007	2007
	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(audited)</i>
	£	£	£
<b>ASSETS</b>			
<b>Non current assets</b>			
Intangible assets	637,598	576,187	611,507
Property, plant and equipment	11,071	4,233	8,792
Investments	904,976	1,333,770	904,976
	<u>1,553,645</u>	<u>1,914,190</u>	<u>1,525,275</u>
<b>Current assets</b>			
Trade and other receivables	104,146	79,108	153,305
Cash and cash equivalents	468,121	413,433	88,275
	<u>572,267</u>	<u>492,541</u>	<u>241,580</u>
<b>TOTAL ASSETS</b>	<u>2,125,912</u>	<u>2,406,731</u>	<u>1,766,855</u>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Borrowings	(1,898)	-	(2,332)
Trade and other payables	(156,332)	(157,262)	(93,974)
	<u>(158,230)</u>	<u>(157,262)</u>	<u>(96,306)</u>
<b>Non current liabilities</b>			
Borrowings	(1,436)	-	(1,322)
	<u>(159,666)</u>	<u>(157,262)</u>	<u>(97,628)</u>
<b>NET ASSETS</b>	<u>1,966,246</u>	<u>2,249,469</u>	<u>1,669,227</u>
<b>SHAREHOLDERS' EQUITY</b>			
Share capital	2,789,985	11,155,855	1,896,786
Share premium account	76,479	6,951,186	145,643
Merger reserve	637,500	637,500	637,500
Reverse acquisition reserve	602,413	(15,760,591)	602,413
Retained earnings	(2,054,295)	(704,798)	(1,593,692)
<b>Total shareholders' equity</b>	<u>2,052,082</u>	<u>2,279,152</u>	<u>1,688,650</u>
<b>Minority interest</b>	<u>(85,836)</u>	<u>(29,683)</u>	<u>(19,423)</u>
	<u>1,966,246</u>	<u>2,249,469</u>	<u>1,669,227</u>

**Consolidated cash flow statement**  
**For the six months ended 30 June 2008**

	<b>Six months ended 30 June</b>	<b>Six months ended 30 June</b>	<b>Year ended 31 December</b>
	2008	2007	2007
	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(audited)</i>
	£	£	£
<b>Operating activities</b>			
Operating loss	(530,066)	(420,644)	(840,668)
Depreciation of tangible assets	2,226	600	2,733
Amortisation of intangible assets	4,500	2,400	8,741
Decrease in debtors	49,159	75,371	1,174
Increase/(decrease) in creditors within one year	62,358	51,840	(10,884)
Other non-cash movement	1,325	-	276
<b>Cash outflows from operating activities</b>	<u>(410,498)</u>	<u>(290,433)</u>	<u>(838,628)</u>
<b>Investing activities</b>			
Interest received	2,210	9,583	13,198
Interest paid	(485)	(12)	(121)
Payments to acquire intangible assets	(30,591)	(90,560)	(132,221)
Payments to acquire tangible assets	(4,505)	-	(2,963)
<b>Net cash used in investing activities</b>	<u>(33,371)</u>	<u>(80,989)</u>	<u>(122,107)</u>
<b>Financing activities</b>			
Issue of ordinary share capital	893,199	2,800	320,124
Cost of share issue	(69,164)	(28,584)	(48,078)
Cost of share reorganisation	-	-	(33,600)
Capital element of hire purchase contracts	(320)	-	(75)
<b>Net cash generated from/(used in) financing activities</b>	<u>823,715</u>	<u>(25,784)</u>	<u>238,371</u>
<b>Net increase/(decrease) in cash and cash equivalents</b>	379,846	(397,206)	(722,364)
Cash and cash equivalents at start of period	<u>88,275</u>	<u>810,639</u>	<u>810,639</u>
<b>Cash and cash equivalents at end of period</b>	<u><u>468,121</u></u>	<u><u>413,433</u></u>	<u><u>88,275</u></u>



## Notes to the interim financial statements

### 1. General information

Valirx Plc is a company incorporated in the United Kingdom, which is quoted on AIM. The address of its registered office is 24 Greville Street, London EC1N 8SS.

### 2. Financial information

The interim financial information set out above does not constitute statutory accounts within the meaning of Section 240 of the Companies Act 1985. It has been prepared under applicable International Financial Reporting Standards adopted by the European Union ('IFRS').

The accounting policies applied in preparing the interim financial information are consistent with those set out in the statutory accounts of the Group for the year ended 31 December 2007. The comparative figures for the year ended 31 December 2007 are extracted from the statutory accounts for that period which have been filed with the Registrar of Companies. The report of the auditors on those accounts was unqualified.

The financial information for the six months ended 30 June 2008 and the six months ended 30 June 2007 has not been audited. As permitted, the Group has chosen not to adopt IAS 34 'Interim Financial Statements' in preparing this interim financial information.

### 3. Taxation

On the basis of these accounts there is no tax charge for the period.

### 4. Loss per share

The loss and number of shares used in the calculation of loss per share are as follows:

	<b>Six months ended 30 June</b>	<b>Six months ended 30 June</b>	<b>Year ended 31 December</b>
	2008	2007	2007
	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(audited)</i>
Basic:			
Loss for the financial period	461,928	350,369	1,239,541
Weighted average number of shares	33,953,736	29,506,380	30,064,923
Loss per share	<u>1.36p</u>	<u>1.19p</u>	<u>4.11p</u>

There was no dilutive effect from the share options outstanding during the period.

Comparative loss per share for the six months ended 30 June 2007 has been re-calculated to reflect the share consolidation that took place on 27 July 2007.

### 5. Dividends

The directors do not propose to declare a dividend for the period.