

Interim Report 2004

**XTL**bio





XTL Biopharmaceuticals Ltd.

XTL Biopharmaceuticals Ltd. (XTLbio) is a biopharmaceutical company developing drugs against hepatitis. XTLbio's HepeX™ product line – now in clinical trials – has the potential to introduce revolutionary therapies for viral hepatitis, including prevention of re-infection in transplanted livers, the Company's primary focus, and a longer-term cocktail approach in treating chronic illness. XTLbio believes its primary competitive advantage lies in its patented TrimerA™ technology, which enables the development of fully human monoclonal antibodies and models of human disease for pre-clinical drug validation. Established in 1993, XTLbio became a public company in 2000 and its shares are listed on the Official List of the UK Listing Authority and are traded on the London Stock Exchange under the symbol XTL.

Conquering hepatitis C in our time



## CEO Letter to Shareholders

### Chief Executive's Review

I am pleased to give an update on XTLbio's progress. The past six months have been a time of significant change for the Company, with the achievement of several milestones and the initial steps being taken in an important evolution in the Company's strategy.

### Commercial Agreement

The establishment of a commercial agreement with Cubist Pharmaceuticals Inc. for the licensing and development of HepeX-B, our drug for the prevention of HBV re-infection in patients after liver transplant, was a key milestone during this period. With this validation of XTLbio's technology and a clear commitment to fund HepeX-B development and commercialization, XTLbio is now able to reallocate its resources to the higher-value hepatitis C development programs.

### HepeX-C

Last month we were pleased to report that agreement was reached with the FDA to reopen enrolment in the Phase 2 HepeX-C trial for the prevention of re-infection in liver transplant patients. After observing reduced levels of HCV in some HepeX-C treated patients at the 240mg dose level, we are eager to establish further safety criteria for this dose before moving on to higher doses. Additionally, our second HepeX-C antibody product continues to advance toward the clinic.

XTLbio's advanced pre-clinical small molecule program for chronic HCV ("HCV-SM") has yielded two clinical candidates. The candidates are proprietary synthetic compounds which inhibit the enzyme which is responsible for the replication of HCV. XTLbio plans to submit an Investigational New Drug application for one of these candidates early next year.



We were able to significantly strengthen our financial position with the successful closing of a \$17.8M financing in July. Given the prevailing market conditions, we were delighted to have been able to raise significant new funds for the Company and to have attracted a number of new top tier institutional investors both from the UK and internationally. The participation of several US based firms in this offering along with the appointment to our Board earlier this year of Peter Stalker III, a New York-based retired Managing Director at E.M. Warburg Pincus and Co. Inc., one of the largest private equity and venture capital firms in the world, has solidified our commitment to secure a stock listing in the US, a dynamic center for biotechnology investment, innovation and commercialization, at the appropriate time. A US listing would provide further opportunity for management to grow the business.

## Financial Review

As at 30 June 2003, the Company's cash short and long-term investments were US \$13.3 million (31 December 2003: US \$22.4 million). Research and Development expenses increased by \$1.8 million as a result of continued development of our clinical trials. General and Administration costs for the period ending 30 June 2004 decreased to US\$ 1.2 million from US\$ 1.7 million for the first half of 2003. Business Development expenses increased as a result of negotiations in both our two lead programs. The expected reduction in cash outflow as a result of the deal with Cubist will be reflected in future financials.

## Summary

With our recent key alliance, a strengthened balance sheet focused clinical programs and a strategy to penetrate the US capital markets, XTLbio is poised for growth. You, the investors, have made this possible and we, the management, will continue to focus on doing that which is essential to achieve this growth and to create shareholder value.

**Martin Becker, PhD**  
President and Chief Executive Officer



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The Board of Directors of XTL Biopharmaceuticals Ltd.

Re: Review of condensed consolidated unaudited interim financial statements for the six months period ended 30 June 2004

At your request, we have reviewed the condensed consolidated interim balance sheet of XTL Biopharmaceuticals Ltd. (hereafter - the Company) and its subsidiary at 30 June 2004 and the condensed consolidated statements of operations, changes in shareholders' equity and cash flows for the six months period then ended. We have also reviewed the consolidated statements of operations and cash flows for the period from 9 March 1993 (incorporation date) to 30 June 2004 (the amounts included therein, which relate to the period through 31 December 2000, are based on the financial statements for 2000, which were audited by another accounting firm).

Our review was performed in accordance with auditing standards generally accepted in Israel and in the United States including those prescribed by the Institute of Certified Public Accountants in Israel. Inter alia, these procedures include: reading of the financial statements referred to above, reading of minutes of meetings of shareholders, the board of directors and its committees, and making inquiries of Company officers responsible for financial and accounting matters.

Since our review was limited in scope and did not constitute an audit in accordance with auditing standards generally accepted in Israel and in the United States, we do not express an opinion on the condensed consolidated interim financial statements.

In performing our review, nothing came to our attention that indicated that material adjustments should be made to the interim condensed consolidated financial statements referred to above in order for them to be considered as having been prepared in accordance with the accounting principles generally accepted in the United States.

Sincerely yours,

  
**Kesselman & Kesselman**

Certified Public Accountants (Israel)

A member of PricewaterhouseCoopers International

Tel-Aviv, Israel

5 September 2004



US dollars in thousands

Condensed Consolidated Balance Sheet at 30 June 2004

30 June  
**2004**  
(Unaudited)

31 December  
**2003**  
(Audited)

**Assets**

Current Assets:

Cash and cash equivalents	7,841	9,854	4,184
Short-term deposits	5,026	17,187	17,329
Marketable securities	336	836	749
Accounts receivable	1,330	2,167	706
<b>Total current assets</b>	<b>14,533</b>	<b>30,044</b>	<b>22,968</b>
Asset Held for Sale		354	
Severance Pay funds	745	656	673
Long-Term Deposits	107	157	159
Property and Equipment, net	904	1,226	1,053
	<b>16,289</b>	<b>32,437</b>	<b>24,853</b>

**Liabilities and shareholders' equity**

Current Liabilities -

accounts payable and accruals:

Trade	1,913	805	1,334
Other	1,828	2,028	1,667
Deferred gain, (note 4)	164		
<b>Total current liabilities</b>	<b>3,905</b>	<b>2,833</b>	<b>3,001</b>
Liability for Employee Rights upon Retirement	1,294	1,235	1,244
Deferred gain, (note 4)	572		
<b>Total long-term liabilities</b>	<b>1,866</b>	<b>1,235</b>	<b>1,244</b>

**Shareholders' Equity:**

Share capital	594	594	594
Additional paid in capital	88,977	88,966	88,966
Other capital surplus	337	337	337
Accumulated other comprehensive income (loss)	(19)	29	14
Deficit accumulated during the development stage	(79,371)	(61,557)	(69,303)
<b>Total shareholders' equity</b>	<b>10,518</b>	<b>28,369</b>	<b>20,608</b>
	<b>16,289</b>	<b>32,437</b>	<b>24,853</b>

Date of approval of the interim financial statements: 5 September 2004.

  
**Geoffrey Vernon**  
Chairman of the Board of Directors

  
**Martin Becker**  
President and Chief Executive Officer



US dollars in thousands

	Six months ended 30 June	Year ended 31 December	Period from 9 March 1993* to 30 June
	2004 (Unaudited)	2003 (Audited)	2004 (Unaudited)

Condensed Consolidated Statements of Operations for the Periods Ended 30 June 2004

Research and Development Costs, net	8,368	6,577	13,793	72,352
Less - Participations		1,886	3,229	10,950
	8,368	4,691	10,564	61,402
General and Administrative Expenses	1,230	1,727	3,058	20,017
Business Development Costs	548	316	664	4,024
Gain from License Agreement, (note 4)	(14)			(14)
Impairment of Asset Held for Sale			354	354
Operating Loss	10,132	6,734	14,640	85,783
Financial income, net	64	192	352	6,412
<b>Net Loss for the Period</b>	<b>10,068</b>	<b>6,542</b>	<b>14,288</b>	<b>79,371</b>
Basic and Diluted Per Share Data:				
Loss per ordinary share	\$ 0.09	\$ 0.06	\$ 0.13	
Weighted average number of ordinary shares used to compute loss per ordinary share	112,019,464	111,212,003	111,712,916	

\* Incorporation date see note 1(a).

The accompanying notes are an integral part of these condensed financial statements.



Condensed Consolidated Statements of Changes in Shareholders' Equity for the Six Month Period Ended 30 June 2004

US dollars in thousands	Number of shares
Balance at 1 January 2004 (audited)	112,019,464
Changes During the Six Months Ended 30 June 2004 (unaudited):	
Loss	
Net unrealized gain	
Comprehensive loss	
Stock-based compensation to non-employees	
<b>Balance at 30 June 2004 (unaudited)</b>	<b>112,019,464</b>
Balance at 1 January 2003 (audited)	111,165,364
Changes During the Six Months Ended 30 June 2003 (unaudited):	
Loss	
Net unrealized loss	
Comprehensive loss	
Exercise of employee stock options	849,550
<b>Balance at 30 June 2003 (unaudited)</b>	<b>112,014,914</b>
Balance at 1 January 2003 (audited)	111,165,364
Changes During the Year Ended 31 December 2003 (audited):	
Loss	
Net unrealized loss	
Comprehensive loss	
Exercise of employee stock options	854,100
<b>Balance at 31 December 2003 (audited)</b>	<b>112,019,464</b>



Share capital	Additional paid-in capital	Other capital surplus	Accumulated other comprehensive income (loss)	Deficit accumulated during the development stage	Total
594	88,966	337	14	(69,303)	20,608
				(10,068)	(10,068)
			(33)		(33)
					(10,101)
	11				11
594	88,977	337	(19)	(79,371)	10,518
590	88,966	337	(48)	(55,015)	34,830
				(6,542)	(6,542)
			77		77
					(6,465)
4					4
594	88,966	337	29	(61,557)	28,369
590	88,966	337	(48)	(55,015)	34,830
				(14,288)	(14,288)
			62		62
					(14,226)
4					4
594	88,966	337	14	(69,303)	20,608



US dollars in thousands

Condensed Consolidated Statements of Cash Flows for the Periods Ended 30 June 2004

	Six months ended 30 June 2004 (Unaudited)	2003	Year ended 31 December 2003 (Audited)	Period from 9 March 1993(**) to 30 June 2004 (Unaudited)
<b>Cash Flows from Operating Activities:</b>				
Loss for the period	(10,068)	(6,542)	(14,288)	(79,371)
Adjustments to reconcile loss to net cash used in operating activities:				
Depreciation	177	243	440	2,445
Capital (gain) loss on property and equipment	(1)		2	10
Liability for employee rights upon retirement	99	177	187	1,419
Impairment of asset held for sale			354	354
Gain on marketable securities	(7)	(7)	(27)	(430)
Stock based compensation expenses				483
Compensation arising from options granted to services providers	11			11
Changes in operating asset and liability items:				
Increase in accounts receivable	(624)	(1,901)	(440)	(1,283)
Increase in deferred gain	736			736
Increase in accounts payable and accruals	740	331	499	3,694
<b>Net cash used in operating activities (*)</b>	<b>(8,937)</b>	<b>(7,699)</b>	<b>(13,273)</b>	<b>(71,932)</b>
<b>Cash Flows from Investing Activities:</b>				
Short-term deposits, net	12,303	14,866	14,724	(5,026)
Long-term deposits	52	(18)	(20)	(107)
Investment in available for sale securities		(11)	(71)	(3,363)
Proceeds from sales of available for sale securities	387	896	1,048	3,438
Severance pay funded	(121)	(147)	(165)	(870)
Purchase of property and equipment	(31)	(53)	(81)	(3,834)
Proceeds from sale of property and equipment	4		2	121
<b>Net cash provided by (used in) investing activities</b>	<b>12,594</b>	<b>15,533</b>	<b>15,437</b>	<b>(9,641)</b>



US dollars in thousands

	Six months ended 30 June		Year ended 31 December	Period from 9 March 1993(**) to 30 June
	2004	2003	2003	2004
	(Unaudited)		(Audited)	(Unaudited)

Condensed Consolidated Statements of Cash Flows for the Periods Ended 30 June 2004

Cash Flows from Financing Activities:

Issuance of share capital, net of share issue expenses		4	4	88,941
Exercise of share warrants and employee stock options				473
Proceeds from long-term debt				399
Proceeds from short-term debt				50
Payments relating to long-term debt				(399)
Payments relating to short-term debt				(50)
<b>Net cash provided by financing activities</b>		<b>4</b>	<b>4</b>	<b>89,414</b>

Net Increase in Cash and Cash Equivalents	3,657	7,838	2,168	7,841
<b>Balance of Cash and Cash Equivalents</b> at Beginning of Period	<b>4,184</b>	<b>2,016</b>	<b>2,016</b>	

<b>Balance of Cash and Cash Equivalents</b> at End of Period	<b>7,841</b>	<b>9,854</b>	<b>4,184</b>	<b>7,841</b>
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Supplementary information on financing activities not involving cash flows - conversion of convertible subordinated debenture into shares				1,700
Supplemental disclosures:				
Income taxes paid	34	109	161	252
Interest paid				350

(\*) Including effect of changes in the exchange rate on cash (9) (1,820)

(\*\*) Incorporation date see note 1(a).

The accompanying notes are an integral part of these condensed financial statements.



## 1. General

- a. XTL Biopharmaceutical Ltd. ("the Company") was incorporated under the Israel Companies Ordinance on 9 March 1993. The Company is a development stage company in accordance with Financial Accounting Standard 7 ("FAS") "Accounting and Reporting by Development Stage Enterprises".

The principal activity of the Company is the development of therapeutic pipeline for the treatment of infectious diseases.

The Company has a wholly-owned subsidiary in the United States - XTL Biopharmaceuticals Inc. ("Subsidiary"), which was incorporated in 1999 under the law of the state of Delaware. The subsidiary is primarily engaged in business development and clinical activities.

- b. Through 30 June 2004, the Company has incurred losses in an aggregate amount of US\$ 79,371,000. Such losses have resulted primarily from the Company's activities as a development stage company. Considering the Company's current reserves and the proceeds from the fundraising (see note 5) the Company does not foresee any cash limitations to finance its operations for the coming year.
- c. The interim financial statements at 30 June 2004 ("the interim statements") were drawn up in condensed form, in accordance with accounting principles generally accepted applicable to interim statements. Thus, the accounting principles applied in preparation of the interim statements are consistent with those applied in the preparation of annual financial statements. Nevertheless, the interim statements do not include all the information and explanations required for annual financial statements.
- d. Certain comparative figures have been reclassified to conform to the current period presentation.



## 2. Functional Currency

The currency of the primary economic environment in which the operations of the Company are conducted is the U.S. dollar (“\$” or “dollar”). Most of the Company’s research and development expenses are incurred in dollars. Significant part of the Company’s capital expenditures and substantially all of its financing is in dollars. Thus, the functional currency of the Company is dollar.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in non-dollar currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-dollar transactions and other items reflected in the statements of operations, the following exchange rates are used: (i) for transactions - exchange rates at transaction dates or average rates and (ii) for other items (derived from non-monetary balance sheet items) - historical exchange rates. The resulting currency transaction gains or losses are carried to financial income or expenses, as appropriate.

Following are the changes in the exchange rate of the dollar, the pounds sterling and in the Israeli Consumer Price Index (“CPI”):

	Six months ended 30 June	Year ended 31 December	
	2004	2003	2003
	%	%	%
Rate of change of the Israeli currency against the dollar	2.7	(8.9)	(7.6)
Changes in the Israeli CPI	1.4	(0.5)	(1.9)
Exchange rate of one dollar (at end of period)	NIS 4.497	NIS 4.312	NIS 4.379



### 3. Employee Stock Based Compensation

The Company accounts for its employee stock option plans using the intrinsic value based method of accounting prescribed by APB 25 and related interpretations.

The following table illustrates the effect on loss and loss per share assuming the Company had applied the fair value recognition provisions of FAS 123 (as amended by FAS 148) to its stock-based employee compensation:

	Six months ended 30 June		Year ended 31 December	Period from 9 March 1993* to 30 June
	2004 (Unaudited)	2003	2003 (Audited)	2004 (Unaudited)
US dollars in thousands				
Loss for the period, as reported	10,068	6,542	14,288	79,371
Deduct: stock based employee compensation expense, included in reported loss				(483)
Add: stock based employee compensation expense determined under fair value method for all awards	162	514	821	6,278
<b>Loss Pro-forma</b>	<b>10,230</b>	<b>7,056</b>	<b>15,109</b>	<b>85,166</b>
Basic and diluted loss per share:				
<b>As reported</b>	<b>\$ 0.09</b>	<b>\$ 0.06</b>	<b>\$ 0.13</b>	
<b>Pro-forma</b>	<b>\$ 0.09</b>	<b>\$ 0.06</b>	<b>\$ 0.14</b>	

(\*) Incorporation date see note 1(a).



## 4. License agreement

The Company has entered into a licensing agreement with Cubist Pharmaceuticals, Inc. (hereinafter "Cubist") dated 2 June 2004, under which the Company has granted to Cubist an exclusive, worldwide license (with the right to sub-license) to commercialize HepeX-B and any other product containing a hMAB or humanized monoclonal antibody or fragment directed at the hepatitis B virus owned or controlled by the Company.

Cubist paid the Company an initial up front nonrefundable payment of US\$1 million upon the signing of the agreement (out of which \$14,000 was recorded as income), a further aggregate amount of US\$2 million as collaboration support to be paid in installments until the end of 2005 and an additional amount of up to US\$3 million upon achievement of certain regulatory milestones.

Under the agreement, the Company is entitled to receive royalties from net sales by Cubist, if any, generally ranging from 10 per cent to 17 per cent, depending on levels of net sales achieved by Cubist, subject to certain deductions based on patent protection of HepeX-B in that territory, total costs of HepeX-B development, third party license payments and indemnification obligations, see also note 6 to the annual financial statements.

In addition, Cubist may request the Company to provide future development services that will be reimbursed by Cubist.

## 5. Subsequent event

On 2 August 2004, the Company completed a Placing and Open Offer for new ordinary shares, as result of which 56,009,732 Ordinary shares of NIS 0.02 each have been issued. The gross proceeds of the issuance of shares amount to £9.8 million - US\$17.8 million (net, approximately £8.5 million - US\$15.4 million).

[www.xtlbio.com](http://www.xtlbio.com)



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The logo for XTLbio features the letters 'X', 'T', and 'L' in a bold, blue, sans-serif font. The 'X' has a small circle above its top-left stroke. To the right of these letters, the word 'bio' is written in a lowercase, blue, sans-serif font.