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BIGMAR INC  
Form 10QSB  
November 15, 2001

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-QSB

MARK ONE

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2001

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NO. 1-14416

BIGMAR, INC.

(Exact name of small business issuer as specified in its charter)

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

31-1445779  
(I.R.S. Employer Identification No.)

9711 SPORTSMAN CLUB ROAD  
JOHNSTOWN, OHIO  
(Address of principal executive offices)

43031  
(Zip Code)

Issuer's telephone number, including area code: (740) 966-5800

Indicate by checkmark whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. YES  NO

As of November 11 2001, 10,168,973 shares of common stock of the issuer were outstanding.

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BIGMAR, INC. AND SUBSIDIARIES

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PART I: FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

BIGMAR, INC. AND SUBSIDIARIES  
Consolidated Condensed Balance Sheets

|   | Sept<br>2001         |
|---|----------------------|
|   | -----<br>(Unaudited) |
| ASSETS                                    |                      |
| Current assets:                           |                      |
| Cash and cash equivalents                 | \$                   |
| Accounts receivable, net                  | 1,                   |
| Accounts receivable related party         |                      |
| Inventories                               | 2,                   |
| Prepaid expenses and other current assets |                      |
|   | -----                |
| Total current assets                      | 4,                   |
| Property, plant and equipment, net        | 12,                  |
| Intangibles and other assets, net         |                      |

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|  |        |
|--|--------|
| Total  | \$ 17, |
| -----  |        |
| =====  |        |
| LIABILITIES AND STOCKHOLDERS' EQUITY   |        |
| Current liabilities:   |        |
| Accounts payable   | 2,     |
| Notes payable  |        |
| Current portion of long-term debt  |        |
| Due to related party   | 1,     |
| Accrued expenses and other current liabilities   | 2,     |
| Deferred revenue   | 3,     |
| -----  |        |
| Total current liabilities  | 10,    |
| Long-term debt   | 5,     |
| -----  |        |
| Total liabilities  | 16,    |
| -----  |        |
| Stockholders' equity:  |        |
| Preferred stock (\$.001 par value; 5,000,000 shares authorized; 1,000,000 designated as Series A and 10,000 designated as Series B): Series B Preferred Stock, 7,000 and 1,000 shares issued and outstanding at September 30, 2001 and December 31, 2000, respectively |        |
| Common stock (\$.001 par value; 30,000,000 shares authorized; 10,168,973 shares issued and outstanding at September 30, 2001 and December 31, 2000)  |        |
| Additional paid-in capital   | 34,    |
| Retained earnings (deficit)  | (32,   |
| Cumulative translation adjustment  | (1,    |
| -----  |        |
| Total stockholders' equity   |        |
| -----  |        |
| Total  | \$ 17, |
| =====  |        |

See accompanying notes to consolidated condensed financial statements.

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BIGMAR, INC. AND SUBSIDIARIES  
Consolidated Condensed Statements of Operations  
(Unaudited)

|                    | Three months ended September 30, |              |
|--------------------|----------------------------------|--------------|
|                    | 2001                             | 2000         |
|                    | -----                            | -----        |
| Net sales          | \$ 1,904,251                     | \$ 1,927,885 |
| Cost of goods sold | 1,735,175                        | 1,553,540    |
|                    | -----                            | -----        |
| Gross margin       | 169,076                          | 374,345      |
|                    | -----                            | -----        |

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|  |                |                |
|--|----------------|----------------|
| Operating expenses:  |                |                |
| Research and development   | 678,832        | 899,860        |
| Selling, general and administrative  | 1,181,027      | 716,381        |
|  | -----          | -----          |
| Total operating expenses   | 1,859,859      | 1,616,241      |
|  | -----          | -----          |
| Operating loss   | (1,690,783)    | (1,241,896)    |
| Other income (expense), net  | (6,037)        | 8,283          |
| Interest expense   | (4,045)        | (264,665)      |
| Gain (loss) on foreign currency transactions                                     | (355,553)      | 109,869        |
|  | -----          | -----          |
| Loss before income taxes and extraordinary item                                  | (2,056,418)    | (1,388,409)    |
| Income taxes (benefit)   | --             | --             |
|  | -----          | -----          |
| Loss before extraordinary item   | (2,056,418)    | (1,388,409)    |
| Extraordinary item-Gain on extinguishment of debt,<br>net of income taxes of \$0 | --             | --             |
|  | -----          | -----          |
| Net loss   | (2,056,418)    | (1,388,409)    |
| Preferred stock dividends  | 122,500        | --             |
|  | -----          | -----          |
| Net loss applicable to common stockholders                                       | \$ (2,178,918) | \$ (1,388,409) |
|  | =====          | =====          |
| Basic and diluted loss per share from continuing operations                      | \$ (0.20)      | \$ (0.14)      |
|  | =====          | =====          |
| Basic and diluted extraordinary gain per share                                   | \$ --          | \$ --          |
|  | =====          | =====          |
| Basic and diluted net loss per share   | \$ (0.21)      | \$ (0.14)      |
|  | =====          | =====          |
| Basic and diluted net loss per share applicable to common<br>stockholders        | (0.21)         | (0.14)         |
|  | =====          | =====          |
| Weighted average shares outstanding  | 10,168,973     | 10,010,640     |
|  | =====          | =====          |

See accompanying notes to consolidated condensed financial statements.

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|   | -----<br>2001<br>----- |
|---|------------------------|
| Cash flow from operating activities :   |                        |
| Net loss  | \$(4,866,769)          |
| Adjustments to reconcile net loss to net cash used in operating activities:   |                        |
| Depreciation and amortization   | 1,082,880              |
| Unrealized foreign exchange losses (gains)                                    | 23,962                 |
| Changes in operating assets and liabilities:                                  |                        |
| Decrease in accounts receivable   | 114,077                |
| Increase in accounts receivable related parties                               | (170)                  |
| Decrease in inventories   | 435,350                |
| Increase in prepaid expenses and other current assets                         | (122,000)              |
| (Increase) decrease in accounts payable                                       | (239,846)              |
| Decrease in due to related parties  | (133,719)              |
| Increase in deferred revenue  | 3,429,780              |
| Increase in accrued expenses and other current liabilities                    | 1,793,622              |
|   | -----                  |
| Net cash provided by (used in) operating activities                           | 1,517,167              |
|   | -----                  |
| Cash flows from investing activities :  |                        |
| Purchase of property, plant and equipment                                     | (356,154)              |
|   | -----                  |
| Net cash used in investing activities   | (356,154)              |
|   | -----                  |
| Cash flows from financing activities :  |                        |
| Short-term borrowings   | 411,765                |
| Long-term borrowings  | --                     |
| Proceeds from borrowing from related party                                    | --                     |
| Repayment of short term debt  | (3,328,432)            |
| Repayment of related party loan   | (100,000)              |
| Repayment of long-term borrowings   | (4,285,490)            |
| Preferred stock redemption  | (1,012,833)            |
| Proceeds from issuance of common stock and warrants                           | 411,554                |
| Proceeds from issuance of preferred stock and warrants, net of offering costs | 6,825,000              |
|   | --                     |
|   | -----                  |
| Net cash provided by (used in) financing activities                           | (1,078,436)            |
|   | -----                  |
| Effect of exchange rates on cash  | (21,650)               |
|   | -----                  |
| Net increase (decrease) in cash and cash equivalents                          | 60,927                 |
| Cash and cash equivalents, beginning of period                                | 72,971                 |
|   | -----                  |
| Cash and cash equivalents, end of period                                      | \$ 133,898             |
|   | =====                  |
| Supplemental disclosure of cash flow information :                            |                        |
| Cash paid during the period for :   |                        |
| Interest  | \$ 427,629             |
| Income taxes  | \$ --                  |

See accompanying notes to consolidated condensed financial statements.

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BIGMAR, INC. AND SUBSIDIARIES  
 Consolidated Statements of Comprehensive Loss  
 (Unaudited)

|   | Three months ended September 30, |                |
|---|----------------------------------|----------------|
|   | 2001                             | 2000           |
|   | -----                            | -----          |
| Net loss  | \$ (2,056,418)                   | \$ (1,388,409) |
| Other comprehensive income (loss), net of tax:  |                                  |                |
| Foreign currency translation adjustments,<br>net of income taxes of \$ 0 in both<br>2001 and 2000, respectively | 629,203                          | (481,146)      |
|   | -----                            | -----          |
| Comprehensive loss  | \$ (1,427,215)                   | \$ (1,869,555) |
|   | =====                            | =====          |

See accompanying notes to consolidated condensed financial statements.

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BIGMAR, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

(1) BASIS OF PRESENTATION

Bigmar, Inc. (the "Company") is a Delaware corporation that owns 100% of the outstanding common stock of two Swiss corporations, Bioren, SA ("Bioren") and Bigmar Pharmaceuticals, SA ("Pharmaceuticals"), and 100% of the outstanding common stock of a Delaware corporation, Bigmar Therapeutics, Inc. ("Therapeutics").

In the opinion of management, the accompanying unaudited financial statements include all adjustments necessary to present fairly the Company and its subsidiaries' financial position at September 30, 2001 and December 31, 2000, and the results of operations, cash flows and comprehensive income for all periods presented. The results of the interim periods are not necessarily indicative of the results to be obtained for the entire fiscal year.

For a summary of significant accounting policies (which are consistent with those in place at December 31, 2000) and additional financial information, see Bigmar, Inc.'s Annual Report on Form 10-KSB, for the year ended December 31, 2000. The 10-KSB should be read in conjunction with these financial statements.

The consolidated financial statements include the accounts of the Company and its subsidiaries, all of which are wholly owned. All significant intercompany accounts and transactions have been eliminated.

The financial statements of subsidiaries outside the United States are stated using the local currency as the functional currency. Assets and liabilities of these companies are translated at the rates of exchange at the balance sheet

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date. The resulting translation adjustments are included in accumulated and other comprehensive loss. Income and expenses are translated at average rates of exchange for the period.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The construction of the Company's pharmaceutical manufacturing plant in Barbengo, Switzerland and the process of obtaining regulatory approvals have consumed a substantial amount of the Company's resources. The manufacturing plant received regulatory approval in February 1999 from the United States Food and Drug Administration ("FDA") and the Intercantonal Office for the Control of Medications ("IKS") in Switzerland to manufacture and sell certain injectible pharmaceutical products in the United States and Switzerland. As a result, the Company anticipates that these operations will begin to generate cash to help fund its expansion and further planned research and development activities. During the nine-month period ending September 30, 2001, the Company received approximately \$6.8 million in proceeds from the private placements of preferred stock and warrants. The Company anticipates raising additional funds during 2001 through private stock offerings and

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through additional bank borrowings. However, there can be no assurance that the Company will be successful in these efforts.

### (2) INVENTORIES

The components of inventory at September 30, 2001 and December 31, 2000 are as follows:

|                | September 30,<br>2001 | December 31,<br>2000 |
|----------------|-----------------------|----------------------|
|                | -----                 | -----                |
| Raw Materials  | \$1,062,030           | \$ 1,169,320         |
| Finished Goods | 1,104,122             | 1,469,679            |
|                | -----                 | -----                |
| Total          | \$ 2,166,152          | \$ 2,638,999         |
|                | -----                 | -----                |

### (3) AGREEMENT WITH BAXTER AG

On May 17, 2001, the Company signed a supply and distribution and an asset purchase agreement with Baxter AG ("Baxter"). The purpose of the agreements is to allow Baxter to gradually take over and carry on the intravenous solutions business at Bioren (a wholly owned subsidiary of Bigmar, Inc.). Under the agreement, the Company retains ownership of the plant and will continue to produce and sell other products including various pain management and antibacterial products.

#### Asset Purchase Agreement

Baxter agrees to purchase many of the assets of Bioren and obtains exclusive distribution rights as defined in the agreement. The assets include all specifications and know-how related to the production, all documentation related to clinical trials for the products, all rights related to trademarks, all finished goods at the date of closing equal to \$425,000, and all agreements with suppliers and customers. Assets do not include the plant and equipment.

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Consideration totals \$7,075,000 to be paid as follows: \$3,990,000 at closing, \$1,851,000 on May 17, 2002 and \$1,234,000 on May 17, 2003. The fees are nonrefundable once paid except in the event of breach, as defined, prior to year 4.

### Supply and Distribution Agreement

The Company will continue to manage the manufacturing process at Bioren. Baxter commits to purchasing a minimum amount of product per year and retains exclusive distribution rights for the products produced. Prices of the products are defined in the agreement. Baxter is required to buy at least 10 million units during the four-year period (amounts each year defined in the agreement) after the signing of the agreement. After four years, no minimums exist. In addition, Baxter also reimburses Bioren for various services as defined in the agreement including: warehousing and distribution, marketing and sales, and customer service.

This supply and distribution agreement service portion expires in May 2005, however Baxter can extend it through May 2007. The distribution rights to distribute Bioren's products expire in June 2006 but can also be extended through May 2007. The exclusive

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distribution rights to distribute the products under the agreement expire in June 2006, but can be extended through May 2011.

The Company has elected to defer the \$3,990,000 received at closing, except for the amount related to the sale of inventory at \$425,000. The Company will recognize the remainder of the amount through May 2007 based upon the lower of straight-line amortization or units of production amortization.

#### (4) LONG-TERM DEBT

As of September 30, 2001, the Company had various notes, bonds, mortgages and other borrowings from related parties totaling approximately \$7.90 million, including \$2.44 million that is short term in nature. These monies were used to partially fund the acquisition of Bioren, to acquire, construct, and equip the manufacturing facility and to fund ongoing research and development and product registration activities. In February 2001, the Company repaid \$4.0 million convertible notes and related interest pursuant to a private placement of preferred stock and warrants. During May 2001, the Company extinguished \$2.0 million of its short-term debt and related interest of \$11,922.

#### (5) COMMON STOCK ISSUED

On December 21, 2000, the Company executed an agreement with Banca del Gottardo to issue 1,000 shares of Series B Convertible Preferred Stock, \$0.001 par value per share, for \$1,000,000. On February 27, 2001, the Company redeemed these shares of preferred stock for \$1,012,833 and reissued 7,000 shares of Series B preferred stock and a warrant for the purchase of 1,400,000 shares of the Company's common stock for \$2.00 per share for a total of \$7 million.

In connection with the February issuance, the Company was required to use the proceeds as follows:

- \$4,160,000 was paid to Banca del Gottardo to pay off the \$4 million 8% convertible debt and related interest;
- \$1,012,833 was used to redeem the original preferred stock plus cumulative dividends;



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- \$175,000 was paid as fees to the Bank for offering costs;

The remaining amount was deposited for working capital purposes with the Company.

The following is a discussion of each of the major terms of the preferred stock:

- Cumulative Dividends - The preferred stock has dividends of \$70 per share per annum. Such dividends shall be cumulative and shall be due and payable annually in arrears. Cumulative dividends were approximately \$286,000 at September 30, 2001.
- Liquidation Preference - The preferred has a liquidation preference of \$1,000 per share, plus all accrued plus unpaid dividends.

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- Redemption - The Corporation may on or after January 1, 2003 redeem, from any source of funds legally available, the Series B Preferred Stock. The redemption price shall be the conversion price (see below).
- Voting Rights - The preferred shareholders have no voting rights.
- Conversion - The preferred is convertible at any time to common stock prior to December 31, 2005. At that point, it automatically converts into common stock. The conversion price shall initially be \$2.50 per share through December 31, 2001. Between January 1, 2002 through December 31, 2005, the Series B Conversion price shall be 90 percent of the 20 trading day average closing price of the Common Stock prior to the date the certificate is surrendered for conversion. At no time will the Series B conversion price be less than \$2.00 per share of common stock.
- Warrant - The agreement has a detachable warrant to purchase common stock of the Company. The warrant is exercisable at any time prior to February 2006 and the exercise price is \$2.00 per share. In addition, the Company may call all or part of the unexercised warrants at a price of \$2.50 per share at any time. Upon receipt of the call notice, Banca del Gottardo may either exercise the unexercised warrants or surrender the warrants to the Company for the \$2.50 per share payment. The Company determined the warrant to be valued at \$1,778,000 as of the date of issuance.

In October 2001, the Company issued 60,000 shares of common stock to two private investors at \$.50 per share.

In October 2001, the Company committed to issue 200,000 shares of common stock to Massimo Pedrani, a director of the Company, through a Professional Consulting Services Agreement. Massimo Pedrani is performing certain professional consulting services, in regards to strategic planning and development of certain proprietary technology.

In October 2001, the Company committed to issue 108,000 shares of common stock to Declan Service, a director of the Company, through a Professional Consulting Services Agreement. Declan Service is performing certain professional consulting services, including but not limited to strategic planning and negotiations in regards to the business relationship with Baxter.

(6) RECENTLY ISSUED ACCOUNTING STANDARDS

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On October 3, 2001, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", which addresses financial accounting and reporting for the impairment or disposal of

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long-lived assets. While Statement No. 144 supersedes FASB Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of", it retains many of the fundamental provisions of that Statement. Statement No. 144 also supersedes the accounting and reporting provisions of Accounting Principles Board (APB) Opinion No. 30, "Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions", for the disposal of a segment of a business. However, it retains the requirement in APB Opinion 30 to report separately discontinued operations and extends that reporting to a component of an entity that either has been disposed of (by sale, abandonment, or in a distribution to owners) or is classified as held for sale. By broadening the presentation of discontinued operations to include more disposal transactions, the FASB has enhanced managements' ability to provide information that helps financial statement users to assess the effects of a disposal transaction on the ongoing operations of an entity. Statement No. 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. The Company has not determined what impact this pronouncement will have on its accounting for its assets.

In July 2001, the FASB issued Statement No. 141, "Business Combinations", and Statement No. 142, "Goodwill and Other Intangible Assets". Statement No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001 as well as all purchase method business combinations completed after June 30, 2001. Statement No. 142 will require that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead tested for impairment on an annual basis in accordance with the provisions of Statement No. 142. Statement No. 142 will also require that intangible assets with estimable useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of". The Company has not determined what impact these new pronouncements will have on its accounting for its intangible assets.

### (7) SEGMENT DATA

The Company manages its business segments primarily on a geographic basis with each location representing a distinct segment. The Company's reportable segments are comprised of the following: Bioren, located in Couvet, Switzerland; Pharmaceuticals, located in Barbengo, Switzerland; and the Company's Corporate Headquarters, located in Johnstown, Ohio, U.S.A.

The Company evaluates the performance of its segments based on segment profit/(loss). Segment profit/(loss) for each segment includes sales and marketing expenses, certain research and development expenses, and overhead charges directly attributable to the segment. Segment profit/(loss) excludes certain expenses, which are managed outside the reportable segments. Costs excluded from segment profit primarily consist of corporate expenses, other research and development charges for the testing of products targeted for

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U.S. markets, as well as other general and administrative expenses which are separately managed.

The Company does not include intercompany transfers between segments for management reporting purposes. Summary information by segment for the nine months and three months ended September 30, 2001 and 2000 is as follows:

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### NINE MONTHS ENDED SEPTEMBER 30, 2001:

|                                       | BIOREN      | PHARMA-<br>CEUTICALS |
|---------------------------------------|-------------|----------------------|
| Sales - International                 | 4,912,671   | 1,500,288            |
| Gross Margin                          | 1,093,354   | (385,076)            |
| Operating expenses and other expenses | (1,508,638) | (2,119,609)          |
| Segment Income (Loss)                 | (415,284)   | (2,504,685)          |

### NINE MONTHS ENDED SEPTEMBER 30, 2000:

|                                       | BIOREN      | PHARMA-<br>CEUTICALS |
|---------------------------------------|-------------|----------------------|
| Sales - International                 | 4,280,622   | 1,542,723            |
| Gross Margin                          | 950,646     | 150,877              |
| Operating expenses and other expenses | (1,166,580) | (1,811,872)          |
| Segment Income (Loss)                 | (215,934)   | (1,660,995)          |

### THREE MONTHS ENDED SEPTEMBER 30, 2001:

|                                       | BIOREN    | PHARMA-<br>CEUTICALS |
|---------------------------------------|-----------|----------------------|
| Sales - International                 | 1,508,162 | 396,089              |
| Gross Margin                          | 478,142   | (309,066)            |
| Operating expenses and other expenses | (601,649) | (480,646)            |
| Segment Income (Loss)                 | (123,507) | (789,912)            |

### THREE MONTHS ENDED SEPTEMBER 30, 2000:

|                       | BIOREN    | PHARMA-<br>CEUTICALS |
|-----------------------|-----------|----------------------|
| Sales - International | 1,341,148 | 586,737              |
| Gross Margin          | 242,376   | 131,969              |

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|                                       |           |           |
|---------------------------------------|-----------|-----------|
| Operating expenses and other expenses | (414,386) | (721,784) |
| Segment Income (Loss)                 | (172,010) | (589,815) |

### (8) GOING CONCERN

The Company anticipates that additional capital funding together with cash from operations will be required to sustain operations through December 2001. However, there can be no assurance that events affecting the Company's operations will not result in the Company depleting its funds before that time and, therefore, raises substantial doubt about the Company's ability to continue as a going concern. Management is currently discussing additional financing with a number of financial institutions and investors, but there are no assurances that the Company will be able to obtain additional financing or that such financing, if available, will be available on acceptable terms.

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### ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following is management's discussion of significant factors that affected the Company's interim financial condition and results of operations. This should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations included in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2000.

#### Research and Development

In October 2001, the Company filed a patent application for its ready-to-use formulation of acetaminophen (paracetamol), a common analgesic and antipyretic drug with a broad spectrum of indication and with a well-known low toxicity profile. The patent will cover the preparation of acetaminophen in a ready-to-use infusion bag of 100 ml. This drug has an analgesic effect, alleviating pain, as well as an antipyretic action, which means it helps to reduce fever. The indications for use of this ready-to-use drug is to offer pain relief during the immediate post-operative period when oral administration is not possible. Clinical trials are expected to commence shortly in Europe, where the market potential has been estimated by the Company to be approximately \$80 million.

In October 2001, the Company received approval from ANVISA (the Brazilian equivalent to the United States FDA) to market the following oncological drugs in Brazil: Doxorubicin, Daunorubicin, Calcium Leucovorin, Methotrexate, Fluorouracil and Etoposide. These drugs are used in the treatment of the following cancers: breast and lung carcinomas, leukemia, ovarian, bladder, cervix, head and neck, colorectal, prostate and in the rescue therapies. Once the products are fully introduced, the Company expects to capture a relevant share of this market that is estimated to be approximately \$100 million.

In July 2001, the Company received approval from the Intercantonal Office for the Control of Medications ("IKS") to market a specialty injectable preparation of Bupivacaine in Switzerland in three dosage strengths and two different presentations. Five different products of Bupivacaine will be marketed in the "ready to use" polypropylene infusion bag and five in glass vials. Bupivacaine HCl is a long-acting local anesthetic used for caudal, epidural or peripheral nerve block. Although injectable Bupivacaine was approved by the FDA in 1972, Bioren's easy-to-use pre-mix solution delivered in the IV infusion bag is the first such formulation of the drug.

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### Marketing and Sales

In the second quarter of 2001, the Company completed a distribution agreement with Baxter A.G. ("Baxter"), based in Volketswil, Switzerland. The distribution agreement gives to Baxter exclusive rights to market Bioren's standard intravenous solutions products throughout Switzerland and Liechtenstein for a minimum period of 4 years. Terms of the agreement call for Bioren to continue to manufacture the Pre-Mix Solutions for Baxter and Baxter is contractually obligated to purchase from Bioren a minimum of 10 million units of product over the next four years. In addition, Bioren will provide

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Baxter regulatory support for the products throughout the four-year period of the agreement. The agreement also provides Baxter first refusal rights for other geographic distribution areas as well as other products currently sold or under development stage by Bioren.

The Company plans to continue to develop commercial partnerships in other countries for current registered products and sign significant distribution agreements with major pharmaceutical companies for new products.

### Production

The Company intends to devote additional capital resources to increase the production capacity in the next 12 months, especially in the field of lyophilized products. The Company believes its manufacturing concept is attractive to a number of pharmaceutical companies and hopes to fund some of its manufacturing growth needs through joint ventures with other pharmaceutical companies, although no contractual agreements are in place as of September 30, 2001.

## RESULTS OF OPERATIONS

### Sales

The Company reported net sales of \$1,904,000 for the third quarter of 2001, representing a decrease of 1.2% over sales of \$1,928,000 for the same quarter of 2000. This decrease resulted from a lower average selling price in the third quarter 2001 with regard to the intravenous solution business that was sold to Baxter during the second quarter. The Company expects the impact of Baxter sales to decrease in subsequent quarters due primarily to the registrations recently obtained. With respect to the Baxter acquisition, \$392,000 on the deferred \$3,990,000 received at closing was recognized in the third quarter 2001.

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For the nine-month period ended September 30, 2001 net sales increased by \$590,000 or 10.1% over the same period in 2000, from \$5,823,000 in 2000 to \$6,413,000 in 2001. The rise in sales resulted from new customers and new products as well as the recognition of \$392,000 related to the Company's agreement with Baxter.

The Company expects product sales to increase in 2001 compared to 2000 resulting from the continued growth of the Company's existing product lines as well as from introductions of new products, which are currently awaiting FDA approval. The Company expects several of their new products to be approved for sale by regulatory agencies in Europe, the United States and South America during 2001.

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### Gross Margin

Gross margin decreased from approximately \$374,000 for the third quarter of 2000 to \$169,000 for the third quarter of 2001. For the nine-month period ended September 30, 2001, gross margin amounted to \$708,000 compared with \$1,102,000 in the prior year. The gross margin was at approximately 11.0% for the first nine months of 2001, compared to approximately 18.9% for the prior year. The decrease in the gross margin percent was somewhat due to a different product mix resulting in lower unit margins of certain products. However, most of the decrease can be attributed to the Company's agreement with Baxter; the selling prices to Baxter are lower than those that the Company typically would receive selling to end customers. During third quarter 2001, a customer return was accepted by the Company which negatively impacted gross margin by \$119,000.

### Operating Expenses

Operating expenses increased from approximately \$1,616,000 in the third quarter of 2000 to \$1,860,000 in the third quarter of 2001, a 15% increase. This increase is primarily due to lower research and development expenses and higher general and administrative expenses. For the nine month period ended September 30, 2000 and September 30, 2001 respectively, operating expenses increased from approximately \$4,634,000 to \$4,924,000, an increase of 6.3%. This increase is also primarily due to lower research and development expenses as well as higher general and administrative expenses. Research and development expenses decreased by \$268,000 in the same nine month period from \$2,337,000 in 2000 to \$2,069,000 in 2001. Selling, general and administrative expenses increased by \$558,000 from \$2,297,000 in the nine month period of 2000 to \$2,855,000 in the same period of 2001. This increase is primarily due to higher consultant services.

### Other Income and Expenses

Other expense was \$6,000 in the third quarter of 2001 compared with an income of \$8,000 in the same period of 2000. For the nine-month period ended September 30, 2001, other expense was \$17,000 compared with an income of \$121,000 in the prior year.

### Interest expense

Interest expense decreased \$278,000 from the nine-month period ending September 30, 2000 to the same period of 2001, due to a decrease of total debt in the first nine months of 2001, as compared to the first nine months of 2000.

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### Gain, Loss on Foreign Currency Transactions

Foreign exchange losses amounted to \$205,000 for the nine-month period ending September 30, 2001, compared to a gain of \$122,000 in the prior year during the same time period. Fluctuations are due primarily to changes in the exchange rates between the Swiss Franc and the U.S. Dollar.

The Company recorded an extraordinary gain during the first quarter 2000 due to the forgiveness of \$362,000 in long-term debt from a Swiss bank.

### Net Loss

As a result of all of the foregoing, the Company's net loss for the nine month period ended September 30, 2001 amounted to \$4,867,000 or (\$0.48) per share on a basic and diluted basis versus \$3,634,000 during the same period of 2000 or (\$0.42) per share on a basic and diluted basis. Net loss for the quarter ended September 30, 2001 was \$2,056,000 in comparison to a net loss of \$1,388,000 in

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the comparable quarter ended September 30, 2000.

### LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2001 and December 31, 2000, the Company had cash and cash equivalents of \$134,000 and \$73,000, respectively. The Company's working capital was a \$6.4 million deficit and \$3.6 million deficit at September 30, 2001 and December 31, 2000, respectively.

The Company has incurred and will continue to incur substantial expenditures for research and development activities related to bringing its products to the commercial market. The Company intends to devote significant additional funds to product development, formulation, clinical testing, product registration, and other activities required for regulatory review of generic oncological products. The amount required to complete such activities depends upon the outcome of regulatory reviews and the number of new products the Company plans to add during the year. The regulatory bodies may require more testing than is currently planned by the Company. There can be no assurance that the Company's generic oncological products will be approved for marketing by the FDA or any foreign government agency, or that any such products will be successfully introduced or achieve market acceptance.

Property, plant and equipment totaled \$12.6 million and \$13.4 million at September 30, 2001 and at December 31, 2000, respectively. Additions were approximately \$356,000 whereas depreciation expense was \$1.1 million.

As of September 30, 2001, the Company had various notes, bonds, mortgages and other borrowings totaling approximately \$7.90 million including \$2.44 million that is short term in nature. These monies were used to partially fund the acquisition of Bioren, to acquire, construct, and equip the manufacturing facility and to fund ongoing research and development and product registration activities.

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During the first quarter of 2001, pursuant to a private placement transaction with Banca del Gottardo, the Company raised \$6,825,000 after bank commission of 2.5% or \$175,000, which was applied: to repay \$4 million convertible notes and related interest and to repurchase 1,000 shares of Series B Convertible Preferred Stock including accrued dividends. Net proceeds were applied to working capital and general corporate purposes.

The Company anticipates that additional capital funding together with cash from operations will be required to sustain operations through December 2001. However, there can be no assurance that events affecting the Company's operations will not result in the Company depleting its funds before that time and, therefore, raises substantial doubt about the Company's ability to continue as a going concern. Management is currently discussing additional financing with a number of financial institutions and investors, but there are no assurances that the Company will be able to obtain additional financing or that such financing, if available, will be available on acceptable terms.

The Swiss Federal Code of Obligation provides that at least 5% of a Swiss company's net income each year must be appropriated to a legal reserve until such time as this reserve is equal to 20% of the company's paid-in share capital. In addition, 10% of any distribution made by a company in excess of a 5% dividend must also be appropriated to the legal reserve. The reserve of up to 5% of share capital is not available for distribution to stockholders.

The results of the Company's operations are affected by changes in exchange rates between the United States and Swiss currencies. Changes in exchange rates

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between currencies may negatively impact the Company's results of operations, specifically, net sales and gross profit margins from international operations. In addition, the dollar-value equivalent of anticipated cash flows could also be adversely affected. When the Company determines that this risk has become significant, the Company may attempt to manage that risk by using hedging techniques.

### QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

On January 1, 1999, 11 member countries of the European Union (Switzerland excluded) established fixed conversion rates between their existing sovereign currencies, and adopted the Euro as their own common legal currency. The Euro is currently trading on currency exchanges and the legacy currencies will remain legal tender in the participating countries for a transition period between January 1, 1999 and December 31, 2001. Between January 1, 2002 and July 1, 2002, the participating countries will introduce Euro notes and coins and withdraw all legacy currencies so that they will no longer be available. Based on current information and management's current assessment, the Company does not expect that the Euro conversion will have a material adverse effect on its business or financial condition.

In the normal course of business, operations of the Company are exposed to fluctuations in currency values. These fluctuations can vary the costs of financing, investing, and

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operating activities. The Company does not have any programs in place to control these risks.

The Company's foreign currency risk exposure results from fluctuating currency exchange rates, primarily the fluctuation of the U.S. dollar against the Swiss Franc ("Sfr"). The Company faces transactional currency exposures that arise when its foreign subsidiaries (or the Company itself) enter into transactions denominated in currencies other than their local currency. The Company also faces currency exposure that arises from translating the results of its Swiss operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. The Company does not have any programs in place to control these risks.

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Certain statements in this report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including, without limitation, statements regarding future cash requirements and statements which include words such as "expect", "anticipate", "hope", "intend", and other similar words. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors, which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied in such forward-looking statements. Such factors and risks include, but are not limited to the following: delays in product development, problems with clinical testing, failure to receive regulatory approvals, lack of proprietary rights and changes in business strategy. These risk factors and their associated impact on the Company are discussed in greater detail in the Company's Form 10-KSB for the 2000 fiscal year. Many of the factors that will determine results and values are beyond the Company's ability to control or predict. For those statements, the Company claims the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.



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BIGMAR, INC. AND SUBSIDIARIES

PART II. OTHER INFORMATION

ITEM 2 (c) CHANGES IN SECURITIES - RECENT SALES OF UNREGISTERED SECURITIES

On February 28, 2001, the Company issued 7,000 shares of Series B Convertible Preferred Stock, \$0.001 par value per share and warrants at \$2.00 for the purchase of 1,400,000 shares of the Company's Common Stock, \$0.001 par value per share, to Banca del Gottardo via a private placement offering. Proceeds from the sale of shares after bank commission of 2.5% or \$175,000 totaled \$6,825,000 and were applied to repay \$4 million convertible notes and related interest and to repurchase 1,000 shares of Series B Convertible Preferred Stock including accrued dividends. Net proceeds will be applied to working capital and general corporate purposes.

The above-described offering of Preferred Stock and warrants was made pursuant to an exemption from registration under Regulation S.

ITEM 5. OTHER INFORMATION

In August 2001, the Company decided to initiate a stock repurchase program. The Board of Directors believes that the Company's common stock is significantly undervalued and presents an attractive investment opportunity for the Company. Up to \$500,000 of the Company's funds may be used to repurchase its common stock in the open market. However, given the Company's current financial situation, there are no current plans to repurchase stock.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

- (a) Exhibits  
None.
- (b) Reports on Form 8-K.  
No reports on Form 8-K were filed during the quarter ended September 30, 2001.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

November 11, 2001

BIGMAR, INC.  
Registrant

By: /s/ Philippe J.H. Rohrer

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Philippe J.H. Rohrer  
Chief Financial Officer and Treasurer

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