

SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

QUARTERLY REPORT

Pursuant to sections 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Report) JANUARY 24, 1997

Commission File Number 0-12305

REPRO-MED SYSTEMS, INC

(Exact name of registrant as specified in its charter)

NEW YORK

13-3044880

(State or other jurisdiction of
incorporation or organization)

(IRS Employer
identification No.)

24 Carpenter Road, Chester, New York

10918

(Address of principle executive offices)

(Zip Code)

(914) 469-2042

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act 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 X No

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ITEM 5. OTHER EVENTS

Background

On April 12, 1994 the Board of Directors of Repro-Med Systems, Inc's 58.3% owned subsidiary, Gamogen ("Gamogen") approved and on April 14, 1994 signed with Zonagen, Inc. ("Zonagen"), a small US based biotechnology company, an agreement ("Impotence Agreement") under which Zonagen acquired all rights of Gamogen to Gamogen's Oral Treatment for Male Impotence ("Oral Treatment"). In exchange for the above rights Gamogen received from Zonagen \$100,000 in cash and 19,512 shares of restricted common stock of Zonagen and rights to royalties on Zonagen's future sales of the Oral Treatment. On June 20, 1996 Gamogen sold the restricted common stock received from Zonagen to a small group of private investors for \$87,800. As of January 24, 1997 Gamogen has not received any royalty payments under the Impotence Agreement. As of January 24, 1997 Zonagen had not received approval by the US FDA or approvals in other countries for the marketing of the product. There can be no guarantee concerning the Oral Treatment that approvals by the US FDA or approvals in

other countries will be secured and if secured that Zonagen will be successful in marketing of the product.

Amendment To Impotence Agreement

On January 24, 1997 the Board of Directors Gamogen approved and signed with Zonagen a conditional amendment to the Impotence Agreement granting Zonagen the right ("Option") to amend the Impotence Agreement as follows:

- 1) Gamogen's rights to royalties on Zonagen's future sales of the Oral Treatment;
- 2) Gamogen's rights to market the Oral Treatment in countries where Zonagen does not timely obtain regulatory approval for and commence marketing of the Oral Treatment.

The Option is conditioned on the payment to Gamogen of one of the following amounts ("Option Price") less any Maintenance Payments (see below) received by Gamogen pursuant to the conditional amendment:

- (i) if the Option is exercised on or before January 24, 1998, \$750,000;
- (ii) if the Option is exercised after January 24, 1998 but on or before January 24, 1999, \$1,000,000;
- (iii) if the Option is exercised after January 24, 1999 but on or before July 24, 1999, \$1,500,000;
- (iv) if the Option is exercised after July 24, 1999 but before the expiration of the Option, \$1,750,000.

Under the conditional amendment Zonagen is granted the option for a period of three years ending January 24, 2000, however, Gamogen may terminate the Option prior to January 24, 2000 if Zonagen fails to make any of the following payments ("Maintenance Payments") in cash to Gamogen: \$75,000 upon the execution of the conditional amendment and \$75,000 on each July 24 and January 24 which occurs after the execution of the conditional amendment and before Zonagen's exercise of the Option, with the final payment due on July 24, 1999. On January 24, 1997 Gamogen received from Zonagen the initial Maintenance Payment of \$75,000.

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS

(c) EXHIBITS

10.1 Conditional Amendment No. 1 To Assignment Agreement Between Gamogen, Inc. and Zonagen, Inc.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15 (d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the following persons, thereunto duly authorized.

REPRO-MED SYSTEMS, INC

/s/ Andrew I. Sealfon

January 28, 1997

Andrew I. Sealfon
President, Treasurer, Chairman of the Board,
Director, and Chief Executive Officer

/s/ Jesse A. Garringer

January 28, 1997

Jesse A. Garringer
Executive Vice-President, Secretary,
Director, and Chief Financial Officer

EXHIBIT 10.1 - CONDITIONAL AMENDMENT NO. 1 TO ASSIGNMENT AGREEMENT
BETWEEN GAMOGEN, INC. AND ZONAGEN, INC.

CONDITIONAL AMENDMENT NO. 1 TO
ASSIGNMENT AGREEMENT

This Conditional Amendment No. 1 to Assignment Agreement (this "Amendment"), dated as of January 24, 1997, amends that certain Assignment Agreement, dated as of April 13, 1994 (the "Assignment Agreement"), among Zonagen, Inc., a Delaware corporation ("Zonagen"), Gamogen, Inc., a New York corporation ("Gamogen"), and Dr. Adrian Zorngiotti ("Zorngiotti"). Capitalized terms used without definition in this Amendment shall have the meanings ascribed thereto in the Assignment Agreement.

WITNESSETH

WHEREAS, Gamogen and Zorngiotti assigned certain technology (referred to in the Assignment Agreement as the "Subject Technology") to Zonagen pursuant to the Assignment Agreement; and

WHEREAS, Zonagen agreed in the Assignment Agreement to pay certain royalties to Gamogen with respect to its sales of any Royalty-Bearing Product; and

WHEREAS, Gamogen and Zonagen desire to amend the Assignment Agreement to provide Zonagen with the option to terminate its obligations with respect to royalties on Royalty-Bearing Products in exchange for payments by Zonagen;

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and promises contained in this Amendment, the parties hereto agree as follows:

1. Grant of Option. Gamogen hereby grants Zonagen the right, exercisable in the sole discretion of Zonagen in the manner set forth in this Amendment, (a) to amend Section 2.1(b) of the Assignment Agreement by deleting subsection (iii) thereof in its entirety and (b) to further amend Article II of the Assignment Agreement by deleting Section 2.3 thereof in its entirety. Without limiting the foregoing, Zonagen's exercise of the right granted hereby (referred to herein as the "Option") in accordance with the terms of this Amendment shall terminate (x) any and all obligations of Zonagen with respect to (i) the payment of royalties on Royalty-Bearing Products and (ii) obtaining regulatory approval for and marketing Royalty-Bearing Products, and (y) any and all rights whatsoever of Gamogen under the Assignment Agreement; provided that such obligations of Zonagen and rights of Gamogen shall remain in effect unless and until the Option is exercised.

2. Term of Option. Zonagen shall have the right to exercise the Option at any time prior to January 24, 2000 [third anniversary of Amendment], provided that Gamogen shall have the right to terminate the Option prior to such date (as provided below) if Zonagen fails to make any of the following payment ("Maintenance Payments") in cash to Gamogen:

- (a) \$75,000 upon the execution of this Amendment;
- (b) \$75,000 on each July 24 and January 24 which occurs after the execution of this Amendment and before Zonagen's exercise of the Option, with the final such payment to be due on July 24, 1999.

If Zonagen fails to make any Maintenance Payment on the date indicated, Gamogen shall have the right to terminate the Option by delivering written notice of such termination to Zonagen; provided that the Option shall not terminate if Zonagen pays such Maintenance Payment to Gamogen within 30 days after its receipt of such termination notice. Zonagen shall have no obligation to make any Maintenance Payment except for the payment due upon the execution of this Amendment. The sole consequence of Zonagen's failure to make any

Maintenance Payment on the date indicated shall be the right of Gamogen to terminate the Option as provided above.

3. Exercise of Option. Zonagen may exercise the Option by delivering to Gamogen (a) notice of such exercise and (b) the payment in cash to Gamogen of the amount (the "Option Price") specified below:

(i) if the Option is exercised on or before January 24, 1998, the Option Price shall be \$750,000;

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(ii) if the Option is exercised after January 24, 1998 but on or before January 24, 1999, the Option Price shall be \$1,000,000;

(iii) if the Option is exercised after January 24, 1999 but on or before July 24, 1999, the Option Price shall be \$1,500,000; and

(iv) if the Option is exercised after July 24, 1999 but before the expiration of the Option, the Option Price shall be \$1,750,000.

In determining the amount to be paid by Zonagen upon exercise of the Option, Zonagen shall receive credit against the applicable Option Price in an amount equal to the total of all Maintenance Payments previously made by Zonagen pursuant to this Amendment. Upon Zonagen's exercise of the Option as contemplated hereby, the Assignment Agreement shall automatically be amended as reflected in Section 1 of this Amendment, without the necessity of any further action by any party to this Amendment or the Assignment Agreement.

4. Representations and Warranties. Each party hereto represents and warrants to the other party as follows:

(a) It is a corporation duly organized, validly existing, and in good standing under the laws of jurisdiction of its incorporation, with the requisite power to enter into and perform its obligations under this Amendment in accordance with terms hereof.

(b) It has the full right, power and authority to execute and deliver this Amendment and to perform the terms hereof. It has taken all required corporate actions to approve and adopt this Amendment. This Amendment has been duly authorized by all necessary corporate action, and upon execution and delivery thereof will be its valid and binding agreement enforceable against it in accordance with the terms hereof, subject as to enforcement to bankruptcy, insolvency and other laws of general applicability relating to or affecting creditors' rights and to general principles of equity.

(c) Its execution and delivery of this Amendment and the consummation of the transactions required hereby (i) do not and will not violate or conflict with any statute, regulation, judgment, order, writ, decree, or injunction, currently applicable to it, any of its subsidiaries or any of their respective property or assets, and (ii) will not violate or conflict with any provision of its articles of incorporation or bylaws or any existing mortgage, indenture, contract, licensing agreement, financing statement, or other agreement binding on it or any of its subsidiaries.

(d) No consent or approval of its stockholders or any third party is required to be obtained by it in connection with the execution and delivery of this Amendment or the performance of the transactions contemplated hereby. No material contract or agreement to which it is a party restricts its ability to fulfill its obligations and responsibilities under this Amendment or to carry out the activities contemplated herein.

5. No Other Changes. The Assignment Agreement shall continue to be in full force and effect in accordance with the terms thereof, except to the extent such terms are amended by this Amendment upon exercise of the Option by Zonagen.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first set forth above.

ZONAGEN, INC.

By: /s/ Joseph Podolski

Name: Joseph Podolski

Title: President

GAMOGEN, INC.

By: /s/ Jesse A. Garringer

Name: Jesse A. Garringer

Title: Executive Vice-President