

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934**

**September 1, 2004**

Date of Report (date of Earliest Event Reported)

**ISOLAGEN, INC.**

(Exact Name of Registrant as Specified in its Charter)

**DELAWARE**

(State or Other Jurisdiction of  
Incorporation or Organization)

**001-31564**

(Commission File No.)

**87-0458888**

(I.R.S. Employer  
Identification No.)

**2500 Wilcrest, 5th Floor, Houston, Texas 77042**

(Address of principal executive offices and zip code)

**(713) 780-4754**

(Registrant's telephone number, including area code)

**Not applicable**

(Former name or former address, if changed from last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).
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**Item 1.01 Entry into a Material Definitive Agreement.**

Effective September 1, 2004, Isolagen, Inc. ("Isolagen") and Mr. Robert Bitterman entered into an employment agreement (the "Agreement") pursuant to which Mr. Bitterman agreed to serve as Isolagen's chief executive officer and president from September 1, 2004 until December 31, 2007. The Agreement provides for annual salary of \$400,000, a \$1,000 per month automobile allowance, and, beginning in fiscal 2005, a merit-based bonus to be determined based upon mutually agreeable criteria. For fiscal 2004, Mr. Bitterman shall receive a bonus of \$50,000. Under the Agreement, Mr. Bitterman was issued a five-year option to purchase 500,000 shares of Isolagen common stock at an exercise price equal to the average market value of the common stock during the ten days preceding the issuance, which vests ratably on a monthly basis over three years. If Mr. Bitterman achieves certain criteria during the term of the Agreement, then prior to September 30, 2005, he will be eligible to earn an additional option to purchase 166,666 shares of Isolagen common stock at an exercise price equal to the average market value of the common stock during the ten days preceding such additional issuance, if any, which would vest ratably on a monthly basis over three years. The vesting provisions of each of these options would accelerate and Mr. Bitterman would be entitled to a severance payment equal to his base salary plus a pro rata portion of his bonus, if any, for the greater of twelve months or the remainder of the term of the Agreement, if Mr. Bitterman were terminated without "cause," or if Mr. Bitterman were to terminate his employment with Isolagen for "good reason" (each of the terms as defined in the Agreement). During any period in which severance payments are being made, Mr. Bitterman has agreed not to compete with Isolagen.

**Item 5.02 Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers.**

- (a) Not applicable.
- (b) On September 1, 2004, Mr. Michael Macaluso resigned as chief executive officer and president of Isolagen.
- (c) (1) On September 1, 2004, Isolagen appointed Robert Bitterman to serve as Isolagen's chief executive officer and president.  
(2) Mr. Bitterman, age 53, has not served with Isolagen in any capacity prior to his appointment as chief executive officer and president. There are no familial relationships between Mr. Bitterman and any director or executive officer of Isolagen. From 1995 until August 2004, Mr. Bitterman served as president of Dermik Laboratories, a division of Aventis. Mr. Bitterman holds an A.B. in Economics from College of the Holy Cross and an M.B.A. from Boston University.
- (3) See Item 1.01 for a discussion of the employment agreement between Isolagen and Mr. Bitterman.
- (d) On September 1, 2004, Mr. Bitterman was elected to the Board of Directors, as a Class II director, and he will stand for re-election at Isolagen's 2005 annual meeting of stockholders.

**Item 9.01 Financial Statements and Exhibits**

- (a) Not applicable.
- (b) Not applicable.
- (c) Exhibits.

99.1 Press release dated September 7, 2004

**[THE SIGNATURE PAGE FOLLOWS.]**

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**SIGNATURE**

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

**ISOLAGEN, INC.**

Date: September 7, 2004

By: /s/ JEFFREY TOMZ

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Chief Financial Officer

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QuickLinks

[Item 1.01 Entry into a Material Definitive Agreement.](#)

[Item 5.02 Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers.](#)

[Item 9.01 Financial Statements and Exhibits](#)

[SIGNATURE](#)

**Tuesday, September 7, 2004, 9:00 AM Eastern Time  
Press Release**

SOURCE: Isolagen, Inc.

**ROBERT J. BITTERMAN APPOINTED ISOLAGEN PRESIDENT AND CEO**

**Former President of Aventis' Dermik Labs to Direct Global Operations, Product  
Development and Commercialization of Isolagen's  
Autologous Cellular Process Regeneration of Soft and Hard Tissue**

HOUSTON—(PRNewswire)—September 7, 2004—Isolagen, Inc. (AMEX: ILE) is pleased to announce that its Board of Directors appointed Robert J. Bitterman to succeed Michael Macaluso as president and chief executive officer of Isolagen. Mr. Macaluso will remain active with the Company, serving on its Board of Directors.

Bitterman brings to Isolagen more than 27 years of experience in the pharmaceutical industry. He recently concluded ten year's of service as President of Aventis Pharmaceutical's dermatology division, Dermik Laboratories. At Dermik, Bitterman directed comprehensive product development and operations in the U.S., Canada and China. During his tenure, revenues grew six fold through the successful launch and commercialization of six new therapeutics. Prior to being named President of Dermik Laboratories, Bitterman held a variety of financial, investor relations and business development positions across multiple therapeutic segments at Aventis and its predecessor companies.

As President and CEO of Isolagen, Bitterman will assume the overall direction of Isolagen's global operations, including product development and commercialization of the Company's proprietary autologous cellular therapies for the regeneration of soft and hard tissue.

"After a thorough search for a new president and CEO with the experience and enthusiasm to lead Isolagen's commercialization on a world-wide basis, we are confident we made the right decision in selecting Bob. During his tenure as President at Dermik, Bob grew a relatively small business in the dermatology pharmaceutical segment into a recognized leader in that industry. Bob brings us the large pharmaceutical experience necessary to lead Isolagen from the clinical development phase with limited production to worldwide commercialization," said Mike Macaluso. "I am proud of the strides that Isolagen has made in the past year, particularly our receipt of a Special Protocol Assessment from the Food and Drug Administration and our very successful recent public financing. I look forward to assisting Bob during this transition and continuing my work with the company as a director."

Robert Bitterman expressed excitement about Isolagen's future: "The strong operational foundation built by Mike and his team combined with the therapeutic potential of Isolagen's unique technology have created an exciting opportunity. I am pleased to be associated with this dynamic organization and to dedicate my experience and use my contacts to bring the Isolagen Process to the global markets and the forefront of this competitive industry."

"Bob's worldwide dermatological and broad pharmaceutical experience, vision and leadership bring new depths to our management team," said Frank DeLape, Isolagen's Chairman. "Isolagen is entering an exciting growth period and we expect that under Bob's leadership the Company will reach its full potential. We are confident of a smooth managerial transition."

*About Isolagen, Inc.*

Isolagen specializes in the development and commercialization of autologous cellular therapies for soft and hard tissue regeneration. The company's product candidates are based on its proprietary Isolagen Process. Based on the accumulated experience of the company through its retrospective study, clinical trials and treatment of patients in the United Kingdom, the company believes that the Isolagen Process utilizes the patient's own cells to create safe and effective therapies to treat the underlying cause of the patient's condition. Autologous cellular therapy is the process whereby a patient's own cells are extracted, allowed to multiply and then injected into the patient. Isolagen's product candidates are designed to be minimally invasive and non-surgical.

Forward-looking statements in this release are made pursuant to the safe harbor provisions of the federal securities laws. Information contained in forward-looking statements is based on current expectations and is subject to change, and actual results may differ materially from the forward-looking statements. Isolagen, Inc. does not undertake to update any such forward-looking statements or to publicly announce developments or events relating to the matters described herein.

Isolagen's corporate headquarters are located in Houston, TX. For further information, please see [www.isolagen.com](http://www.isolagen.com).

Contact:

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QuickLinks

[Exhibit 99.1](#)