BIOENVISION INC
Form SC14D9C
May 29, 2007

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 14D-9

(RULE 14d-101)

SOLICITATION/RECOMMENDATION STATEMENT
PURSUANT TO SECTION 14(d)(4) OF THE
SECURITIES EXCHANGE ACT OF 1934

BIOENVISION, INC.

(Name of Subject Company)

BIOENVISION, INC.

(Name of Person(s) Filing Statement)

COMMON STOCK, PAR VALUE $0.001 PER SHARE
AND
SERIES A CONVERTIBLE PARTICIPATING PREFERRED STOCK,
PAR VALUE $0.001 PER SHARE
(Title of Class of Securities)

Common Stock - 09059N100
Preferred Stock - None
(CUSIP Number of Class of Securities)

David P. Luci
345 Park Avenue, 41st Floor
New York, New York 10154
(212) 750-6700
(Name, Address and Telephone Number of Person Authorized to Receive Notices and Communications on Behalf of the Person(s) Filing Statement)

With copies to:

Christopher J. Denn, Esq.
James R. Kasinger, Esq.
Goodwin Procter LLP
Exchange Place
Boston, Massachusetts 02109-2881
(617) 570-1000

x Check the box if the filing relates solely to preliminary communications made before the commencement of a tender offer.

Attached hereto is a joint press release of Genzyme Corporation (Genzyme) and Bioenvision, Inc. (Bioenvision), dated May 29, 2007, announcing that Genzyme and Bioenvision have signed a definitive agreement pursuant to which Genzyme will acquire Bioenvision.

This press release has been posted on Genzyme s website at www.genzyme.com and on Bioenvision s website at www. bioenvision.com.

CONTACTS:

For Genzyme
Sally J. Curley (investors)
(617) 768-6140

Maria E. Cantor (media)
(617) 768-6690

For Bioenvision
James S. Scibetta (investors)
(212) 750-6700

Andrea L. Johnston (media)
(910) 616-5858

For Immediate Release
May 29, 2007

Genzyme Corporation to Acquire Bioenvision, Inc.

To Gain Exclusive, Worldwide Rights to Clofarabine

CAMBRIDGE, Mass. and NEW YORK, NY Genzyme Corporation (Nasdaq: GENZ) and Bioenvision, Inc. (Nasdaq: BIVN) announced today that they have reached an agreement under which Genzyme will acquire Bioenvision in an all cash transaction valued at $5.60 per

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outstanding common share, or approximately $345 million, representing a premium of approximately 50 percent over the last twenty trading day average. The transaction is expected to be approximately six cents dilutive in 2007, slightly dilutive to break-even in 2008, and accretive in 2009.

With this transaction, which has unanimous Bioenvision Board support, Genzyme takes another significant step in enhancing its existing oncology business by gaining the exclusive, worldwide rights to clofarabine. Bioenvision and Genzyme co-developed clofarabine in Europe where Bioenvision currently markets the product for the treatment of acute lymphoblastic leukemia (ALL) in relapsed and refractory pediatric patients. Clofarabine is also being developed by Genzyme and Bioenvision for significantly larger indications, including use as a first-line therapy for the treatment of adult acute myeloid leukemia (AML). Clofarabine is branded as Clolar® in the U.S. and Canada, where it is marketed by Genzyme for relapsed and refractory pediatric ALL patients. Clofarabine has been granted orphan drug status for ALL and AML in both the United States and European Union.

Building an international commercial presence for our oncology business has been a focus for the corporation and we are very pleased to reach agreement with Bioenvision on this transaction, stated Henri A. Termeer, chairman and chief executive officer of Genzyme Corp. We are deeply committed to furthering the clinical development of clofarabine and making it available on a global basis so that patients around the world with these very difficult forms of cancer will have access to the therapy.

Strategically, financially and operationally, this acquisition makes great sense for our business, stated Mark J. Enyedy, senior vice president and general manager of Genzyme Oncology, a business unit of Genzyme Corporation. We have developed a comprehensive

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understanding of clofarabine and its clinical potential, and are fully engaged in expanding its use into adult populations, most notably and nearest-term in AML. Full ownership will accelerate the development and commercialization of this important therapy.

Christopher B. Wood, M.D., chairman and chief executive officer of Bioenvision, said, We believe this transaction brings significant value to Bioenvision shareholders. Genzyme has the global clinical, regulatory and commercial infrastructure to advance clofarabine, as well as very significant experience with the product from its U.S. approval, launch, and continued development and commercialization. We are confident that they will build upon the solid foundation our organization has established in Europe to further expand access to clofarabine for patients with serious unmet medical need.

In addition to clofarabine, Bioenvision also markets Modrenal® (trilostane), approved in the United Kingdom for the treatment of post-menopausal breast cancer following relapse from initial hormone therapy, and has a pipeline in development to address unmet needs in autoimmune disease and infectious disease.

Clofarabine Development

Genzyme and Bioenvision each have robust clinical development programs aimed at expanding clofarabine into adult indications. The National Cancer Research Institute (NCRI), an independent, UK-based cooperative group, is currently enrolling patients in AML-16, a phase 2/3 study in older patients with AML or high-risk myelodysplastic syndromes (MDS), in collaboration with Bioenvision. The trial has two components: one focusing on patients who are candidates for intensive chemotherapy, and another non-intensive component focusing on patients who are not considered fit for intensive chemotherapy. Each component will evaluate the efficacy of clofarabine. Genzyme expects that the results from AML-16 will enhance the

data from its own pivotal trials of clofarabine that are currently ongoing in adult AML populations.

Genzyme is advancing a phase 3 study (CLASSIC I) in adult AML patients aged 55 and older and previously treated with at least one, but not more than two, prior induction regimens. It is a randomized, double-blind, controlled study that will compare the combination of Clolar and cytarabine (Ara-C) to cytarabine alone.

A phase 2 pivotal clinical trial (CLASSIC II) evaluating the safety and effectiveness of clofarabine in previously untreated, older adult patients with AML who are unlikely to benefit from standard induction therapy is expected to be fully enrolled later this year. Each of these studies is expected to yield substantial evidence supporting the expansion of the current clofarabine product label, which is expected to occur in 2008.

A separate phase 3 study of clofarabine sponsored by the Eastern Cooperative Oncology Group is expected to begin enrolling patients later this year. This study will focus on previously untreated AML patients over the age of 60 who are considered suitable for standard induction chemotherapy.

Clolar is indicated in the U.S. for the treatment of pediatric patients aged 1 to 21 years old with relapsed or refractory ALL after at least two prior regimens. This use is based on the induction of complete responses. Randomized trials demonstrating increased survival or other clinical benefit have not been conducted.

Genzyme also is actively exploring additional therapeutic indications for Clolar, including in MDS and bone marrow transplant.

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Transaction Terms

Genzyme s acquisition of Bioenvision will take the form of an all cash tender offer, which is expected to be completed in July. The transaction has been approved by both boards of directors. Executive officers, directors and shareholders of Bioenvision, representing approximately 20 percent of shares, have entered into agreements in support of the transaction. The transaction is subject to customary closing conditions.

In association with the acquisition, Genzyme anticipates that it will incur certain one time charges, which will be detailed at the close of the transaction.

About Genzyme

One of the world s leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Since 1981, the company has grown from a small start-up to a diversified enterprise with more than 9,000 employees in locations spanning the globe and 2006 revenues of $3.2 billion. Genzyme has been selected by FORTUNE as one of the 100 Best Companies to Work for in the United States.

With many established products and services helping patients in nearly 90 countries, Genzyme is a leader in the effort to develop and apply the most advanced technologies in the life sciences. The company s products and services are focused on rare inherited disorders, kidney disease, orthopaedics, cancer, transplant, and diagnostic testing. Genzyme s commitment to innovation continues today with a substantial development program focused on these fields, as well as immune disease, infectious disease, and other areas of unmet medical need.

About Bioenvision, Inc.

Bioenvision s primary focus is the acquisition, development, and marketing of compounds and technologies for the treatment of cancer. Bioenvision has a pipeline of products for the treatment of cancer, including: Evoltra® (clofarabine), Modrenal® (for which Bioenvision has obtained regulatory approval for marketing in the United Kingdom for the treatment of post-menopausal breast cancer following relapse to initial hormone therapy), and other products. Bioenvision is also developing anti-infective technologies, including the OLIGON® technology; an advanced biomaterial that has been incorporated into various FDA approved medical devices and Suvus®, an antimicrobial agent currently in clinical development for refractory chronic hepatitis C infection. For more information on Bioenvision please visit our Web site at www.bioenvision.com.

Important Information About the Tender Offer

This announcement is not a recommendation, an offer to purchase or a solicitation of an offer to sell shares of Bioenvision stock. Genzyme has not commenced the tender offer for shares of Bioenvision stock described in this announcement. Upon commencement of the tender offer,

Genzyme will file with the Securities and Exchange Commission a tender offer statement on Schedule TO and related exhibits, including the offer to purchase, letter of transmittal, and other related documents. Following commencement of the tender offer, Bioenvision will file with the Securities and Exchange Commission a solicitation/recommendation statement on Schedule 14D-9. Shareholders should read the offer to purchase and solicitation/recommendation statement and the tender offer statement on Schedule TO and related exhibits when such documents are filed and become available, as they will contain important information about the tender offer. Shareholders can obtain these documents when they are filed and become available free of charge from the Securities and Exchange Commission s website at www.sec.gov, or from Genzyme by directing a request to Genzyme, 500 Kendall Street, Cambridge, MA 02142, Attention: Sally Curley, Investor Relations, (617) 768-6140, or from Bioenvision, Inc., 345 Park Avenue, 41st Floor, New York, New York 10154, Attention: James Scibetta, Chief Financial Officer, (212) 750-6700.

In connection with the proposed transactions contemplated by the definitive agreement between Genzyme and Bioenvision, Bioenvision and its directors, executive officers and other employees may be deemed to be participants in any solicitation of Bioenvision stockholders in connection with such proposed transactions. Information about Bioenvisions s directors and executive officers is available in Bioenvision s proxy statement for its 2006 annual meeting of stockholders, as filed with the SEC on October 20, 2006.

Conference Call Information

There will be a joint conference call today at 10:00 a.m. ET to discuss the proposed tender offer. If you would like to participate, please call (773) 799-3828 and use the passcode Genzyme. A replay of this call will be available from 9 a.m. ET on May 30, 2007, until midnight ET on June 5, 2007, by calling (402) 220-3138. This call will also be webcast live at the investor section of http://www.genzyme.com.

Safe Harbor Statement

This press release contains forward-looking statements, including the statements regarding: structure and timing of the tender offer; the potential benefits of the anticipated transaction; the extent to which the acquisition ultimately advances Genzyme s oncology businesses; expectations regarding the timing of, and announcement of data from, clinical trials for clofarabine; estimates of the potential markets and indications for clofarabine; and the expected impact of the anticipated transaction on Genzyme s earnings and expected dilutive/accretive effect. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties include, among others, the possibility that certain closing conditions will not be met; the ability to successfully integrate Bioenvision s operations and programs with Genzyme s and the time and resources required to do so; the ability to attract and retain qualified employees; the actual design, results and timing of clinical studies for clofarabine; enrollment rates for clinical trials; the extent to which the safety and efficacy of clofarabine is demonstrated; the actual timing and content of submissions to and decisions made by regulatory authorities concerning the approval of clofarabine; the ability to manufacture

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sufficient quantities of clofarabine for development and commercialization activities and to do so in a timely and cost-efficient manner; the availability and extent of reimbursement from third party payers for clofarabine in territories outside of the United States; the scope, validity and enforceability of patents directed to, and the effect of any third party proprietary rights on, clofarabine; the accuracy of Genzyme s information concerning the markets for clofarabine, including growth projections; and the risks and uncertainties described in Genzyme s SEC reports filed under the Securities Exchange Act of 1934, including the factors discussed under the caption Risk Factors in Genzyme s Quarterly Report on Form 10-Q for the period ended March 31, 2007. We caution investors not to place undue reliance on the forward-looking statements contained in this document. These statements speak only as of the date of this document and we undertake no obligation to update or revise the statements.

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Genzyme s press releases and other company information are available at www.genzyme.com and by calling Genzyme s investor information line at 1-800-905-4369 within the United States or 1-678-999-4572 outside the United States.

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