

ISOLAGEN INC
Form 10-K/A
April 28, 2005

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K/A

Amendment No. 1

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2004

OR

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Isolagen, Inc.

(Exact name of registrant as specified in its Charter.)

Delaware
(State or other jurisdiction
of incorporation)

001-31564
(Commission File Number)

87-0458888
(I.R.S. Employer
Identification No.)

**102 Pickering Way
Exton, Pennsylvania 19341**

(Address of principal executive offices, including zip code)

(484) 875-3099

(Issuer's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class
Common Stock, \$.001 par value

Name of Each Exchange on which Registered
American Stock Exchange

Indicate by check mark whether the registrant: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for any 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

Indicate by check mark if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-K contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in the Exchange Act Rule 12b-2) Yes No

As of June 30, 2004, the aggregate market value of the issuer's common stock held by non-affiliates of the issuer based upon the price at which such common stock was sold on the American Stock Exchange as of such date was \$251,550,808.

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As of March 14, 2005, issuer had 30,219,899 shares outstanding common stock, par value \$0.001.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2005 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the end of the fiscal year ended December 31, 2004, are incorporated by reference in Part III hereof. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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EXPLANATORY NOTE

We are filing this Amendment No. 1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, as filed with the Securities and Exchange Commission on March 15, 2005 to include an amended and restated Item 9A and the related "Attestation report of the registered public accounting firm," required by Item 308(b) of Regulation S-K as permitted by paragraph (b) of the conditions of the Order Under Section 36 of the Securities Exchange Act of 1934 Granting an Exemption from Specified Provisions of Exchange Act Rules 13a-1 and 15d-1 (Release No. 34-50754, November 30, 2004).

This Amendment does not affect the consolidated financial statements or notes thereto originally included in our Annual Report on Form 10-K as filed on March 15, 2005, or change the information included in any sections of that Annual Report on Form 10-K except for the restatement of Item 9A as set forth below. Additionally, this Amendment does not affect the original financial statements or footnotes as originally filed. This amendment does not reflect events occurring after the original filing of the Form 10-K, and does not modify or update the disclosures therein in any way other than as required to reflect the amendment as described above and set forth below. Accordingly, this Form 10-K/A should be read in conjunction with our other filings made with the Securities and Exchange Commission subsequent to the filing of the original Annual Report on Form 10-K, including any amendments to those filings.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

In accordance with Rule 13a-15(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), as of the end of the period covered by this Annual Report on Form 10-K/A, our management evaluated, with the participation of our Interim Chief Executive Officer and our Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). Based upon their evaluation of these disclosure controls and procedures, our Interim Chief Executive Officer and our Chief Financial Officer have concluded that the disclosure controls and procedures were not effective as of the date of such evaluation to ensure that material information relating to us, including our consolidated subsidiaries, was made known to them by others within those entities, particularly during the period in which this Annual Report on Form 10-K/A was being prepared.

Management's Report on Internal Control over Financial Reporting.

We are responsible for establishing and maintaining an adequate internal control structure and procedures for our financial reporting. We have assessed the effectiveness of internal control over financial reporting as of December 31, 2004. Our assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control Integrated Framework (COSO Framework).

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles (GAAP). Our internal control over financial reporting includes those policies and procedures that:

- 1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of assets;
 - 2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and
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3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness in internal control over financial reporting is a control deficiency (within the meaning of Public Company Accounting Oversight Board (PCAOB) Auditing Standard No. 2), or combination of control deficiencies, that results in there being more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. As of December 31, 2004, we have identified five material weaknesses, which are described further below.

The Company's accounting systems and control procedures, including certain control procedures that are depended on the review of the Company's accounting by management, were inadequate to insure that certain indirect costs associated with the production process were properly classified in the Company's financial statements. As a result the Company improperly classified as selling, general and administrative expenses approximately \$3.1 million in costs incurred during 2004 associated with the production of patient injections in the United Kingdom. These costs should have been classified as costs of goods sold. This misstatement was corrected before the issuance of Company consolidated financial statements included in the Company's Annual Report on Form 10-K as filed March 15, 2005.

The Company failed to perform certain control procedures designed to ensure that the financial statement presentations and related disclosures were complete and in accordance with GAAP. As a result of this weakness, the Company did not identify that approximately \$51.8 million of marketable debt securities were improperly included in cash and cash equivalents instead of being separately presented as short term investments. This misstatement was corrected before the issuance of Company consolidated financial statements included in the Company's Annual Report on Form 10-K as filed March 15, 2005.

The Chief Financial Officer is actively involved in the preparation of the financial statements, and therefore cannot provide an independent review and quality assurance function within the accounting and financial reporting group.

The number of qualified accounting personnel with experience in public company SEC reporting and GAAP is extremely limited. There is a risk that a material misstatement of the financial statements could be caused, or at least not be detected in a timely manner, by this shortage of qualified resources. As a result of this weakness, the Company improperly accounted for its investments in marketable securities as discussed above, made certain errors in the preparation of its income tax disclosures, improperly classified as selling, general and administrative expenses as discussed above and under accrued certain costs related to the closure of its Australian operations. These misstatements were corrected before the issuance of Company consolidated financial statements included in the Company's Annual Report on Form 10-K as filed March 15, 2005.

The Company lacks effective controls to prevent or detect fraud, including that insuring that transactions are properly authorized, in a timely manner. This material weakness exists because of the aggregate effect of multiple significant deficiencies in internal control which affect the Company's fraud detection and prevention controls, including: a) a failure to effectively implement, follow, and enforce the limits on the delegation of authority for expenditure from

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the Board of Directors to management, including the failure by management to obtain the required Board approvals for certain expenditures; b) the lack of an effective risk assessment process for the identification of fraud risks; c) a failure to ensure the consistent and timely completion of employee acknowledgments of the Company's Code of Ethics required by Company policy; d) the lack of an internal audit function or other effective mechanism for ongoing monitoring of the effectiveness of internal controls.

Based on the material weaknesses described above and the criteria set forth by the COSO Framework, we have concluded that our internal control over financial reporting at December 31, 2004 was not effective.

The Company's independent registered public accounting firm, BDO Seidman, LLP, has issued an attestation report on management's assessment of the Company's internal control over financial reporting. That report appears below.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Isolagen, Inc.
Exton, Pennsylvania

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Isolagen, Inc. did not maintain effective internal control over financial reporting as of December 31, 2004, because of the effect of material weaknesses identified in management's assessment, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Isolagen Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject

to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The following material weaknesses have been identified and included in management's assessment:

- 1) Ineffective controls over financial reporting resulting in the reclassification of certain production costs from selling, general and administrative expenses to cost of goods sold for the year ended December 31, 2004 and all prior periods.
- 2) Ineffective application of generally accepted accounting principles in relation to marketable securities, resulting in adjustments to the Company's financial statements and disclosures.
- 3) The inability of the Chief Financial Officer to provide an independent review and quality assurance function within the accounting and financial reporting group.
- 4) Lack of qualified accounting personnel with expertise with SEC reporting and generally accepted accounting principles.
- 5) Lack of effective controls to prevent or detect fraud in a timely manner.

These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the financial statements as of and for the year ended December 31, 2004, and this report does not affect our report dated March 14, 2005 on those financial statements.

In our opinion, management's assessment that Isolagen, Inc. did not maintain effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, Isolagen, Inc. has not maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

/s/ BDO Seidman, LLP
Houston, Texas
April 27, 2005

Changes in Internal Controls

During the quarter ended December 31, 2004, the Company completed its implementation of a new internal control framework, including a) improved segregation of duties in the United Kingdom; b) formalized the documentation of certain procedures; and c) daily reconciliation of cash received to the general ledger, that was designed to remediate previously identified deficiencies in internal controls and comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements. Incorporated by reference hereto, from the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2004.

(a)(2) Financial Statement Schedule.

All schedules are omitted because of the absence of conditions under which they are required or because the required information is presented in the Financial Statements or Notes thereto.

(a)(3) The exhibits listed under Item 15(c) are filed or incorporated by reference herein

(b) Exhibits.

The following exhibits are filed as part of this annual report:

EXHIBIT NO. IDENTIFICATION OF EXHIBIT

EXHIBIT NO.	IDENTIFICATION OF EXHIBIT
2	Agreement and Plan of Merger by and among American Financial Holding, Inc., ISO Acquisition Corp., Isolagen Technologies, Inc., Gemini IX, Inc., and William K. Boss, Jr., Olga Marko and Dennis McGill dated August 1, 2001(1)
3(i)	Amended Certificate of Incorporation(7)
3(ii)	Bylaws(10)
4.1	Specimen of Common Stock certificate(2)
4.2	Certificate of Designations of Series A Convertible Preferred Stock(7)
4.3	Certificate of Designations of Series B Convertible Preferred Stock(5)
4.4	Indenture, dated November 3, 2004, between the Company and The Bank of New York Trust Company, N.A., as trustee(11)
10.1	2003 Stock Option and Stock Appreciation Rights Plan(3)*
10.2	2001 Stock Option and Appreciation Rights Plan(4)*
10.3	Reserved
10.4	Employment Agreement dated May 28, 2002 between Isolagen, Inc. and Vaughan Clift(7)*
10.5	Employment Agreement dated September 5, 2003 between Isolagen, Inc. and Frank DeLape(7)*
10.6	Employment Agreement dated September 5, 2003 between Isolagen, Inc. and Michael Macaluso(7)*
10.7	Employment Agreement dated September 5, 2003 between Isolagen, Inc. and Jeffrey W. Tomz(7)*
10.8	Reserved
10.9	Lease Agreement dated March 24, 2002 by and between the Registrant as Lessee and Claire O Aceti Gbmh as Lessor(7)
10.10	Lease Agreement dated November 20, 2002 by and between the Registrant as Lessee and Lego Australia Pty Limited as Lessor(7)
10.11	Intellectual Property Purchase Agreement between Isolagen Technologies, Inc., Gregory M. Keller, and PacGen Partners(8)
10.12	Employment Agreement effective September 1, 2004 between Isolagen, Inc. and Robert Bitterman(12)
10.13	Employment Agreement effective September 13, 2004 between Isolagen, Inc. and Dr. Kimberley Forbes-McKean(12)

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10.14	Employment Agreement effective September 27, 2004 between Isolagen, Inc. and Dennis L. Bevan(12)
10.15	Purchase Agreement among CIBC World Market Corp., UBS Securities LLC, and Adams, Harkness & Hill, Inc. dated October 28, 2004(11)
10.16	Registration Rights Agreement among CIBC World Market Corp., UBS Securities LLC, and Adams, Harkness & Hill, Inc. dated November 3, 2004(11)
14	Code of Ethics(9)
21	List of Subsidiaries(10)
23.1	Pannell Kerr Forster of Texas, P.C. Consent(12)
23.2	BDO Seidman, LLP Consent(12)
23.3	BDO Seidman, LLP Consent(13)
31.1	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(12)
31.2	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(12)
31.3	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(13)
31.4	Certification pursuant to Rule 13a-14(a) and 15d-14(a), required under Section 302 of the Sarbanes-Oxley Act of 2002(13)
32.1	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(12)
32.2	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(12)

*

Indicates a management contract or a compensatory plan or arrangement.

- (1) Previously filed as an exhibit to the company's Form 8-K, filed on August 22, 2001, and is incorporated by reference hereto.
- (2) Previously filed as an exhibit to the company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001, and is incorporated by reference hereto.
- (3) Previously filed as an appendix to the company's Definitive Proxy Statement, as filed on May 6, 2003, in connection with the 2003 Annual Stockholder Meeting, and is incorporated by reference hereto.
- (4) Previously filed as an appendix to the company's Definitive Proxy Statement, as filed on October 23, 2001, in connection with the 2001 Annual Stockholder Meeting, and is incorporated by reference hereto.
- (5) Previously filed as an exhibit to the company's Form 10-Q for the fiscal quarter ended March 31, 2003, as filed on May 15, 2003, and is incorporated by reference hereto.
- (6) Previously filed as an exhibit to the company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, and is incorporated by reference hereto.
- (7) Previously filed as an exhibit to the company's Form S-1, as filed on September 12, 2003, and is incorporated by reference hereto.
- (8) Previously filed as an exhibit to the company's amended Form S-1, as filed on October 24, 2003, and is incorporated by reference hereto.
- (9) Previously filed as an exhibit to the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and is incorporated by reference hereto.

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- (10) Previously filed as an exhibit to the company's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2003, and is incorporated by reference hereto.
- (11) Previously filed as an exhibit to the company's Current Report on Form 8-K dated November 4, 2004, and is incorporated by reference hereto.
- (12) Previously filed as an exhibit to the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2004, and is incorporated by reference hereto.
- (13) Filed herewith.

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 undersigned, thereunto duly authorized.

Isolagen, Inc.

By: /s/ MARTIN E. SCHMIEG

Martin E. Schmieg, *Chief Financial Officer*

Date: April 28, 2005

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the date indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ FRANK DELAPE</u> Frank DeLape	Chairman of the Board, Director, and Interim Chief Executive Officer	April 28, 2005
<u>/s/ MARTIN E. SCHMIEG</u> Martin E. Schmieg	Chief Financial Officer	April 28, 2005
<u>/s/ MICHAEL MACALUSO</u> Michael Macaluso	Director	April 28, 2005
<u>/s/ STEVEN MORRELL</u> Steven Morrell	Director	April 28, 2005
<u>/s/ HENRY TOH</u> Henry Toh	Director	April 28, 2005
<u>/s/ RALPH DE MARTINO</u> Ralph De Martino	Director	April 28, 2005
<u>/s/ MARSHALL G. WEBB</u> Marshall G. Webb	Director	April 28, 2005

QuickLinks

Item 9A. Controls and Procedures

Part IV

Item 15. Exhibits and Financial Statement Schedules

SIGNATURES