PUMA BIOTECHNOLOGY, INC.
Form S-3
January 29, 2014
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As filed with the Securities and Exchange Commission on January 29, 2014

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

Under

The Securities Act of 1933

Puma Biotechnology, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**77-0683487**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

10880 Wilshire Boulevard, Suite 2150

Los Angeles, California 90024

(424) 248-6500

(Address, including zip code, and telephone number, including area code, of Registrant s principal executive offices)

Alan H. Auerbach

President and Chief Executive Officer

Puma Biotechnology, Inc.

10880 Wilshire Boulevard, Suite 2150

Los Angeles, California 90024

(424) 248-6500

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: Promptly after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated Filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller Reporting Company ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price (1)(2)**	**Amount of Registration Fee**

Common Stock, par value $0.0001 per share	$115,000,000	$14,812

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act.
(2) Includes shares subject to the underwriters option to purchase additional shares.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion

Preliminary Prospectus dated January 29, 2014

PROSPECTUS

Shares

Puma Biotechnology, Inc.

Common Stock

We are selling shares of our common stock.

Our shares trade on the New York Stock Exchange under the symbol PBYI. On January 28, 2014, the last sale price of the shares as reported on the New York Stock Exchange was $125.18 per share.

Investing in the common stock involves risks that are described in the Risk Factors section beginning on page 7 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discount [1]	$	$
Proceeds, before expenses, to us	$	$

(1) See Underwriting for additional disclosure regarding underwriting discounts, commissions and estimated offering expenses.

The underwriters may also exercise their option to purchase up to an additional shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about , 2014.

BofA Merrill Lynch **Citigroup** **Leerink Partners**

The date of this prospectus is , 2014.

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Neither we nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

This prospectus includes estimates, statistics and other industry and market data that we obtained from industry publications, research, surveys and studies conducted by third parties and publicly available information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. This prospectus also includes data based on our own internal estimates. We caution you not to give undue weight to such projections, assumptions and estimates.

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PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere or incorporated by reference in this prospectus. This summary is not complete and does not contain all of the information that should be considered before investing in our common stock. Before making an investment decision, investors should carefully read the entire prospectus, including the information incorporated by reference in this prospectus, paying particular attention to the risks referred to under the headings Cautionary Statement Regarding Forward-Looking Statements, Risk Factors and our financial statements and the notes to those financial statements. As used in this prospectus, unless the context requires otherwise, the terms Company, we, our and us refer to Puma Biotechnology, Inc., a Delaware corporation formed on April 27, 2007 and formerly known as Innovative Acquisitions Corp., together with its wholly-owned subsidiary, Puma Biotechnology Ltd, and the term Former Puma refers to Puma Biotechnology, Inc., a private Delaware corporation that merged with and into us in October 2011.

Our Company

We are a development-stage biopharmaceutical company with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. We aim to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. Our efforts and resources to date have been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel.

We currently license the rights to three drug candidates:

- PB272 (neratinib (oral)), which we are developing for the treatment of advanced breast cancer patients, non-small cell lung cancer patients and patients with HER2 mutation-positive solid tumors;
- PB272 (neratinib (intravenous)), which we are developing for the treatment of advanced cancer patients; and
- PB357, which we believe can serve as a backup compound to PB272, and which we are evaluating for further development.

We are initially focused on developing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2, positive breast cancer, HER2 mutated non-small cell lung cancer, HER2-negative breast cancer that has a HER2 mutation and other solid tumors that have an activating mutation in HER2. Studies show that approximately 20% to 25% of breast cancer tumors have an over-expression of the HER2 protein. Women with breast cancer that over-expresses HER2, referred to as HER2-positive breast cancer, are at greater risk for disease progression and death than women whose tumors do not over-express HER2. Therapeutic strategies, such as the use of Herceptin (trastuzumab), Perjeta (pertuzumab), and Kadcyla (T-DM1), produced by Genentech, and Tykerb (lapatinib), produced by GlaxoSmithKline, given either alone or in combination with chemotherapy, have been developed to improve the treatment of this cancer by binding HER2. Based on pre-clinical and clinical studies to date, we believe that neratinib may offer an advantage over existing treatments by more potently inhibiting HER2 at a different site and using a different mechanism than these other drugs.

Currently, the first-line therapy approved by the U.S. Food and Drug Administration, or FDA, for treatment of HER2-positive metastatic breast cancer is the combination of Perjeta plus Herceptin and taxane chemotherapy. The

drug Tykerb, given in combination with the chemotherapy drug capecitabine, is also FDA approved for the treatment of HER2-positive metastatic breast cancer that has failed prior treatment. In a Phase III clinical trial, patients with HER2-positive metastatic breast cancer who received the combination of Tykerb plus capecitabine demonstrated a median progression free survival, or PFS, of 27.1 weeks and a response rate of 23.7%.

Results from a Phase II clinical study, where patients with HER2-positive metastatic breast cancer who had failed prior treatments were administered the combination of neratinib and capecitabine, demonstrated a median PFS of 40.3 weeks and an overall response rate of 64%. In February 2013, we announced that we had reached an agreement with the FDA under a Special Protocol Assessment, or SPA, for our planned Phase III clinical trial of PB272 in patients with HER2-positive metastatic breast cancer who have failed two or more prior treatments

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(third-line disease). The European Medicines Agency, or EMA, has also provided follow-on scientific advice, or SA, consistent with that of the FDA regarding our Phase III trial design and endpoints to be used and ability of such design to support the submission of a European Union, or EU, Market Authorization Application, or MAA. We commenced our Phase III clinical trial of neratinib (oral) for breast cancer patients who have previously failed two or more prior HER2-directed treatments in the second quarter of 2013.

The Phase III trial is a randomized trial of PB272 plus Xeloda versus Tykerb plus Xeloda in patients with third-line HER2-positive metastatic breast cancer. The trial is expected to enroll approximately 600 patients who will be randomized (1:1) to receive either PB272 plus Xeloda or Tykerb plus Xeloda. The trial will be conducted at approximately 150 sites in North America, Europe and Asia-Pacific. The co-primary endpoints of the trial are progression free survival and overall survival. We plan to use the progression free survival data from the trial as the basis for submission of a New Drug Application, or NDA, to the FDA for accelerated approval of PB272 for this indication. We also plan to use the progression free survival data from this trial to support a MAA to the EMA for conditional approval for PB272 in the same indication.

We are also exploring the safety and efficacy of neratinib (oral):

- in combination with temsirolimus in patients with HER2-positive metastatic breast cancer who have failed multiple prior treatments;
- for the treatment of patients with HER2-positive metastatic breast cancer with brain metastases;
- for the treatment of HER2-positive neoadjuvant breast cancer;
- for the adjuvant treatment of HER2-positive breast cancer in patients who have completed adjuvant treatment with Herceptin;
- for the treatment of patients with first line HER2-positive metastatic breast cancer who have not previously received treatment in the metastatic setting;
- for the treatment of HER2 mutated non-small cell lung cancer;
- for the treatment of patients with HER2-negative breast cancer that has a HER2 mutation; and
- for the treatment of patients with solid tumors who have an activating HER2 mutation.

We have on-going Phase II clinical trials for each of these indications.

We licensed the exclusive worldwide rights to our current drug candidates from Pfizer Inc., or Pfizer, which had previously been responsible for the clinical trials regarding neratinib. We have modified Pfizer s clinical development

strategy and during the next 12 to 18 months plan to:

- continue our Phase III clinical trials of neratinib in patients with HER2-positive metastatic breast cancer who have previously failed two or more prior treatments;

- commence a Phase III trial of neratinib for the neoadjuvant treatment of HER2-positive breast cancer and for the neoadjuvant treatment of a subset of patients with HER2-negative breast cancer;

- continue the on-going Phase II clinical trials of neratinib in the neoadjuvant treatment of HER2-positive breast cancer, the ongoing Phase II trial in patients with HER2-positive metastatic breast cancer that has metastasized to the brain, the ongoing Phase II trial in the treatment of HER2 mutated non-small cell lung cancer, the ongoing Phase II trial in the treatment of patients with HER2-negative breast cancer that have a HER2 mutation, the ongoing Phase II trial in the treatment of solid tumors that have an activating HER2 mutation, the ongoing Phase III trial for the adjuvant treatment of HER2 positive breast cancer in patients who have completed adjuvant treatment with Herceptin, and the ongoing Phase II trial for the treatment of patients with first line HER2-positive metastatic breast cancer who have not previously received treatment in the metastatic setting; and

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continue to evaluate the application of neratinib in the treatment of other forms of HER2-positive or HER2 mutated cancers where there may be unmet medical needs.

Recent Developments

In December 2013, we announced top line results from the Phase II clinical trial of neratinib for the neoadjuvant treatment of breast cancer, referred to as the I-SPY 2 TRIAL. The I-SPY 2 TRIAL, or Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2, is a randomized Phase II clinical trial for women with newly diagnosed Stage 2 or higher (tumor size at least 2.5 cm) breast cancer that addresses whether adding investigational drugs to standard chemotherapy in the neoadjuvant setting is better than standard chemotherapy. The primary endpoint is pathological complete response, or pCR, in the breast and the lymph nodes at the time of surgery. The goal of the trial is to match investigational regimens with patient subsets on the basis of molecular characteristics, referred to as biomarker signatures, that benefit from the regimen.

The I-SPY 2 TRIAL involves an adaptive trial design based on Bayesian predictive probability that a regimen will be shown to be statistically superior to standard therapy in an equally randomized 300-patient confirmatory trial. Regimens that have a high Bayesian predictive probability of showing superiority in at least one of 10 predefined signatures graduate from the trial. Regimens are dropped for futility if they show a low predictive probability of showing superiority over standard therapy in all 10 signatures. A maximum total of 120 patients can be assigned to each experimental regimen. A regimen can graduate early and at any time after having 60 patients assigned to it. The neratinib-containing regimen, which was neratinib plus paclitaxel followed by doxorubicin and cyclophosphamide, graduated from the I-SPY 2 TRIAL based on having a high probability of success in Phase III with a signature of HER2-positive/HR-negative. In this group, treatment with the neratinib-containing regimen resulted in a higher pCR rate compared to the control arm, which was standard neoadjuvant chemotherapy: paclitaxel in combination with Herceptin (trastuzumab) followed by doxorubicin and cyclophosphamide. The Bayesian probability of superiority for the neratinib-containing regimen compared to standard therapy is 94.7%, which is analogous to a p-value of 0.053. In addition, the Bayesian predictive probability of showing statistical superiority in a 300-patient Phase III randomized trial of paclitaxel plus neratinib versus paclitaxel plus trastuzumab, both followed by doxorubicin/cyclophosphamide, is 78.1%.

There were 115 patients assigned to neratinib in the trial, including 65 patients who were HER2-positive. For the patients in the trial who were HER2-positive, including those who were either hormone receptor-positive or negative, treatment with the neratinib-containing regimen also resulted in a higher pCR rate compared to the control arm. The Bayesian probability of superiority for the neratinib-containing regimen is 95.3%, which is analogous to a p-value of 0.047. In addition, the Bayesian predictive probability of showing statistical superiority in a 300-patient Phase III randomized trial of paclitaxel plus neratinib versus paclitaxel plus trastuzumab is 72.5%. Based on the results from the I-SPY 2 TRIAL, neratinib is now eligible for the upcoming I-SPY 3 Phase III trial. We intend to provide additional detail regarding the results of the I-SPY 2 TRIAL for PB272 at a future scientific meeting.

Risks Affecting Us

Our business is subject to numerous risks, as more fully described in the section of this prospectus entitled Risk Factors, including the following:

We currently have no product revenues and no products approved for marketing, and will need to raise additional capital to operate our business.

We have a limited operating history and are not profitable and may never become profitable.

We are heavily dependent on the success of neratinib (oral), our lead drug candidate, which is still under clinical development, and we cannot be certain that neratinib (oral) will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

Clinical trials are very expensive, time-consuming and difficult to design and implement.

The results of our clinical trials may not support our drug candidate claims.

We depend significantly on intellectual property licensed from Pfizer and the termination of this license would significantly harm our business and future prospects.

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Our ability to commercialize our potential products will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any such litigation would have a material adverse effect on our business.

Corporate Information

We were incorporated on April 27, 2007 in Delaware under the name Innovative Acquisitions Corp. Until October 4, 2011, we were a shell company with nominal assets and no operations. On September 29, 2011, we entered into an Agreement and Plan of Merger with IAC Merger Corporation, a Delaware corporation and our wholly-owned subsidiary, or Merger Sub, and Former Puma. On October 4, 2011, Merger Sub merged with and into Former Puma, and Former Puma, as the surviving entity, became our wholly-owned subsidiary. In this prospectus, we refer to the merger between Merger Sub and Former Puma as the Merger. In November 2012, we established and incorporated Puma Biotechnology Ltd, a wholly owned subsidiary, for the sole purpose of serving as our legal representative in the United Kingdom and the European Union in connection with our clinical trial activity in those countries.

Our principal executive offices are located at 10880 Wilshire Boulevard, Suite 2150, Los Angeles, California 90024. Our telephone number is (424) 248-6500. Our website is *www.pumabiotechnology.com*. Information contained on our website is not incorporated by reference into, and should not be considered a part of, this prospectus.

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THE OFFERING

Common Stock Offered by Us	shares
Common Stock Outstanding After this Offering	shares
Option to Purchase Additional Shares	The underwriters have a 30-day option to purchase up to an additional shares of our common stock at the public offering price less the underwriting discounts and commissions.
Use of Proceeds	We intend to use the net proceeds of this offering for the overall development of our drug candidates, including, but not limited to, research and development and clinical trial expenditures, and for general corporate and working capital purposes. See Use of Proceeds.
Assumed Public Offering Price	$
Risk Factors	You should read the Risk Factors section beginning on page 7 of this prospectus for a discussion of factors to consider before deciding to invest in shares of our common stock.
New York Stock Exchange Symbol	PBYI

Unless otherwise noted, the number of shares of our common stock outstanding prior to and after this offering is based on 28,689,304 shares outstanding as of September 30, 2013, and excludes:

- 2,373,309 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2013 at a weighted average exercise price of $14.76 per share;
- 1,143,465 shares of common stock reserved for future issuance under our incentive award plan; and
- 2,116,250 shares of our common stock issuable upon the exercise of a warrant held by Alan Auerbach, our President and Chief Executive Officer, at $16.00 per share.

Unless otherwise indicated, the information in this prospectus assumes no exercise by the underwriters of their option to purchase additional shares of common stock from us.

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SUMMARY FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of, and for the periods ended on, the dates indicated. The statement of operations data for the period from September 15, 2010 (inception) to December 31, 2010 and the years ended December 31, 2011 and 2012 is derived from our audited financial statements incorporated by reference in this prospectus. The statement of operations data for the nine months ended September 30, 2012 and 2013 and for the period from September 15, 2010 (inception) to September 30, 2013 and the balance sheet data as of September 30, 2013 have been derived from our unaudited financial statements incorporated by reference in this prospectus. You should read this data together with Management s Discussion and Analysis of Financial Condition and Results of Operations and our audited financial statements and related notes incorporated by reference in this prospectus. Our historical results are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results to be expected for a full fiscal year.

(in thousands except share and per share data)	Period from September 15, 2010 (date of inception) to December 31, 2010	Year ended December 31, 2011	Year ended December 31, 2012	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2013	Period from September 15, 2010 (date of inception) to September 30, 2013
Operating expenses:						
General and administrative	$ 7	$ 9,331	$ 24,814	$ 11,149	$ 6,804	$ 40,956
Research and development		826	49,636	41,354	32,040	82,502
Totals	7	10,157	74,450	52,503	38,844	123,458
Loss from operations	(7)	(10,157)	(74,450)	(52,503)	(38,844)	(123,458)
Other income (expenses):						
Interest income		4	98	63	128	230
Other income (expense)		(80)			3	(77)
Totals		(76)	98	63	131	153
Net loss	$ (7)	$ (10,233)	$ (74,352)	$ (52,440)	$ (38,713)	$ (123,305)
Net loss per common share basic and diluted	$ (0.002)	$ (1.321)	$ (3.422)	$ (2.617)	$ (1.350)	
Weighted-average common shares outstanding basic and diluted	4,000,000	7,746,529	21,725,986	20,040,000	28,678,439	

(1)

Please see Note 2 to our audited financial statements for the year ended December 31, 2012 and Note 2 to our unaudited financial statements for the nine months ended September 30, 2013 incorporated by reference in this prospectus for an explanation of the method used to calculate basic and diluted net loss per share of common stock.

	As of September 30, 2013	
Balance sheet data (in thousands)	**Actual**	**As Adjusted(1)**
Cash and cash equivalents	$ 51,261	$
Marketable securities	44,377	
Total Assets	115,109	
Total Liabilities	20,349	
Deficit accumulated during the development stage	(123,305)	
Total stockholders equity	94,760	

(1) Reflects the sale by us of an assumed shares of our common stock in this offering at an assumed public offering price of $ per share, the last reported sale price of our common stock on , 2014, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed public offering price, would increase (decrease) each of cash and cash equivalents, total assets and total stockholders equity by approximately $ million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming that the number of shares offered by us, as set forth above, remains the same. Each increase (decrease) of 100,000 shares in the number of shares offered by us at the assumed public offering price would increase (decrease) each of cash and cash equivalents, total assets and total stockholders equity by approximately $ million. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. In addition to the other information set forth in this prospectus, you should carefully consider the factors discussed below when considering an investment in our common stock. If any of the events contemplated by the following discussion of risks should occur, our business, results of operations and financial condition could suffer significantly. As a result, you could lose some or all of your investment in our common stock. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.

Risks Related to our Business

We currently have no product revenues and no products approved for marketing, and will need to raise additional capital to operate our business.

To date, we have generated no product revenues. Until, and unless, we receive approval from the U.S. Food and Drug Administration, or FDA, and other regulatory authorities overseas for one or more of our drug candidates, we cannot market or sell our products and will not have product revenues. Currently, our only drug candidates are neratinib (oral), neratinib (intravenous) and PB357, and none of these products has been approved by the FDA for sale in the United States or by other regulatory authorities for sale outside the United States. Moreover, each of these drug candidates is in clinical development and will require significant time and capital before we can even apply for approval from the FDA. Therefore, for the foreseeable future, we do not expect to achieve any product revenues and will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants, and potentially, future offerings of our securities. We believe that our cash on hand is sufficient to fund our operations into the first half of 2015. However, changes may occur that would consume our available capital faster than anticipated, including changes in and progress of our development activities, acquisitions of additional drug candidates and changes in regulation. In such situations, we may need to seek additional sources of financing, which may not be available on favorable terms, if at all. If we do not succeed in timely raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of any drug candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of additional equity securities, which will have a dilutive effect on our stockholders.

We have a limited operating history and are not profitable and may never become profitable.

We were formed in April 2007 and were a shell company with no specific business plan or purpose until we acquired Former Puma on October 4, 2011. Former Puma was a development stage company formed in September 2010 and, prior to entering into the license agreement with Pfizer in August 2011, its operations were limited to identifying compounds for in-licensing. As a result, we have a history of operating losses and no meaningful operations upon which to evaluate our business. We expect to incur substantial losses and negative operating cash flow for the foreseeable future as we continue development of our drug candidates, which we do not expect will be commercially available for a number of years, if at all. Even if we succeed in developing and commercializing one or more drug candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. The successful development and commercialization of any drug candidates will require us to perform a variety of functions, including:

- undertaking pre-clinical development and clinical trials;

hiring additional personnel;

participating in regulatory approval processes;

formulating and manufacturing products;

initiating and conducting sales and marketing activities; and

implementing additional internal systems and infrastructure.

We will likely need to raise additional capital in order to fund our business and generate significant revenue in order to achieve and maintain profitability. We may not be able to generate this revenue, raise additional capital or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

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We are heavily dependent on the success of neratinib (oral), our lead drug candidate, which is still under clinical development, and we cannot be certain that neratinib (oral) will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

We currently have no products that are approved for commercial sale, and we may never be able to develop marketable drug products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our lead drug candidate, neratinib (oral). Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of neratinib (oral). We cannot be certain that neratinib (oral) will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market neratinib (oral) or any of our drug candidates in the United States until they receive approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries until they receive the requisite approval from such countries. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of an NDA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of neratinib (oral) for many reasons, including:

- we may not be able to demonstrate that neratinib (oral) is safe and effective as a treatment for our targeted indications to the satisfaction of the FDA;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the clinical research organization that we retain to conduct clinical trials or any other third parties involved in the conduct of the trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of neratinib (oral) outweigh its risks;
- the FDA may disagree with our interpretation of data from our pre-clinical studies and clinical trials or may require that we conduct additional studies;
- the FDA may not accept data generated at one or more of our clinical study sites;

if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

the advisory committee may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions;

the FDA may require development of a Risk Evaluation and Mitigation Strategy as a condition to approval;

the FDA may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or

the FDA may change its approval policies or adopt new regulations.

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Clinical trials are very expensive, time-consuming and difficult to design and implement.

Each of our drug candidates is still in development and will require extensive clinical testing before we can submit an NDA for regulatory approval. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval for any of our drug candidates or whether any such NDA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We estimate that clinical trials of our drug candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- imposition of a clinical hold or failure to obtain regulatory authorization or approval to commence a trial;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- inability to reach agreement on acceptable terms with prospective clinical research organizations and clinical trial sites;

The board of directors recommends a vote FOR ratification of the appointment of Deloitte & Touche LLP as independent public accountants for 2004.

Representatives of Deloitte & Touche LLP are expected to be present at the Annual Meeting and will be given the opportunity to make a statement if they desire to do so. They will also be available to respond to appropriate questions.

Audit Fees and Non-Audit Fees

The following table presents fees for professional audit services by Deloitte & Touche LLP, the member firms of Deloitte Touche Tohmatsu, and their respective affiliates ("the Deloitte Entities") for the audit of Abbott's annual financial statements for the years ended December 31, 2003 and December 31, 2002, and fees billed for other services rendered by the Deloitte Entities during these periods. Certain amounts for 2002 have been reclassified to conform to the 2003 presentation.

	2003	2002
Audit fees:(1)	$ 6,725,000	$ 4,748,000
Audit related fees:(2)	1,873,000	
Tax fees:(3)	2,032,000	1,653,000
All other fees:(4)		120,000
Total	10,630,000	$ 6,521,000

(1) The Deloitte Entities billed or will bill Abbott for professional services rendered for the audit of Abbott's annual financial statements and the review of Abbott's financial statements included in Abbott's quarterly reports on Securities and Exchange Commission Form 10-Q for the quarters ended March 31, 2003, June 30, 2002 and 2003, and September 30, 2002 and 2003. In addition, Abbott's former auditors, Arthur Andersen LLP and its affiliates, billed Abbott an aggregate of eighty-seven thousand dollars for professional services rendered for the review of Abbott's financial statements included in Abbott's quarterly report on Securities and Exchange Commission Form 10-Q for the quarter ended March 31, 2002.

(2) Audit related fees include: employee benefit plan audits, accounting consultations and audits in connection with proposed acquisitions and divestitures, and internal control consultations related to Sarbanes-Oxley Section 404 compliance.

(3) Tax fees consist principally of professional services rendered by the Deloitte Entities for tax compliance and tax planning and advice including assistance with tax audits and appeals, tax advice related to mergers and acquisitions and employee benefit plans.

(4) Other fees in 2002 consist principally of professional services rendered by the Deloitte Entities for litigation support. No fees for other service were incurred in 2003.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of the Independent Auditor

The audit committee has established policies and procedures to pre-approve all audit and permissible non-audit services performed by the Deloitte Entities after January 1, 2003.

Prior to engagement of the independent auditor for the next year's audit, management will submit a schedule of all proposed services expected to be rendered during that year for each of four categories of services to the audit committee for approval.

Prior to engagement, the audit committee pre-approves these services by category of service. The fees are budgeted and the audit committee requires the independent auditor and management to report actual fees versus the budget periodically by category of service. During the year, circumstances may arise when it may become necessary to engage the independent auditor for additional services not contemplated in the original pre-approval. In those instances, the audit committee requires specific pre-approval before engaging the independent auditor.

The audit committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report any pre-approval decisions to the audit committee at its next scheduled meeting.

Change of Independent Public Accountants in 2002

Arthur Andersen LLP formerly served as Abbott's auditors. On March 15, 2002, Abbott's board of directors adopted the recommendation of its audit committee that Arthur Andersen LLP be dismissed as Abbott's auditors upon the later of: (i) the engagement of a new independent public accounting firm or (ii) the filing of Abbott's quarterly report on Securities and Exchange Commission Form 10-Q for the period ending March 31, 2002. On May 2, 2002, Abbott filed its quarterly report on Securities and Exchange Commission Form 10-Q for the period ending March 31, 2002 and dismissed Andersen as Abbott's auditors. Andersen's reports on Abbott's consolidated financial statements for each of the years ended December 31, 2000 and 2001 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles. During the years ended December 31, 2000 and 2001 and through May 2, 2002 (the date of the Form 8-K reporting the change in Abbott's certifying accountant) there were no disagreements with Andersen on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure which, if not resolved to Andersen's satisfaction, would have caused Andersen to make reference to the subject matter in connection with its report on Abbott's consolidated financial statements for such years; and there were no reportable events as defined in Item 304(a)(1)(v) of Regulation S-K.

On April 26, 2002, Abbott's board of directors, upon the recommendation of its audit committee, engaged Deloitte & Touche LLP as Abbott's independent auditors. During Abbott's two most recent fiscal years prior to the engagement of Deloitte as Abbott's independent auditors and the subsequent interim period through May 2, 2002, neither Abbott nor anyone on its behalf consulted with Deloitte regarding any of the matters or

reportable events listed in Items 304(a)(2)(i) and (ii) of Regulation S-K.

Report of the Audit Committee

Management is responsible for Abbott's internal controls and the financial reporting process. The independent auditors are responsible for performing an audit of Abbott's financial statements in accordance with generally accepted auditing standards and for expressing an opinion on those financial statements based on their audit. The audit committee reviews these processes on behalf of the board of directors. In this context, the committee has reviewed and discussed the audited financial statements contained in the 2003 Annual Report on Form 10-K with Abbott's management and its independent auditors.

The committee has discussed with the independent auditors the matters required to be discussed by the Statement on Auditing Standards No. 61 (*Communication with Audit Committees*), as amended.

The committee has received the written disclosures and the letter from the independent auditors required by Independence Standards Board Standard No. 1 (*Independence Discussions with Audit Committees*), as amended, and has discussed with the independent auditors their independence. The committee has also considered whether the provision of the services described on page 18 under the caption "Audit Fees and Non-Audit Fees" is compatible with maintaining the independence of the independent auditors.

Based on the review and discussions referred to above, the committee recommended to the board of directors that the audited financial statements be included in Abbott's Annual Report on Form 10-K for the year ended December 31, 2003 filed with the Securities and Exchange Commission.

Audit Committee

J. M. Greenberg, chairman, R. S. Austin, D. A. L. Owen, B. Powell Jr., and J. R. Walter.

Section 16(a) Beneficial Ownership Reporting Compliance

Due to a clerical oversight on the part of Abbott, an option grant was reported late for R. S. Austin, H. L. Fuller, J. M. Greenberg, D.A.L. Owen, B. Powell Jr., A. B. Rand, W. A. Reynolds, R. S. Roberts, W. D. Smithburg, and J. R. Walter, each of whom is a director of Abbott. In addition, one report for B. Powell Jr. of a charitable gift of stock was filed late.

Shareholder Proposals

Four shareholder proposals have been received. Abbott is advised that the proposals will be presented for action at the Annual Meeting. The proposed resolutions and the statements made in support thereof are presented below.

The board of directors recommends that you vote AGAINST the proposals.

Shareholder Proposal Concerning Prescription Drugs (Item 3 on Proxy Card)

Catholic Healthcare West, 185 Berry Street, Suite 300, San Francisco, California 94107-1739 owner of 87,500 Abbott common shares, and 13 other proponents have informed Abbott that they intend to present the following proposal at the meeting. Abbott will provide proponents' names and addresses to any shareholder who requests that information and, if provided by a proponent to Abbott, the number of Abbott common shares held by that proponent.

Resolved: That the Board of Directors review pricing and marketing policies and prepare a report (at reasonable cost and omitting proprietary information), available to shareholders by September, 2004, on how our company will respond to rising regulatory, legislative and public

pressure to increase access to and affordability of needed prescription drugs.

Proponent's Statement in Support of Shareholder Proposal

The pharmaceutical industry faces a number of long-term challenges that threaten our Company's viability and could adversely affect shareholder value.

"The pharmaceutical industry and its legal representatives are now beset by a torrent of suits alleging fraud and predatory pricing, demands for more stringent regulation, and investigation of longstanding practices in patenting, promoting and producing drugs." (Drug Wars, American Bar Association Journal, December 2002).

The pharmaceutical industry "depends heavily on public trust" and is particularly vulnerable in times of crisis and/or controversy, according to Rating Research LLC. (Reputation Strength Rating, Rating Research LLC, June 2003).

Only 13% of people "normally believe a statement by a pharmaceutical company." (Attitudes to Government Regulation Vary Greatly For Different Industries, Harris Interactive, 2 April 2003).

57% of Americans think our industry "should be more regulated by government." Only 7% responded they preferred less regulation. (Attitudes to Government Regulation Vary Greatly For Different Industries, Harris Interactive, 2 April 2003).

In an annual survey conducted by Kaiser Commission on Medicaid and the Uninsured, nearly all states reported taking action to rein in prescription drug costs in the past year (Rising Costs Prompt States to Reduce Medicaid Further, NY Times, 23 September 2003).

Given the social and political pressures to resolve the issue of accessibility and affordability of healthcare in the US, we believe the directors of our company have a duty to inform shareholders of the steps taken to address the challenges confronting our industry: negative public perceptions, legal actions at state and federal levels on prescription access and anti-trust issues, law suits alleging antitrust and consumer fraud violations.

Board of Directors Statement in Opposition to the Shareholder Proposal Concerning Prescription Drugs (Item 3 on Proxy Card)

The Abbott board of directors recognizes the public's concerns about access to affordable medicines. Solutions to ensuring access and affordability for those most in need the uninsured, elderly and poor require the efforts of many parties, including government, medical professionals, health care companies and patients. For its part, Abbott is working to expand access to affordable medicines in a number of ways:

Product Access Programs. Abbott makes its medicines available through a number of product access programs to help patients who are uninsured, financially disadvantaged and not eligible for publicly funded prescription coverage.

Abbott's Patient Assistance Program. Since this physician-based referral program was launched in 1996, it has provided free Abbott medicines to hundreds of thousands of patients. In 2003, our program served over 152,000 patients and provided free products valued at $71 million.

Together Rx *Discount Program.* Abbott is a founding member of this prescription drug discount program along with six other pharmaceutical companies. Launched in mid-2002, the program has no enrollment fee and is

available to qualifying seniors with limited incomes in the United States and Puerto Rico. This discount card is accepted at 98 percent of all retail pharmacies in the United States and provides discounts of approximately 20 percent to 40 percent at the point of sale for over 170 medicines. To date, the program has enrolled over 1.1 million members and accounted for approximately $245 million in savings to seniors. The program will continue until the Medicare drug benefit is implemented.

HUMIRA Medicare Assistance Program. Launched in January 2003, this program provides HUMIRA, Abbott's novel rheumatoid arthritis medicine, at no cost to Medicare-eligible seniors in the United States without prescription drug coverage. In 2003, the program served 6,360 patients, and provided free products valued at $52 million.

Pricing Practices. Pharmaceutical research and development is a risky enterprise. In 2003, Abbott invested nearly $1.8 billion in research and development, including over a billion dollars to develop new medicines to address unmet medical needs. When determining prices of its medicines, Abbott considers multiple factors, including research and development costs; manufacturing and quality assurance costs; therapeutic value of the product; and government regulations. As such, Abbott works to strike a balance between maximizing patient access, ensuring a sustainable return to fund future research and development, and meeting an obligation to earn a return for shareholders.

Public Policy Advocacy. Abbott has supported a Medicare prescription drug benefit since the inception of the National Bipartisan Commission on Medicare in 1997. In 2003, we worked with a diverse number of patient and health professional organizations to secure passage of this benefit. Thousands of patients have benefited as we worked with patient groups at the state and national levels to ensure economically disadvantaged patients are not denied access to needed treatments. For example, Abbott worked with oncology organizations to secure Medicare coverage for patients using oral cancer drugs, and with arthritis groups to secure coverage for patients using self-injectable medicines. We estimate that similar efforts have assisted 750,000 Medicaid patients to gain access to HIV and neurological medicines, and 142,000 Medicare patients to gain access to treatments for end stage renal disease. We also worked closely with state AIDS Drug Assistance Program (ADAP) directors and HIV community groups to increase funding for ADAP.

Abbott already provides information about these activities in our Global Citizenship Report. Another report on marketing and pricing practices is not necessary and does not address the issue of expanding access to affordable medicines.

The board of directors recommends that you vote AGAINST the proposal.

Shareholder Proposal Concerning Political Contributions (Item 4 on Proxy Card)

Mercy Investment Program, 205 Avenue C, #10E, New York, New York 10009, owner of 14,200 Abbott common shares, and the SEIU Master Trust, owner of 17,750 Abbott common shares, have informed Abbott that they intend to present the following proposal at the meeting:

Whereas:

The Pharmaceutical industry, and Abbott in particular, spend what we believe to be significant financial and other resources to support political candidates and political entities.

Between January 1, 1991 and December 31, 2002, the Pharmaceutical Research and Manufacturers Association and its members gave $57.9 million in political contributions, including more than $35.5 million in soft money donations to the national political parties and more than $22.4 million in Political Action Committee (PAC) donations to federal candidates. (*Follow the Dollar Report,* July 1, 2003, Common Cause).

Abbott donated $650,000 in 2002 in soft money and Political Action Committee funds, an increase of over 380% from 1992. (*Pharmaceutical Manufacturing: Long-Term Contribution Trends,* The Center for Responsive Politics, 2003).

Whereas:

Although there are various disclosure requirements for political contributions, in our opinion they are difficult for shareholders to access and they are not complete. For example, corporate soft money contributions are currently legal in 49 states, but the disclosure standards can vary. Also, while corporations are not allowed to make direct contributions to candidates, they are allowed to fund the administrative support for PACs to which employees make contributions. Corporations can also make unlimited contributions to "Section 527" organizations (political committees formed for the purpose of influencing elections, but not supporting or opposing specific candidates). These do not have to be reported.

Whereas:

We believe that our company should be using its resources to win in the marketplace through superior products and services to its customers, not because it has superior access to political leaders. Political power can change, in our opinion leaving companies relying on this strategy vulnerable. In addition public backlash can harm a company's reputation and, as a result, its longer-term business prospects.

Resolved: that the shareholders request the Board of Directors to adopt a policy to report annually to shareholders in a separate report on corporate resources devoted to supporting political entities or candidates on both state and federal levels. We suggest that the requested comprehensive report set forth and quantify, specifically and not in aggregate, company resources devoted to supporting political entities and candidates, to supporting third-party organizations which engage in political activity including section 527 organizations and related expenditures of money and other resources.

Board of Directors Statement in Opposition to the Shareholder Proposal Concerning Political Contributions (Item 4 on Proxy Card)

The Abbott board of directors views Abbott's participation in the political process on issues that impact health care and the company's success over the long term to be an appropriate role for a corporation operating within a democratic society. Information about the political contributions of Abbott and the Abbott Laboratories Employee Political Action Committee (AEPAC) is publicly available on the Federal Election Commission Web site (*www.fec.gov*) and state election Web sites. Similarly, information about Abbott's federal lobbying efforts is also available on the Web site of the Senate Office of Public Records at *sopr.senate.gov*.

Abbott's mission is to improve human health. As such, Abbott has a duty to patients, shareholders and employees to exercise its rights and ensure its voice is heard on public policy issues that influence patients' access to affordable and innovative medicines. In 2003, Abbott's top policy issue was to work with a diverse range of patient and health professional organizations to secure passage of a Medicare prescription drug benefit for seniors. Abbott also worked with patient groups to expand coverage of medicines to treat HIV/AIDS, epilepsy, oncology and rheumatoid arthritis under federal or state funded programs that assist economically disadvantaged patients.

Abbott and Abbott employees participate in the political process with contributions to federal and state political candidates and parties. All Abbott Laboratories Employee Political Action Committee (AEPAC) funds come from voluntary, personal contributions of Abbott employees. These AEPAC contributions represented the primary source of funds of those provided to political candidates and parties during the 2002 election cycle. Abbott and AEPAC's support is bipartisan and based on several criteria: a candidate's policy positions that reflect Abbott's interests; representation of geographic areas where Abbott employees and facilities are located; relevant legislative committee assignments; political track record; ability to be elected; and need for financial support.

We believe it is important to put these contributions in context. The Center for Responsive Politics ranked pharmaceutical and health care companies in terms of size of corporate, PAC and individual contributions during the 2002 election cycle; Abbott ranked 16 out of 20. Furthermore, as tracked by the Federal Election Commission, AEPAC was not ranked among the top 50 corporate PACs during the 2002 election cycle.

In light of these facts, we believe a separate annual report on Abbott and AEPAC's contributions is not needed.

The board of directors recommends that you vote AGAINST the proposal.

Shareholder Proposal Concerning the Grant of Stock Options to Senior Executives (Item 5 on Proxy Card)

Joseph M. Siegman, 41 Burning Tree Lane, Deerfield, Illinois 60015, owner of 750 Abbott common shares, has informed Abbott that he intends to present the following proposal at the meeting.

Resolved: As a shareholder of Abbott Laboratories (the "Company"), I urge the Board of Directors (the "Board") to adopt a policy prohibiting future stock option grants to senior executives. The Board shall implement this policy in a manner that does not violate any existing employment agreement or equity compensation plan.

Proponent's Statement in Support of Shareholder Proposal

Since the accounting scandals of Enron, WorldCom, and other companies, the role of stock options in executive compensation has become controversial. Critics of stock options have argued that they can be a powerful incentive for executives to manipulate earnings or engage

in accounting fraud. By timing their stock option exercises, executives can also inappropriately trade on inside information.

Stock options provide incentives to executives that significantly differ from the interests of shareholders. Stock option grants promise executives all of the gain of share price increases with none of the risk of share price declines. For this reason, they can encourage excessive risk taking by executives. In contrast to direct stock holdings, stock options also discourage executives from increasing dividends because option holders are not entitled to dividends.

Banning stock options for senior executives will decouple executive pay from short-term price movements and the temptation for executives to inappropriately manipulate the Company's stock price in order to exercise their stock options. In my opinion, cash compensation should prevail executives should get 30% of their cash compensation in stock to focus senior executives on building the sustained profitability of the Company.

Leading investors and regulators have questioned the appropriateness of using stock options in executive compensation. Portfolio Manager Bill Miller, whose Legg Mason Value Trust is the only mutual fund to beat the S&P 500 Index 11 years in a row, has said "I support the banning of stock options because anything that can be accomplished with options can be accomplished by giving stock directly. And it has none of the downside of options.'

Board of Directors Statement in Opposition to the Shareholder Proposal Concerning the Grant of Stock Options to Senior Executives (Item 5 on Proxy Card)

The Abbott board of directors opposes this resolution. The independent compensation committee must be able to exercise its judgment to align the executive compensation program with the long-term interests of Abbott shareholders, and with the company's corporate goals and strategies. The committee needs an appropriate mix of compensation tools to perform its function, including the judicious and balanced use of stock options.

To that end, officers of Abbott are required to build and retain a significant equity investment in the company a practice supported by leading business organizations. The Chairman of the Business Roundtable's Corporate Governance Task Force said recently, "CEOs and other senior executives should build and maintain a significant equity investment in their companies to ensure their interests are aligned with long-term shareholders." Along with restricted stock, the committee uses stock option grants to achieve this goal. And, since stock options create real value only when the stock price increases, executives' interests are tied to those of Abbott's shareholders.

The committee conducts an annual evaluation of the company's executive compensation program, assisted by outside independent experts. This evaluation includes an assessment of the appropriate mix between restricted stock and stock options to ensure that the program is helping the company attract and retain management talent and is providing an incentive for Abbott executives to create long-term shareholder value.

The board of directors recommends that you vote AGAINST the proposal.

Shareholder Proposal Concerning Global Infectious Diseases (Item 6 on Proxy Card)

The Maryland Province of the Society of Jesus, 5704 Roland Avenue, Baltimore, Maryland 21210-1399, owner of 100 Abbott common shares, and 16 other proponents have informed Abbott that they intend to present the following proposal at the meeting. Abbott will provide the proponents' names and addresses to any shareholder who requests that information and, if provided by a proponent to Abbott, the number of Abbott common shares held by that proponent.

Whereas:

Shareholders have an interest in how our company's products are being utilized to address global health risks of common infectious diseases with respect to short term and long-term performance and risk;

According to UNAIDS, the HIV/AIDS pandemic is "creating or aggravating poverty among millions of people, eroding human capital, weakening government institutions and threatening business activities and investment";

Our company produces effective products for the treatment of HIV/AIDS and yet;

There are more than 42 million people worldwide currently living with HIV/AIDS, over 95% of whom live in the developing world and only 4% of whom have access to effective treatment;

Our company produces an effective product for the treatment of Malaria and yet;

People with Malaria have difficulty accessing an effective treatment that could save their lives and in some cases people are being treated with drugs that are no longer effective;

The final agreement on the World Trade Organization negotiations over paragraph 6 of the Doha Declaration related to easing access to essential medicines in developing countries has several riders. These riders place new regulatory burdens and additional uncertainty on countries and companies importing and exporting generic essential medicines;

While we affirm our company's partnership initiative with the government of Tanzania to modernize the country's public health infrastructure and develop services and care for people living with HIV/AIDS, we feel this is one focused response and does not address the scope and scale of the HIV/AIDS pandemic in southern Africa and other developing countries;

Core Ratings, a subsidiary of Fitch Ratings, first recognized as a nationally recognized statistical rating organization (NRSRO) by the SEC in 1975, has found that our company's performance relative to its pharmaceutical industry peers: 1) "has not demonstrated flexibility on patents"; 2) "has no formal policy on developing country diseases"; and 3) "its policy on clinical trials does not commit to adherence with WHO guidelines", (*Philanthropy or Good Business? Emerging Market Issues for the Global Pharmaceutical Industry.* Core Ratings, May 2003);

The World Bank reports that in southern Africa and other affected regions "a complete economic collapse will occur" unless there is a response to the HIV/AIDS pandemic. Even a "delay in responding to the outbreak of the epidemic, however, can lead to collapse." (*The Long-Run Economic Costs of AIDS,* June 2003, The World Bank)

We believe that these failures pose investment and public relations risks to our company's market value and good name:

Therefore Be It Resolved: Shareholders request that our Board review the economic effects of the HIV/AIDS, tuberculosis and malaria pandemics on the company's business strategy, and its initiatives to date, and report to shareholders within six (6) months following the 2004 annual meeting. This report developed at reasonable costs and omitting proprietary information will identify the impacts of these pandemics on the company.

Board of Directors Statement in Opposition to the Shareholder Proposal Concerning Global Infectious Diseases (Item 6 on Proxy Card)

The Abbott board of directors recognizes the serious social and health impact of HIV/AIDS globally, which also threatens the economic vitality of many developing countries. Solutions are not within the realm of a single company, industry or government, but will require the leadership, political will, expertise and financial resources of all sectors.

Abbott's long-term business strategy, which encompasses decisions about the company's research and development, product portfolio, entry into new markets and role as an employer around the world, takes into account multiple factors, including major trends such as HIV/AIDS. The company's strategy in HIV/AIDS has been to deploy its expertise, products, influence and other resources where they will make the greatest impact. Abbott is fighting HIV/AIDS on many fronts.

Research and Development. With more than 200 scientists dedicated to antiviral research and development, Abbott's most critical contribution is in the research and development of new and improved HIV medicines. Abbott is also working to characterize the genetic diversity of HIV in order to develop more sensitive diagnostic instruments to detect and monitor the virus.

Product Availability. Abbott markets its HIV medicines and diagnostic products to governments, health care institutions and other organizations around the world. In 68 of the world's poorest countries, the Abbott Access program provides Abbott's HIV medicines at a loss, and rapid HIV tests at no profit to the company. Additionally, Abbott is a member of the Accelerated Access Initiative, a cooperative endeavor of six U.N. agencies, including the World Health Organization and UNAIDS, and six research-based pharmaceutical companies to expand access to HIV medicines in developing countries.

Workplace Policy. As a global employer, Abbott has an opportunity to fight stigma and discrimination, the main barrier that keeps HIV positive individuals from seeking help. Abbott's global workplace policy protects employees against discrimination and ensures confidentiality. Abbott is among a handful of companies with a comprehensive AIDS-in-the-workplace program in Africa, covering education and prevention, voluntary counseling and testing, and treatment for employees and their families.

Humanitarian Programs. Abbott's ongoing AIDS-related humanitarian programs in the developing world are helping to fight stigma, expand access to treatment, prevent mother-to-child transmission of HIV, strengthen health care infrastructure and provide care for orphans and vulnerable children impacted by HIV. These programs, an investment totaling $100 million over five years, reflect partnerships with local communities,

nongovernmental organizations, faith-based groups and governments.

Policy Advocacy. Last year, Abbott worked with many organizations to advocate for full funding of President Bush's Emergency Plan for AIDS Relief, which proposed $15 billion in foreign assistance to address HIV prevention, treatment, and care in developing countries. Abbott also continues to share key findings from its AIDS-related humanitarian programs with policymakers and other donors.

The CoreRatings Report's characterization of Abbott cited in the proposal is inaccurate. These are the facts.

Patents. With the exception of South Africa, Abbott does not have any patents on its HIV medicines in Africa. Moreover, Abbott's patents in South Africa do not stand in the way of access to these medicines, as they are already available in South Africa at a loss to Abbott through the Abbott Access program.

Diseases in developing countries. Some of Abbott's research and development programs address infectious diseases prevalent in the developing world, including HIV/AIDS and hepatitis C virus. Abbott also continues to invest in diagnostic tests for hepatitis B virus, hepatitis C virus, Chagas' disease, SARS virus, West Nile virus and malaria.

Clinical trials. Abbott's policies and practices ensure that global clinical research is conducted in accordance with the International Conference on Harmonization, WHO Guidelines for Good Clinical Practices (GCP), ethical principles of the Declaration of Helsinki, U.S. Food and Drug Administration regulations, and local regulations.

Abbott's response to the global HIV/AIDS pandemic is significant and reflects an appropriate and sustainable balance between commercial and philanthropic endeavors. The company already reports on its business strategy in regular updates with investors and through its Annual Report, and on its AIDS-related humanitarian initiatives in its Global Citizenship Report. Hence, another report as requested by this resolution is unnecessary.

The board of directors recommends that you vote AGAINST the proposal.

Other Matters

In 1999, shareholder derivative actions were filed against Abbott's then current directors and certain former directors relating to Abbott's alleged noncompliance with the United States Food and Drug Administration's Quality System Regulation at Abbott's Diagnostic Division facilities in Lake County, Illinois. In March 2001, the United States District Court for the Northern District of Illinois dismissed these complaints. The plaintiffs appealed to the United States Court of Appeals for the Seventh Circuit. In March 2003, the Seventh Circuit reversed the District Court's dismissal. The case has been remanded and discovery is proceeding. These derivative actions alleged the defendants breached their fiduciary duties by, among other things, allowing the alleged regulatory noncompliance and causing Abbott to pay $100 million to the federal government and withdraw certain medical diagnostic kits from the U.S. market. The plaintiffs requested unspecified monetary damages, including punitive and exemplary damages, to be paid to Abbott, reimbursement of their legal fees and costs, and various other forms of relief.

In 2001, shareholder derivative suits relating to the settlements reached by TAP Pharmaceutical Products Inc. with the United States Department of Justice and with each of the fifty states and the District of Columbia with respect to certain of TAP's marketing and pricing practices were filed in the Circuit Court of Cook County, Illinois against Abbott's current directors, with the exception of R. A. Gonzalez (who was not a director at the time of the settlements). TAP is a 50 percent owned joint venture of Abbott. These derivative actions allege that the defendants breached their fiduciary duties by failing to take action to prevent these marketing and pricing practices. The plaintiffs request a return of salaries, reimbursement of their legal fees and costs, and various other forms of relief. The case has been stayed.

In 2003, three shareholder derivative actions relating to the settlement reached by Abbott in connection with enteral nutrition marketing practices were filed against Abbott's current directors in the Circuit Court of Cook County, Illinois. The suits seek compensatory damages, return of salaries, attorneys fees and other forms of relief. All three actions have been consolidated and are pending in the Circuit Court of Cook County, Illinois. In January 2004, an additional shareholder derivative action related to the enteral nutrition settlement was filed in the United States District Court for the Northern District of Illinois. Abbott and the directors deny all substantive allegations and intend to move to dismiss the cases.

As required by its articles of incorporation, Abbott has advanced defense costs on behalf of the present and former directors named in these suits.

Date for Receipt of Shareholder Proposals for the 2005 Annual Meeting Proxy Statement

Shareholder proposals for presentation at the 2005 Annual Meeting must be received by Abbott no later than November 12, 2004 and must otherwise comply with the applicable requirements of the Securities and Exchange Commission to be considered for inclusion in the proxy statement and proxy for the 2005 meeting.

Procedure for Recommendation and Nomination of Directors and Transaction of Business at Annual Meeting

A shareholder may recommend persons as potential nominees for director by submitting the names of such persons in writing to the chairman of the nominations and governance committee or the secretary of Abbott. Recommendations should be accompanied by a statement of qualifications and confirmation of the person's willingness to serve. A nominee who is recommended by a shareholder following these procedures will receive the same consideration as other comparably qualified nominees.

A shareholder entitled to vote for the election of directors at an Annual Meeting and who is a shareholder of record on:

- the record date for that Annual Meeting,
- on the date the shareholder provides timely notice to Abbott, and
- on the date of the Annual Meeting

may directly nominate persons for director by providing proper timely written notice to the secretary of Abbott. That notice must include the name, age, business address, residence address and principal occupation or employment of the nominee, the class and number of shares of Abbott owned by the nominee and any other information relating to the nominee that is required to be disclosed in solicitations for proxies pursuant to the Securities Exchange Act. In addition, the notice must include the name and record address of the nominating shareholder and the class and number of shares of Abbott owned by the nominating shareholder.

A shareholder of record on the record date for an Annual Meeting of Shareholders, the date the shareholder provides timely notice to Abbott and on the date of the Annual Meeting of Shareholders may properly bring business before the Annual Meeting by providing timely written notice to the secretary of Abbott. For each matter the shareholder proposes to bring before the Annual Meeting, the notice must include a brief description of the business to be discussed, the reasons for conducting such business at the Annual Meeting, the name and record address of the shareholder proposing such business, the class and number of shares of Abbott owned by the shareholder and any material interest of the shareholder in such business.

To be timely, written notice either to directly nominate persons for director or to bring business properly before the Annual Meeting must be received at Abbott's principal executive offices not less than ninety days and not more than one hundred twenty days prior to the anniversary date of the preceding Annual Meeting. If the Annual Meeting is called for a date that is not within twenty five days before or after such anniversary date, notice by the shareholder must be received not later than the close of business on the tenth day following the day on which such notice of the date of the annual meeting was mailed or made public in a press release or in a filing with the Securities and Exchange Commission, whichever occurs first.

General

It is important that proxies be returned promptly. Shareholders are urged, regardless of the number of shares owned, to vote their shares. Most of Abbott's shareholders may vote their shares by telephone or the Internet. Shareholders who wish to vote by mail should sign and return their proxy card in the enclosed business reply envelope. Shareholders who vote by telephone or the Internet do not need to return their proxy card.

The Annual Meeting will be held at Abbott's headquarters, 100 Abbott Park Road, located at the intersection of Route 137 and Waukegan Road, Lake County, Illinois. Admission to the meeting will be by admission card only. A shareholder planning to attend the meeting should promptly complete and return the reservation form. Reservation forms must be received before April 16, 2004. An admission card admits only one person.

By order of the board of directors.

LAURA J. SCHUMACHER
SECRETARY

EXHIBIT A

ABBOTT LABORATORIES AUDIT COMMITTEE CHARTER

1. *Purpose.* The Audit Committee of the Board of Directors shall assist the Board in fulfilling its oversight responsibility with respect to:

   Abbott's accounting and financial reporting practices and the audit process;

the quality and integrity of Abbott's financial statements;

the independent auditors' qualifications, independence, and performance;

the performance of Abbott's internal audit function and internal auditors; and

legal and regulatory compliance (recognizing that other board committees assist the Board of Directors in reviewing certain areas of legal and regulatory compliance);

and shall prepare the report required by the rules of the Securities and Exchange Commission to be included in Abbott's annual proxy statement.

2. *Organization.* The Audit Committee shall be composed of at least three (3) directors. Each member must satisfy the independence and financial literacy requirements of the New York Stock Exchange, Section 10A of the Securities Exchange Act of 1934, the rules under Section 10A (which rules shall be deemed included in any reference in this charter to Section 10A of the Exchange Act), and this charter, as such requirements are interpreted by the Board in its business judgment. At least one member of the Audit Committee shall have accounting or related financial management expertise. Director's fees are the only compensation an Audit Committee member may receive from Abbott. No member of the Audit Committee may serve simultaneously on the audit committee of more than three public companies. Abbott's Board shall appoint, and may remove, members of the Audit Committee and the Committee's Chairman, acting on the recommendation of Abbott's Nominations and Governance Committee.

3. *Authority and Responsibilities.* The Audit Committee is directly responsible for the appointment, termination, compensation, and oversight of the work of Abbott's independent auditors (including the resolution of disagreements between management and the independent auditors regarding financial reporting) for the purpose of preparing or issuing an audit report or related work. It shall report regularly to the Board.

Abbott's independent auditors shall report directly to the Audit Committee. Abbott's internal auditors shall be ultimately accountable to the Audit Committee and the Board of Directors. The Audit Committee shall preapprove all permissible non-audit services and all audit, review or attest engagements required under the securities laws to be rendered by the independent auditors. Alternatively, Abbott may enter into engagements to render such services pursuant to pre-approval policies and procedures established by the Audit Committee; provided, that such polices and procedures are detailed as to the particular service, the Audit Committee is informed of each service and such policies and procedures do not include the delegation of Audit Committee responsibilities under the Exchange Act to management. Moreover, the pre-approval requirement for permissible non-audit services shall be waived under certain circumstances described in Section 10A of the Exchange Act.

The Audit Committee may, to the extent it deems necessary or appropriate, conduct or authorize investigations into any matter within the scope of its authority and may retain legal counsel, accountants and others to assist it in the conduct of its responsibilities, including investigations. The Audit Committee shall receive appropriate funding, as determined by the Audit Committee, from Abbott for payment of (a) compensation to the independent auditor employed by Abbott for the purpose of rendering or issuing an audit report or performing other audit, review or attest services for Abbott, (b) compensation to any special legal, accounting or other consultants employed by the Audit Committee and (c) ordinary administrative expenses of the Audit Committee that are necessary or appropriate in carrying out its duties. The Audit Committee may consult with management and may delegate any of its responsibilities and duties to one or more members of the Audit Committee, except to the extent such delegation would be inconsistent with the requirements of the Exchange Act or the listing rules of the New York Stock Exchange.

The Audit Committee shall:

Prepare the report required by the rules of the Securities and Exchange Commission to be included in Abbott's annual proxy statement.

Meet separately, periodically, with Abbott's independent auditors, with Abbott's management and with Abbott's internal auditors.

At least annually, evaluate the qualifications, performance, and independence of Abbott's independent auditors and appoint a firm of independent public accountants to act as Abbott's independent auditors. This evaluation shall include the review and evaluation of the lead partner of Abbott's independent auditors and take into account the opinions of Abbott's management and internal auditors. In connection with this evaluation and appointment, the Audit Committee shall obtain and review a report by Abbott's then current independent auditors describing:

- the independent auditors' internal quality-control procedures;
- any material issues raised by the most recent internal quality-control review, or peer review, of the independent auditors, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years, respecting one or more independent audits carried out by the independent auditors, and any steps taken to deal with any such issues; and
- all relationships between the independent auditors and Abbott.

The Audit Committee shall discuss with the independent auditors any relationships disclosed in that report and shall, if necessary, take appropriate action to ensure the auditors' independence.

Oversee compliance of Abbott's rotation policy for the partners and employees of its independent auditors with the requirements of Section 10A of the Exchange Act. The Audit Committee shall consider the regular rotation of Abbott's independent auditors and report its conclusions to the Board.

Review and discuss with management and the independent auditors:

- the annual audited financial statements and quarterly financial statements, including Abbott's disclosures under Management's Discussion and Analysis of Financial Condition and Results of Operations (that is, under the section captioned "Financial Review") and the matters required to be discussed pursuant to Statement on Auditing Standards No. 61, before their incorporation into Abbott's filings with the Securities and Exchange Commission;
- the scope, procedures and fees for the proposed audit for the current year and, at its conclusion, review that audit including any comments or recommendations by the independent auditors;
- earnings releases (paying particular attention to any use of "pro-forma" or "adjusted" non-GAAP information), as well as financial information and earnings guidance provided to analysts and rating agencies (this may be done generally and need not occur in advance of each earnings release or each instance in which Abbott may provide earnings guidance);
- the responsibilities, budget and staffing of Abbott's internal audit function;
- major issues regarding accounting principles and financial statement presentations, including significant changes in Abbott's selection or application of accounting principles and major issues as to the adequacy of Abbott's internal controls and any special audit steps adopted in light of material control deficiencies;
- analyses prepared by management or Abbott's independent auditors setting forth significant financial reporting issues and judgments made in connection with the preparation of financial statements, including analyses of the effects of alternative GAAP methods on the financial statements; and
- the effect of regulatory and accounting initiatives, as well as off-balance sheet structures (if any), on Abbott's financial statements.

Review and discuss with Abbott's independent auditors:

any problems or difficulties encountered in the course of the audit work, including any restrictions on the scope of the independent auditors' activities or on access to requested information and management's response, and any significant disagreements with management;

any report by the independent auditors required by Section 10A of the Exchange Act including any report relating to critical accounting policies and practices to be used in connection with the audit of Abbott, all alternative treatments of financial information within generally accepted accounting principles that have been discussed with management, the ramifications of the use of those alternative disclosures

and treatments, and the treatment preferred by the independent auditors, and other material written communications between the independent auditors and management; and

any information obtained from the independent auditors with respect to illegal acts in accordance with Section 10A.

Review and discuss with Abbott's internal auditors the internal audit function, the department's authority and responsibilities, budget, staffing, independence, and reporting obligations, the proposed audit plan for the coming year, the coordination of that proposed audit plan with Abbott's independent auditors, the results of the internal audit and a specific review of any significant issues.

Review and discuss (with management, the internal auditors and the independent auditors, as appropriate) Abbott's major financial risk exposures and the steps management has taken to monitor and control those exposures, including Abbott's risk assessment and risk management policies.

Adopt guidelines governing the hiring of employees or former employees of the independent auditors who were engaged on Abbott's account in compliance with Section 10A of the Exchange Act.

Establish procedures for:

the receipt, retention and treatment of complaints received by Abbott regarding accounting, internal accounting controls or auditing matters, and

the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters.

Review any disclosures made to the Audit Committee by Abbott's chief executive officer or chief financial officer relating to their certification obligations under Rule 13a-14 under the Exchange Act.

Review with the independent auditors, internal auditors and financial management, the adequacy, effectiveness and quality of the Corporation's accounting and financial reporting principles, policies, procedures and controls, and elicit from them any recommendations for improvements.

4. *Annual Performance Evaluation.* The Audit Committee shall review and assess the adequacy of its charter annually and recommend any proposed changes to the Board for approval. It also shall conduct an annual evaluation of the Audit Committee's performance.

A-3

Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064-6400 U.S.A.

Notice of Annual Meeting of Shareholders and Proxy Statement

Meeting Date April 23, 2004

YOUR VOTE IS IMPORTANT!
Please sign and promptly return your proxy in the enclosed envelope or vote your shares by telephone or using the Internet.

Reservation Form for Annual Meeting

I am a shareholder of Abbott Laboratories and plan to attend the Annual Meeting to be held at Abbott's headquarters, 100 Abbott Park Road, located at the intersection of Route 137 and Waukegan Road, Lake County, Illinois at 9:00 a.m. on Friday, April 23, 2004.

Please send me an admission card for each of the following persons.

Name _____	Name _____
Please print name of shareholder	Please print name of guest
Address _____	Address _____
City _____	City _____
State _____ Zip Code _____	State _____ Zip Code _____
Phone Number (____) _____	Phone Number (____) _____

If you plan to attend the meeting, please complete and return the Reservation Form directly to Abbott Laboratories, Annual Meeting Ticket Requests, D-32L AP6D, 100 Abbott Park Road, Abbott Park, Illinois 60064-6049. Due to space limitations, Reservation Forms must be received before April 16, 2004. An admission card, along with a form of personal identification, admits one person. A shareholder may request two admission cards.
To avoid a delay in the receipt of your admission card, do not return this form with

your proxy card or mail it in the enclosed business envelope.

PROXY

ABBOTT LABORATORIES

SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS

The undersigned, revoking previous proxies, acknowledges receipt of the Notice and Proxy Statement dated March 9, 2004, in connection with the Annual Meeting of Shareholders of Abbott Laboratories to be held at 9:00 a.m. on April 23, 2004, at the corporation's headquarters, and hereby appoints MILES D. WHITE and LAURA J. SCHUMACHER, or either of them, proxy for the undersigned, with power of substitution, to represent and vote all shares of the undersigned upon all matters properly coming before the Annual Meeting or any adjournments thereof.

If the undersigned is a participant in the Abbott Laboratories Stock Retirement Plan, then this card also instructs the plan's co-trustees to vote as specified at the 2004 Annual Meeting of Shareholders, and any adjournments thereof, all shares of Abbott Laboratories held in the undersigned's plan account upon the matters indicated and in their discretion upon such other matters as may properly come before the meeting.

INSTRUCTIONS: This proxy when properly executed will be voted in the manner directed herein by the undersigned shareholder. If no direction is made, this proxy will be voted FOR Items 1 and 2 and AGAINST Items 3, 4, 5 and 6 and in accordance with the judgment of the proxy holders on any other matters that are properly brought before the meeting.

SEE REVERSE SIDE

(Important - Please sign and date on other side.)

SEE REVERSE SIDE

ABBOTT LABORATORIES

Your vote is important. Please vote immediately.

Vote-by-Internet

1. Read the accompanying Proxy Statement and Proxy Card.
2. Log on to the Internet and go to http://www.eproxyvote.com/abt
3. Follow the instructions provided.

Your vote is important!
Go to http://www.eproxyvote.com/abt by 11:59 p.m. 4/22/04

OR

Vote-by-Telephone

1. Read the accompanying Proxy Statement and Proxy Card.
2. Call toll-free 1-877-PRX-VOTE (1-877-779-8683). For shareholders residing outside the United States call collect on a touch-tone phone 1-201-536-8073.
3. Follow the recorded instructions.

Your vote is important!
Call 1-877-PRX-VOTE by 11:59 p.m. 4/22/04

Do not return your Proxy Card if you are voting by Telephone or Internet.

DETACH HERE

ý **Please mark votes as in this example.**

The Board of Directors recommends that you vote FOR Items 1 and 2.

1. Election of 13 Directors.
Nominees: (01) R.S. Austin, (02) H.L. Fuller, (03) R.A. Gonzalez, (04) J.M. Greenberg, (05) J.M. Leiden, (06) D.A.L. Owen, (07) B. Powell Jr., (08) A.B. Rand, (09) W.A. Reynolds, (10) R.S. Roberts, (11) W.D. Smithburg, (12) J.R. Walter, and (13) M.D. White.

FOR **o** **WITHHELD** o

For, except vote withheld from the above nominee(s).

2. Ratification of Deloitte & Touche LLP as auditors.

FOR o AGAINST o ABSTAIN o

The Board of Directors recommends that you vote AGAINST Items 3, 4, 5 and 6.

		FOR	AGAINST	ABSTAIN
3.	Shareholder Proposal - Prescription Drugs.	o	o	o
4.	Shareholder Proposal - Political Contributions.	o	o	o
5.	Shareholder Proposal - Option Grants for Senior Executives.	o	o	o
6.	Shareholder Proposal - Global Infectious Diseases.	o	o	o

MARK HERE FOR ADDRESS CHANGE AND NOTE AT LEFT o

Each joint tenant should sign; executors, administrators, trustees, etc. should give full title and, where more than one is named, a majority should sign.

Please read other side before signing.

Signature: _____ Date: _____ Signature: _____ Date: _____

(If held jointly)

QuickLinks