MICROMET, INC.
Form S-3
August 22, 2006

As filed with the Securities and Exchange Commission on August 22, 2006

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM S-3
REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

MICROMET, INC.
(Exact name of registrant as specified in its charter)

Delaware	**52-2243564**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

2110 Rutherford Road
Carlsbad, California 92008
(760) 494-4200
(Address, including zip code, and telephone number,
including area code, of Registrant s principal executive offices)

Christian Itin
President and Chief Executive Officer
Micromet, Inc.
2110 Rutherford Road
Carlsbad, CA 92008
(760) 494-4200
(Name, address, including zip code, and telephone number,
including area code, of agent for service)

Copies to:
Christian E. Plaza, Esq.
Darren K. DeStefano, Esq.
Cooley Godward LLP
One Freedom Square, Reston Town Center
11951 Freedom Drive
Reston, VA 20190-5656
(703) 456-8000

Approximate date of commencement of proposed sale to the public:
From time to time 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. o

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. þ

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. o

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. o

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. o

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. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share (2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common Stock, par value $0.00004	12,644,284(3)	$2.525	$31,926,817	$3,416.17

(1) Pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee in

accordance with Rule 457 under the Securities Act. The price per share and aggregate offering price are based on the average of the high and low sales prices of the registrant s common stock on August 17, 2006, as reported on the Nasdaq Global Market.

(3) Includes 555,556 shares of the registrant s common stock issuable upon the exercise of warrants.

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 the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Subject to Completion, Dated August 22, 2006

The information in this prospectus is not complete and may be changed. The selling stockholders 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 is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

12,644,284 Shares
MICROMET, INC.
Common Stock

This prospectus relates to the resale from time to time of up to 12,644,284 shares of our outstanding common stock in the aggregate, including 555,556 shares of our common stock issuable upon the exercise of warrants, which are held by certain of the selling stockholders named in this prospectus and such stockholders donees, pledgees or successors. Of the shares of common stock offered under this prospectus, 9,866,506 shares were issued in connection with the business combination between the registrant (formerly known as CancerVax Corporation) and Micromet AG, 2,222,222 shares were issued in connection with a private placement of our shares to two institutional investors and 555,556 shares are issuable upon the exercise of warrants issued to the institutional investors in the private placement. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholders, although we may receive proceeds upon the exercise of the warrants.

The selling stockholders may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may sell their shares of common stock in the section entitled Plan of Distribution on page 25. We will not be paying any underwriting discounts or commissions in this offering.

The common stock is traded on the NASDAQ Global Market under the symbol MITI. On August 21, 2006, the reported closing price of the common stock was $2.69 per share.

An investment in the shares offered hereby involves a high degree of risk. See Risk Factors beginning on page 3 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is August , 2006.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus. We have not, and the selling stockholders have not, authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where it is lawful to do so. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus carefully, including the section entitled Risk Factors and the documents that we incorporate by reference into this prospectus, before making an investment decision.

MICROMET, INC.

We are a biopharmaceutical company focusing on the development of novel, proprietary antibody-based products for cancer, inflammatory and autoimmune diseases.

On May 5, 2006, CancerVax Corporation completed a merger with Micromet AG, a privately-held German company, pursuant to which CancerVax s wholly owned subsidiary, Carlsbad Acquisition Corporation, merged with and into Micromet Holdings, Inc., a newly created parent corporation of Micromet AG. Micromet Holdings became a wholly owned subsidiary of CancerVax and was the surviving corporation in the merger. CancerVax issued to Micromet AG stockholders shares of CancerVax common stock and CancerVax assumed all of the stock options, stock warrants and restricted stock of Micromet Holdings outstanding as of May 5, 2006, such that the former Micromet AG stockholders, option holders, warrant holders and note holders owned, as of the closing, approximately 67.5% of the combined company on a fully-diluted basis and former CancerVax stockholders, option holders and warrant holders owned, as of the closing, approximately 32.5% of the combined company on a fully-diluted basis. In connection with the merger, CancerVax was renamed Micromet, Inc. and our Nasdaq National Market ticker symbol was changed to MITI.

Our product pipeline consists of two clinical product candidates, adecatumumab (MT201) and MT103, and six preclinical product candidates, D93, MT110, MT203, MT204, BiTE®-I and BiTE®-II. This does not include a clinical candidate, SAI-EGF, and preclinical product candidates SAI-TGF and SAI-EGFR, which we plan to out-license. To date, we have incurred significant expenses and have not achieved any revenues from sales of products.

We began our clinical program for our lead product candidate (adecatumumab) with a Phase 1 clinical trial in patients with hormone-refractory prostate cancer in September 2001 in Germany. Phase 2 clinical trials were started in February 2004 in patients with prostate cancer and in March 2004 in patients with metastatic breast cancer. Adecatumumab (MT201) is being evaluated as a monotherapy in these two clinical trials. In addition, adecatumumab (MT201) is being evaluated in a Phase 1 clinical trial in combination with docetaxel in patients with metastatic breast cancer. An Investigational New Drug Application, or IND, was approved by the Food and Drug Administration, or FDA, in November 2004 for a Phase 2 clinical trial in patients with metastatic breast cancer.

A second clinical program, MT103, a BiTE® compound, is currently in a Phase 1 dose escalation clinical trial in patients with indolent non-Hodgkin s Lymphoma, or NHL. In August 2006, MedImmune, our collaborator for MT103, filed an IND with the FDA for MT103. Pending FDA review, MedImmune intends to conduct a Phase 1 dose escalation trial in the United States, in patients with B-cell-derived NHL who have not responded to or have become refractory to previous therapies

In addition, we have product candidates in pre-clinical development including therapeutic human antibodies and BiTE® molecules that may be used to treat patients with cancer and inflammatory and autoimmune diseases.

We believe that our novel technologies, product candidates and clinical development experience in these fields will continue to enable us to identify and develop promising new product candidates in these important markets.

Each of our programs will require many years and significant costs to advance through development. Typically it takes many years from the initial identification of a lead compound to the completion of pre-clinical and clinical trials, before applying for possible marketing approval from the FDA, the European Medicines Agency (the EMEA) or other equivalent international regulatory agencies. The risk that a program has to be terminated, in part or in full, for safety reasons, or lack of adequate efficacy is very high. In particular, we can neither predict which if any potential product candidates can be successfully developed and for which marketing approval may be obtained, nor predict the time and cost to complete development.

As we obtain results from pre-clinical studies or clinical trials, we may elect to discontinue clinical trials for certain product candidates for safety and/or efficacy reasons. We may also elect to discontinue development of one or more product candidates in order to focus our resources on more promising product candidates. Our business strategy

includes entering into collaborative agreements with third parties for the development and commercialization of our product candidates. Depending on the structure of such collaborative agreements, a third party may take over the clinical trial process for one of our product candidates. In such a

situation, the third party, rather than us, may in fact control clinical development and commercialization decisions for the respective product candidate. Consistent with our business model, we may enter into additional collaboration agreements in the future. We cannot predict the terms of such agreements or their potential impact on our capital requirements. Our inability to complete our research and development projects in a timely manner, or our failure to enter into new collaborative agreements, when appropriate, could significantly increase our capital requirements and affect our liquidity.

Since our inception, we have financed our operations through private placements of preferred stock, government grants for research, research-contribution revenues from our collaborations with pharmaceutical companies, debt financing and, more recently by accessing the capital resources of CancerVax through the merger and through a private placement of common stock and associated warrants. We intend to continue to seek funding through public or private financings in the future. If we are successful in raising additional funds through the issuance of equity securities, stockholders may experience substantial dilution, or the equity securities may have rights, preferences or privileges senior to existing stockholders. If we are successful in raising additional funds through debt financings, these financings may involve significant cash payment obligations and covenants that restrict our ability to operate our business. There can be no assurance that we will be successful in raising additional capital on acceptable terms, or at all. Based on our capital resources as of the date of this prospectus, we believe that we have adequate resources to fund our operations into the third quarter of 2007.

Currently, we have strategic collaborations with Serono International S.A. and MedImmune, Inc. to develop therapeutic antibodies in cancer. We also have an exclusive marketing agreement with Enzon, Inc. to market and license to third parties the companies respective single-chain antibody patent estates. See Risk Factors for a discussion of risks relating to our business and owning our capital stock.

We were incorporated in Delaware in 1998. Our principal executive offices are located at 2110 Rutherford Road, Carlsbad, California 92008, and our main telephone number is (760) 494-4200. Our Web site is located on the world wide web at http://www.micromet-inc.com. We do not incorporate by reference into this prospectus the information on, or accessible through, our Web site, and you should not consider it as part of this prospectus.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors described below, and all other information contained in or incorporated by reference in this prospectus, before deciding to invest in our common stock. If any of the following risks actually occur, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations and could result in a complete loss of your investment.

Risks Relating to Our Clinical and Regulatory Matters

Our preliminary review of the final results of our Phase 2 clinical trial of adecatumumab, or MT201, in patients with prostate cancer suggests that the primary endpoint of the trial was not reached and, if final assessment of the trial results do not warrant continuation of the development program in this indication, we may discontinue development of this product candidate in prostate cancer.

Our preliminary review of the final results from our Phase 2 clinical trial of adecatumumab, or MT201, in patients with prostate cancer indicates that the primary endpoint (mean change in prostate specific antigen, compared to placebo control) was not reached in the trial. An expert review meeting performed earlier this year suggested that additional post-hoc sub-analyses be performed before coming to a final assessment of this trial. These sub-analyses have been performed and, although a final assessment has not yet been completed, it appears that some measurable level of biological activity was observed in patients with high EpCAM expression. If, upon final assessment, we, and our partner Serono conclude that the results of the trial do not warrant continuation of the development of adecatumumab for the treatment of prostate cancer (or a suitable alternative indication), this would have a material adverse impact on our future results of operations.

Based upon our preliminary review of the final results of our Phase 2 clinical trial of adecatumumab, or MT201, in patients with metastatic breast cancer, it appears that the trial did not reach its primary endpoint and, if final assessment of the trial results do not warrant continuation of the development program in this indication, we may discontinue development of this product candidate in breast cancer.

We previously have reported that our initial review of the preliminary radiography assessments from our Phase 2 clinical trial of adecatumumab in patients with metastatic breast cancer suggested that the trial had more likely than not met its primary clinical endpoint (clinical benefit rate at week 24). We also reported that the radiographs from the patients in this clinical trial would be subjected to the assessment of an independent review board, as some centralized radiology assessments differed from the radiology assessments performed at the local clinical trial sites.

Such radiographs have now been reviewed and the database used to perform the analysis has now been locked and is currently subject to a formal assessment, which will not be completed until later this year. Based upon our initial assessment of the final data set, it now appears that the trial more likely than not failed to satisfy its primary clinical endpoint. However, based on the data that we have reviewed thus far, we believe that the results of the trial are nevertheless encouraging as they appear to indicate clinical activity for adecatumumab, particularly in patients with high EpCAM expression. Moreover, based upon our current assessment, it does not appear that there were significant safety concerns observed during the trial.

A final assessment of the study data will not be possible until a full analysis of the data has been performed, which is currently anticipated to occur in the second half of 2006. Based upon our preliminary review of the final results of this trial, we currently expect to continue with the development of adecatumumab. However, if upon final assessment we and our partner Serono conclude that the results of the trial do not warrant continuation of the development of adecatumumab for the treatment of breast cancer (or a suitable alternative indication), this would have a material adverse impact on our future results of operations.

We previously terminated three Phase 1 trials involving short-term infusion regimens of MT103 due to the adverse event profile and a lack of perceived tumor response, and there can be no assurance that our current continuous infusion Phase 1 clinical trial of MT103 will produce a different outcome.

In April 2004, we initiated a Phase 1, dose finding clinical trial designed to evaluate the safety and tolerability of a continuous intravenous infusion of MT103 over 4-8 weeks at different dose levels in patients with relapsed Non-Hodgkin s Lymphoma. We previously terminated three other Phase 1 clinical trials for MT103, which involved a

short-term, as opposed to a continuous, infusion of MT103, due to adverse events and the lack of observed tumor responses. Although we have redesigned the

dosing regimen for our ongoing Phase 1 clinical trial and, based upon the preliminary data, we currently are seeing considerably fewer adverse events in response to the new dosing regimen. We have also seen objective tumor responses at the current highest dose level tested (15 µg/m2/d). There can be no assurance that our ongoing, continuous-infusion clinical trial will not produce an unacceptable level of adverse events or that the final evaluation will not indicate a lack of efficacy.

Risks Relating to Our Financial Results and Need for Financing

We have a history of losses, we expect to incur substantial losses and negative operating cash flows for the foreseeable future and we may never achieve profitability.

We have incurred losses from the inception of Micromet through June 30, 2006, and we expect to incur substantial losses for the foreseeable future. We have no current sources of material ongoing revenue, other than expense reimbursement and milestone payments from our current collaborators, Serono and MedImmune. We have not commercialized any products to date, either alone or with a third party collaborator. If we are not able to commercialize any products, whether alone or with a collaborator, we may not achieve profitability. Even if our collaboration agreements provide funding for a portion of our research and development expenses for some of our programs, we expect to spend significant capital to fund our internal research and development programs for the foreseeable future. As a result, we will need to generate significant revenues in order to achieve profitability. We cannot be certain whether or when this will occur because of the significant uncertainties that affect our business. Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We will require additional financing, which may be difficult to obtain and may dilute your ownership interest in us. If we fail to obtain the capital necessary to fund our operations, we will be unable to develop or commercialize our product candidates and our ability to operate as a going concern may be adversely affected.

We will require substantial funds to continue our research and development programs and our future capital requirements may vary from what we expect. There are factors that may affect our future capital requirements and accelerate our need for additional financing. Many of these factors are outside our control, including the following:

continued progress in our research and development programs, as well as the magnitude of these programs;

our ability to establish and maintain collaborative arrangements;

the timing, receipt and amount of research funding and milestone, license, royalty and other payments, if any, from collaborators;

the timing, receipt and amount of sales revenues and associated royalties to us, if any, from our product candidates in the market;

the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and technology license fees;

our ability to complete our post-merger integration;

costs associated with litigation, including our ongoing litigation with Curis, Inc.; and

competing technological and market developments.

We have filed a shelf registration statement, declared effective by the Securities and Exchange Commission on December 9, 2004, under which we may raise up to $80 million through the sale of our common stock. This shelf registration statement became inactive in March 2006, and we may decide to activate it by filing a post-effective amendment in the future. We expect to seek additional funding through public or private financings and may seek additional funding for programs that are not currently licensed to collaborators, from new strategic collaborators. However, the biotechnology market in general, and the market for our common stock, in particular, is likely to be

highly volatile. Due to market conditions and the status of our product development pipeline, additional funding may not be available to us on acceptable terms, or at all. Having insufficient funds may require us to delay, scale back or

eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern.

If we raise additional funds through the issuance of equity securities, our stockholders may experience substantial dilution, or the equity securities may have rights, preferences or privileges senior to existing stockholders. If we raise additional funds through debt financings, these financings may involve significant cash payment obligations and covenants that restrict our ability to operate our business and make distributions to our stockholders. We also could elect to seek funds through arrangements with collaborators or others that may require us to relinquish rights to certain technologies, product candidates or products.

We have an outstanding promissory note issued to Curis in the amount of 2.0 million, or $2.5 million. Curis has filed a lawsuit against us claiming that the merger triggered our obligation to repay the note. We dispute Curis position, but agree that an amount of 533,000, or $667,000, of the loan will become payable in October 2006. Our maximum exposure is the amount claimed of 2.0 million, or approximately $2.5 million based on the Euro/U.S. dollar exchange rate as of June 30, 2006, plus the costs of the proceedings. In addition, if Curis prevails in the proceeding, it would be entitled to interest on the claimed amount of 2.0 million, or $2.5 million, at the base rate of the European Central Bank plus 8%, accruing from the time of default. In the event that we are required to immediately repay any substantial portion or all of the amounts outstanding under this note, it would have a material adverse effect on our financial resources in the near term.

Our quarterly operating results and stock price may fluctuate significantly.

We expect our results of operations to be subject to quarterly fluctuations. The level of our revenues, if any, and results of operations at any given time, will be based primarily on the following factors:

the status of development of our product candidates;

the time at which we enter into research and license agreements with strategic collaborators that provide for payments to us, and the timing and accounting treatment of payments to us, if any, under those agreements;

whether or not we achieve specified research or commercialization milestones under any agreement that we enter into with collaborators and the timely payment by commercial collaborators of any amounts payable to us;

the addition or termination of research programs or funding support;

the timing of milestone and other payments that we may be required to make to others;

variations in the level of expenses related to our product candidates or potential product candidates during any given period; and

the progress of our integration activities.

These factors may cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

If the estimates we make and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary significantly.

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us and related disclosure. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot assure you that our estimates, or the assumptions underlying them, will be correct. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements.

Changes in, or interpretations of, accounting rules and regulations, such as expensing of stock options, could result in unfavorable accounting charges or require us to change our compensation policies.

Accounting methods and policies for biopharmaceutical companies, including policies governing revenue recognition, expenses, accounting for stock options and in-process research and development costs are subject to further review, interpretation and guidance from relevant accounting authorities, including the Securities and Exchange Commission. Changes to, or interpretations of, accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements, including those contained in this filing.

Our operating and financial flexibility, including our ability to borrow money, is limited by certain debt arrangements.

In December 2004, CancerVax entered into a loan and security agreement with a financing institution, and borrowed the full $18.0 million available under this credit facility. In order to secure its obligations under this loan and security agreement, CancerVax granted the bank a first priority security interest in substantially all of its assets, excluding its intellectual property. CancerVax used the proceeds from the loan agreement primarily to construct and equip an additional production suite in its manufacturing facility and to create additional warehouse and laboratory space to support its manufacturing operations. The terms of our loan and security agreement require that it be repaid in full upon the occurrence of a change of control event.

The loan agreement contains various customary affirmative and negative covenants, including, without limitation:

financial reporting;

limitation on liens;

limitations on the occurrence of future indebtedness;

maintenance of a minimum amount of cash in deposit accounts of our lenders or in the accounts of affiliates of our lenders;

limitations on mergers and other consolidations;

limitations on dividends;

limitations on investments; and

limitations on transactions with affiliates.

In addition, under this loan agreement, we are generally obligated to maintain, as of the last day of each quarter, cash, cash equivalents and securities available-for-sale in an amount at least equal to the greater of (i) our quarterly cash burn multiplied by 2 or (ii) the then outstanding principal amount of the obligations under such agreement multiplied by 1.5. In the event that we breach this financial covenant, we are obligated to pledge and deliver to the bank a certificate of deposit in an amount equal to the aggregate outstanding principal amount of the obligations under such agreement.

Our loan agreements contain certain customary events of default, which generally include, among others, non-payment of principal and interest, violation of covenants, cross defaults, the occurrence of a material adverse change in our ability to satisfy our obligations under our loan agreements or with respect to one of our lender s security interest in our assets and in the event we are involved in certain insolvency proceedings. Upon the occurrence of an event of default, our lenders may be entitled to, among other things, accelerate all of our obligations and sell our assets to satisfy our obligations under our loan agreements. In addition, in an event of default, our outstanding obligations may be subject to increased rates of interest.

In addition, we may incur additional indebtedness from time to time to finance acquisitions, investments or strategic alliances or capital expenditures or for other purposes. Our level of indebtedness could have negative

consequences for us, including the following:

- our ability to obtain additional financing, if necessary, for working capital, capital expenditures, acquisitions or other purposes may be impaired or such financing may not be available on favorable terms;

payments on our indebtedness will reduce the funds that would otherwise be available for our operations and future business opportunities;

we may be more highly leveraged than our competitors, which may place us at a competitive disadvantage;

our debt level reduces our flexibility in responding to changing business and economic conditions; and

our business and financial condition would be adversely effected if we are unable to service our indebtedness or obtain additional financing, as needed.

Risks Relating to Our Common Stock

Future sales of our common stock may cause our stock price to decline.

Our current stockholders hold a substantial number of shares of our common stock that they will be able to sell in the public market. A significant portion of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of our shares could significantly reduce the market price of our common stock. Moreover, the holders of a substantial number of shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares, including the registration statement of which this prospectus is a part. We have also registered shares of our common stock that we may issue under our stock incentive plans and employee stock purchase plan. These shares generally can be freely sold in the public market upon issuance. Sales of a large number of these shares in the public market, or the mere availability of these shares for resale, could reduce the trading price of our common stock.

Our stock price may be volatile, and you may lose all or a substantial part of your investment.

The market price for our common stock is volatile and may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

the financial markets acceptance of the merger between Micromet and CancerVax, and our ability to successfully integrate our operations following the merger;

our ability to upgrade and implement our disclosure controls and our internal control over financial reporting;

our ability to successfully raise capital to fund our continued operations;

our ability to successfully develop our product candidates within acceptable timeframes;

changes in the regulatory status of our product candidates;

changes in significant contracts, new technologies, acquisitions, commercial relationships, joint ventures or capital commitments;

the execution of new contracts or termination of existing contracts related to our clinical or preclinical product candidates;

announcements of the results of clinical trials by companies with product candidates in the same therapeutic category as our product candidates;

events affecting our collaboration partners;

fluctuations in stock market prices and trading volumes of similar companies;

announcements of new products or technologies, clinical trial results, commercial relationships or other events by us or our competitors;

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our ability to successfully complete sublicensing arrangements with respect to our product candidates that target the EGFR signaling pathway, denatured collagen, GM-CSF and interleukin-2;

variations in our quarterly operating results;

changes in securities analysts estimates of our financial performance;

changes in accounting principles;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

additions or departures of key personnel; and

discussions of Micromet or our stock price by the financial and scientific press and online investor communities such as chat rooms.

If our officers and directors choose to act together, they can significantly influence our management and operations in a manner that may be in their best interests and not in the best interests of other stockholders.

Our officers and directors, together with their affiliates, may significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

Our stockholder rights plan, anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our stockholder rights plan and provisions contained in our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. The provisions in our amended and restated certificate of incorporation and bylaws include:

dividing our board of directors into three classes serving staggered three-year terms;

prohibiting our stockholders from calling a special meeting of stockholders;

permitting the issuance of additional shares of our common stock or preferred stock without stockholder approval;

prohibiting our stockholders from making certain changes to our amended and restated certificate of incorporation or bylaws except with 662/3% stockholder approval; and

requiring advance notice for raising matters of business or making nominations at stockholders meetings.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the holder s acquisition of our stock was approved in advance by our board of directors.

Risks Relating to Our Collaborations

We are dependent on collaborators for the development and commercialization of many of our product candidates. If we lose any of these collaborators, or if they fail or delay in developing or commercializing our product

candidates, our anticipated product pipeline and operating results would suffer.

The success of our strategy for development and commercialization of our product candidates depends upon our ability to form and maintain productive strategic collaborations. We currently have strategic collaborations with Serono and MedImmune. We expect to enter into additional collaborations in the future. Our existing and any future collaborations may not be scientifically or commercially successful.

The risks that we face in connection with these collaborations include the following:

Each of our collaborators has significant discretion in determining the efforts and resources that it will apply to the collaboration. The timing and amount of any future royalty and milestone revenue that we may receive under such collaborative arrangements will depend on, among other things, such collaborator s efforts and allocation of resources.

All of our strategic collaboration agreements are for fixed terms and are subject to termination under various circumstances, including in some cases, on short notice without cause. If Serono or Medimune were to terminate our agreement with them, we may be required to undertake product development, manufacturing and commercialization and we may not have the funds or capability to do this, which could result in a discontinuation or delay of such program.

Our collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the product candidates and services that are the subject of the collaboration with us.

Our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of certain of our product candidates to reach their potential could be limited if our collaborators decrease or fail to increase spending related to such product candidates.

Changes in the laws or regulations of the United States or Cuba related to the conduct of our business with CIMAB may adversely affect our ability to develop and commercialize or sublicense our rights to SAI-EGF and the two other product candidates that we have licensed from that company.

The United States government has maintained an embargo against Cuba for more than 40 years. The embargo is administered by the Office of Foreign Assets Control, or OFAC, of the U.S. Department of Treasury. Without a license from OFAC, U.S. individuals and companies may not engage in any transaction in which Cuba or Cubans have an interest. In order to enter into and carry out our licensing agreements with CIMAB, we have obtained from OFAC a license authorizing us to carry out all transactions set forth in the license agreements that we have entered into with CIMAB for the development, testing, licensing and commercialization of SAI-EGF, and with CIMAB and YM BioSciences for the two other product candidates that target the EGF receptor signaling pathway. In the absence of such a license from OFAC, the execution of and our performance under these agreements could have exposed us to legal and criminal liability. At any time, there may occur for reasons beyond our control a change in United States or Cuban law, or in the regulatory environment in the U.S. or Cuba, or a shift in the political attitudes of either the U.S. or Cuban governments, that could result in the suspension or revocation of our OFAC license or in our inability to carry out part or all of the licensing agreements with CIMAB. There can be no assurance that the U.S. or Cuban governments will not modify existing law or establish new laws or regulations that may adversely affect our ability to develop, test, license and commercialize these product candidates. Our OFAC license may be revoked or amended at anytime in the future, or the U.S. or Cuban governments may restrict our ability to carry out all or part of our respective duties under the licensing agreements between us, CIMAB and YM BioSciences. Similarly, any such actions may restrict CIMAB s ability to carry out all or part of its licensing agreements with us. In addition, we cannot be sure that the FDA, EMEA or other regulatory authorities will accept data from the clinical trials of these product candidates that were conducted in Cuba as the basis for our applications to conduct additional clinical trials, or as part of our application to seek marketing authorizations for such product candidates.

In 1996, a significant change to the United States embargo against Cuba resulted from congressional passage of the Cuban Liberty and Democratic Solidarity Act, also known as the Helms-Burton Bill. That law authorizes private lawsuits for damages against anyone who traffics in property confiscated, without compensation, by the government of Cuba from persons who at the time were, or have since become, nationals of the United States. We do not own any property in Cuba and do not believe that any of CIMAB s properties or any of the scientific centers that are or have been involved in the development of the technology that we have licensed from CIMAB were confiscated by the government of Cuba from persons who at the time were, or who have since become, nationals of the U.S. However, there can be no assurance that our understanding in this regard is correct. We do not intend to traffic in confiscated property, and have included provisions in our licensing agreements to preclude the use of such property in association with the performance of CIMAB s obligations under those agreements.

As part of our interactions with CIMAB, we will be subject to the U.S. Commerce Department s export administration regulations that govern the transfer of technology to foreign nationals. Specifically, we or our sublicensees, if any, will require a license from the Commerce Department s Bureau of Industry and Security, or BIS, in order to export or otherwise transfer to CIMAB any information that constitutes technology under the definitions of the Export Administration Regulations, or EAR, administered by BIS. The export licensing process may take months to be completed, and the technology transfer in question may not take place unless and until a license is granted by the Commerce Department. Due to the unique status of the Republic of Cuba, technology that might otherwise be transferable to a foreign national without a Commerce Department license requires a license for export or transfer to a Cuban national. If we or our sublicensees fail to comply with the export administration regulations, we may be subject to both civil and criminal penalties. There can be no guarantee that any license application will be approved by BIS or that a license, once issued, will not be revoked, modified, suspended or otherwise restricted for reasons beyond our control due to a change in U.S.-Cuba policy or for other reasons.

We may not be successful in establishing additional strategic collaborations, which could adversely affect our ability to develop and commercialize products.

As an integral part of our ongoing research and development efforts, we periodically review opportunities to establish new collaborations, joint ventures and strategic collaborations for the development and commercialization of products in our development pipeline. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish additional strategic collaborations or other alternative arrangements. Even if we are successful in our efforts to establish a collaboration or agreement, the terms that we establish may not be favorable to us. Finally, such strategic alliances or other arrangements may not result in successful products and associated revenue.

Risks Relating to the Life Sciences Industry, Our Business, Strategy and Operations

We face substantial competition, which may result in our competitors discovering, developing or commercializing products before or more successfully than we do.

Our product candidates face competition with existing and new products being developed by biotechnology, medical device and pharmaceutical companies, as well as universities and other research institutions. For example, research in the fields of antibody-based therapeutics for the treatment of cancer and autoimmune and inflammatory diseases is highly competitive. A number of entities are seeking to identify and patent antibodies, potentially active proteins and other potentially active compounds without specific knowledge of their therapeutic function. Our competitors may discover, characterize and develop important inducing molecules or genes in advance of us.

Many of our competitors have substantially greater capital resources, research and development staffs and facilities than we have. Efforts by other biotechnology, medical device and pharmaceutical companies could render our programs or product candidates uneconomical or result in therapies that are superior to those that we are developing alone or with a collaborator. For those programs that we have selected for further internal development, we face competition from companies that are more experienced in product development and commercialization, obtaining regulatory approvals and product manufacturing. As a result, they may develop competing products more rapidly and at a lower cost. For those programs that are subject to a collaboration agreement, competitors may discover, develop and commercialize products, which render our product candidates non-competitive or obsolete. We expect competition to intensify in antibody research as technical advances in the field are made and become more widely known.

The product candidates in our pipeline are in early stages of development and our efforts to develop and commercialize these product candidates are subject to a high risk of failure. If we fail to successfully develop our product candidates, our ability to generate revenues will be substantially impaired.

The process of successfully developing product candidates for the treatment of human diseases is very time-consuming, expensive and unpredictable and there is a high rate of attrition for product candidates in preclinical development and in clinical trials. All of our product candidates are in early stages of development, so we will require substantial additional financial resources, as well as research, product development and clinical development capabilities, to pursue the development of these product candidates, and we may never develop an approvable product.

We do not know whether our planned preclinical development or clinical trials for our product candidates will begin on time or be completed on schedule, if at all. In addition, we do not know whether these clinical trials will result in marketable products. We cannot assure you that any of our product candidates will:

be successfully developed;

prove to be safe and effective in clinical trials;

be approved for marketing by United States or foreign regulatory authorities;

be adequately protected by our intellectual property rights or the rights of our licensors;

be capable of being produced in commercial quantities at acceptable costs;

achieve market acceptance and be commercially viable; or

be eligible for third party reimbursement from governmental or private insurers.

Since our product candidates may have different efficacy profiles in certain clinical indications, sub-indications or patient profiles and we have limited resources, our election to focus on a particular indication, sub-indication and patient profile may result in our failure to capitalize on other potentially profitable applications of our product candidates.

We have limited financial and managerial resources. These limitations require us to focus on a select group of product candidates in specific therapeutic areas and to forego the exploration of other product opportunities. While our technologies may permit us to work in multiple areas, resource commitments may require trade-offs resulting in delays in the development of certain programs or research areas, which may place us at a competitive disadvantage. Our decisions as to resource allocation may not lead to the development of viable commercial products and may divert resources away from other market opportunities, which ultimately prove to be more profitable.

The development process necessary to obtain regulatory approval is lengthy, complex and expensive. If we and our collaborative partners do not obtain necessary regulatory approvals, then our business will be unsuccessful and the market price of our common stock will substantially decline.

To the extent that we, or our collaborative partners, are able to successfully advance a product candidate through the clinic, we, or such partner, will be required to obtain regulatory approval prior to marketing and selling such product candidate.

The process of obtaining FDA and EMEA and other required regulatory approvals is expensive. The time required for FDA and EMEA and other approvals is uncertain and typically takes a number of years, depending on the complexity and novelty of the product candidate. The process of obtaining FDA and EMEA and other required regulatory approvals for many of our product candidates under development is further complicated because some of these product candidates use non-traditional or novel materials in non-traditional or novel ways, and the regulatory officials have little precedent to follow. Moreover, an unrelated biotech company recently observed multiple severe adverse reactions in a Phase 1 trial of an antibody that stimulates T cells. This development could cause the FDA and EMEA or comparable international regulatory authorities to become less supportive of the T-cell related product candidates in our portfolio. With respect to internal programs to date, we have limited experience in filing and prosecuting applications to obtain marketing approval.

Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we, or our collaborative partners, may market the product. These limitations may restrict the size of the market for the product and affect reimbursement by third-party payers. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke or significantly modify previously granted approvals.

We and our collaborative partners also are subject to numerous foreign regulatory requirements governing the manufacturing and marketing of our product candidates outside of the United States. The approval procedure varies among countries, additional testing may be required in some jurisdictions, and the time required to obtain foreign approvals often differs from that required to obtain FDA and EMEA approvals. Moreover, approval by the FDA and EMEA does not ensure approval by regulatory authorities in other countries, and vice versa.

As a result of these factors, we or our collaborators may not successfully begin or complete clinical trials in the time periods estimated, if at all. Moreover, if we or our collaborators incur costs and delays in development programs or fail to successfully develop and commercialize products based upon our technologies, we may not become profitable and our stock price could decline.

We and our collaborators are subject to governmental regulations other than those imposed by the FDA and EMEA. We, and any of our collaborators, may not be able to comply with these regulations, which could subject us, or such collaborators, to penalties and otherwise result in the limitation of our or such collaborators operations.

In addition to regulations imposed by the FDA, EMEA and other international regulatory agencies, we and our collaborators are subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Research Conservation and Recovery Act, as well as regulations administered by the Nuclear Regulatory Commission, national restrictions on technology transfer, import, export and customs regulations and certain other local, state or federal regulations, or their foreign counterparts. From time to time, other federal agencies and congressional committees or international governmental bodies have indicated an interest in implementing further regulation of biotechnology applications. We are not able to predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to our business, or whether we or our collaborators would be able to comply with any applicable regulations.

We expect to rely heavily on third parties for the conduct of clinical trials of our product candidates. If these clinical trials are not successful, or if we or our collaborators are not able to obtain the necessary regulatory approvals, we will not be able to commercialize our product candidates.

In order to obtain regulatory approval for the commercial sale of our product candidates, we and our collaborators will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA, EMEA and other foreign regulatory authorities that our product candidates are safe and effective. We have limited experience in conducting clinical trials and expect to rely primarily on collaborative partners and contract research organizations for their performance and management of clinical trials of our product candidates.

Clinical development, including preclinical testing, is a long, expensive and uncertain process. Accordingly, preclinical testing and clinical trials, if any, of our product candidates under development may not be successful. We and our collaborators could experience delays in preclinical or clinical trials of any of our product candidates, obtain unfavorable results in a development program, or fail to obtain regulatory approval for the commercialization of a product candidate. Preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials. The results from early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials.

Furthermore, the timing and completion of clinical trials, if any, of our product candidates depend on, among other factors, the number of patients we will be required to enroll in the clinical trials and the rate at which those patients are enrolled. Any increase in the required number of patients, decrease in recruitment rates or difficulties retaining study participants may result in increased costs, program delays or both.

Also, our product candidates may not be effective in treating any of our targeted disorders or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use. Institutional review boards or regulators, including the FDA and the EMEA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks. Additionally, the failure of third parties conducting or overseeing the operation of the clinical trials to perform their contractual or regulatory obligations in a timely fashion could delay the clinical trials. Failure of clinical trials can occur at any stage of testing. Any of these events would adversely affect our ability to market a product candidate.

Our growth could be limited if we are unable to attract and retain key personnel and consultants.

Our success depends on the ability to attract, train and retain qualified scientific and technical personnel to further our research and development efforts. The loss of services of one or more of our key employees or consultants could have a negative impact on our business and operating results. Locating candidates with the appropriate qualifications

can be difficult. Although we expect to be able to attract and retain sufficient numbers of highly skilled employees for the foreseeable future, we may not be able to do so.

Any growth and expansion into areas and activities that may require additional human resources or expertise, such as regulatory affairs and compliance, would require us to either hire new key personnel or obtain such services via an outsourcing arrangement. The pool of personnel with the skills that we require is limited, and we may not be able to hire or contract such additional personnel.

If our third-party manufacturers facilities do not follow current good manufacturing practices, our product development and commercialization efforts may be harmed.

There are a limited number of manufacturers that operate under the FDA s and EMEA s good manufacturing practices regulations and are capable of manufacturing products. Third-party manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. A failure of third-party manufacturers to follow current good manufacturing practices or other regulatory requirements and to document their adherence to such practices may lead to significant delays in the availability of products for commercial use or clinical study, the termination of, or hold on a clinical study, or may delay or prevent filing or approval of marketing applications for our product candidates. In addition we could be subject to sanctions being imposed on us, including fines, injunctions and civil penalties. Changing manufacturers may require additional clinical trials and the revalidation of the manufacturing process and procedures in accordance with FDA and EMEA mandated current good manufacturing practices and will require FDA and EMEA approval. This revalidation may be costly and time consuming. If we are unable to arrange for third-party manufacturing of our product candidates, or to do so on commercially reasonable terms, we may not be able to complete development or marketing of our product candidates.

If we fail to obtain an adequate level of reimbursement for our products by third-party payors, there may be no commercially viable markets for our products or the markets may be much smaller than expected.

If any of our product candidates are approved for marketing, the availability and levels of reimbursement by governmental and other third-party payors will affect the market for our product candidates. The efficacy, safety and cost-effectiveness of our product candidates as well as the efficacy, safety and cost-effectiveness of any competing products will determine the availability and level of reimbursement. These third-party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. In certain countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement for our product candidates is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our revenues would be reduced.

Another development that may affect the pricing of drugs is regulatory action regarding drug reimportation into the United States. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, which became law in December 2003, requires the Secretary of the U.S. Department of Health and Human Services to promulgate regulations allowing drug reimportation from Canada into the United States under certain circumstances. These provisions will become effective only if the Secretary certifies that such imports will pose no additional risk to the public s health and safety and result in significant cost savings to consumers. To date, the Secretary has made no such finding, but he could do so in the future. Proponents of drug reimportation may also attempt to pass legislation that would remove the requirement for the Secretary s certification or allow reimportation under circumstances beyond those anticipated under current law. If legislation is enacted, or regulations issued, allowing the reimportation of drugs, it could decrease the reimbursement we would receive for any products that we may commercialize, negatively affecting our anticipated revenues and prospects for profitability.

Even if our product candidates are approved by regulatory authorities, if we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our product candidates, these product candidates could be subject to restrictions or withdrawal from the market following approval.

Any product candidates for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product candidates, will be subject to continual review and periodic inspections by the FDA, EMEA and other regulatory bodies. Even if regulatory approval of a product

candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our approved product candidates, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes, or failure to comply with

regulatory requirements, may result in restrictions on such approved product candidates or manufacturing processes, withdrawal of the approved product candidates from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our product candidates abroad.

We intend to market our product candidates in international markets. In order to market our product candidates in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA and EMEA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA and EMEA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA and EMEA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA and EMEA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any market.

We are subject to uncertainty relating to health care reform measures and reimbursement policies which, if not favorable to our product candidates, could hinder or prevent our product candidates commercial success.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect:

our ability to generate revenues and achieve profitability;

the future revenues and profitability of our potential customers, suppliers and collaborators; and

the availability of capital.

In certain foreign markets, the pricing of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. For example, legislation was enacted on December 8, 2003, which provides a new Medicare prescription drug benefit that began in 2006 and mandates other reforms. While we cannot predict the full effects of the implementation of this new legislation or whether any legislative or regulatory proposals affecting our business will be adopted, the implementation of this legislation or announcement or adoption of these proposals could have a material and adverse effect on our business, financial condition and results of operations.

Our ability to commercialize our product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of our product candidates and related treatments. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States, which could significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for our product candidates or exclusion of our product candidates from reimbursement programs. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially and adversely affect our results of operations.

We face the risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing, and marketing of drugs and related devices. Although we have product liability and clinical trial liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities. In addition, if any of our product candidates are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. These liabilities could prevent or interfere with our

product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity or reduced acceptance of our product candidates in the market.

Our operations involve hazardous materials and we must comply with environmental laws and regulations, which can be expensive.

Our research and development activities involve the controlled use of hazardous materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We are subject in the United States to a variety of federal, state and local regulations, and in Europe to European, national, state and local regulations, relating to the use, handling, storage and disposal of these materials. We generally contract with third parties for the disposal of such substances and store certain low-level radioactive waste at our facility until the materials are no longer considered radioactive. We cannot eliminate the risk of accidental contamination or injury from these materials. We may be required to incur substantial costs to comply with current or future environmental and safety regulations. If an accident or contamination occurred, we would likely incur significant costs associated with civil penalties or criminal fines and in complying with environmental laws and regulations. We do not have any insurance for liabilities arising from hazardous materials. Compliance with environmental laws and regulations is expensive, and current or future environmental regulation may impair our research, development or production efforts.

If physicians and patients do not accept the product candidates that we may develop, our ability to generate product revenue in the future will be adversely affected.

The product candidates that we may develop may not gain market acceptance among physicians, healthcare payors, patients and the medical community. Market acceptance of and demand for any product candidate that we may develop will depend on many factors, including:

our ability to provide acceptable evidence of safety and efficacy;

convenience and ease of administration;

prevalence and severity of adverse side effects;

availability of alternative treatments;

cost effectiveness;

effectiveness of our marketing strategy and the pricing of any product candidate that we may develop;

publicity concerning our product candidates or competitive products; and

our ability to obtain third-party coverage or reimbursement.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our approved product candidates profitably.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system in ways that could impact upon our ability to sell our approved product candidates profitably. In the United States in recent years, new legislation has been enacted at the federal and state levels that would effect major changes in the healthcare system, either nationally or at the state level. These new laws include a prescription drug benefit for Medicare beneficiaries and certain changes in Medicare reimbursement. Given the recent enactment of these laws, it is still too early to determine its impact on the pharmaceutical industry and our business. Further federal and state proposals are likely. More recently, administrative proposals are pending and others have become effective that would change the method for calculating the reimbursement of certain drugs. The adoption of these proposals and potential adoption of pending proposals may affect our ability to raise capital, obtai