

XOMA LTD /DE/  
Form 10-Q/A  
November 12, 2010

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q/A  
(Amendment No. 1)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934

For the quarterly period ended September 30, 2010

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 0-14710

XOMA Ltd.  
(Exact name of registrant as specified in its charter)

Bermuda  
(State or other jurisdiction of incorporation  
or organization)

52-2154066  
(I.R.S. Employer Identification No.)

2910 Seventh Street, Berkeley,  
California 94710  
(Address of principal executive offices,  
including zip code)

(510) 204-7200  
(Telephone Number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Edgar Filing: XOMA LTD /DE/ - Form 10-Q/A

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or 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). (Check one):

Large accelerated filer	<input type="radio"/>	Accelerated filer	<input checked="" type="checkbox"/>	Non-accelerated filer	<input type="radio"/>	Smaller reporting	<input type="radio"/>
				(Do not check if a smaller		company	
				reporting company)		o	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act of 1934). Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at October 28, 2010
Common Shares, U.S. \$0.0075 par value	21,798,576

Explanatory Note

We are filing this Amendment No. 1 (this “Amendment”) to our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2010 (the “Form 10-Q”) for the sole purpose of correcting certain clerical errors appearing on the cover page and in Part II, Item 1A, Risk Factors, and to include our November 4, 2010 earnings release as an exhibit. In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by our principal executive officer and principal financial officer are being filed as exhibits to the Form 10-Q.

Except as described above, no other changes have been made to the Form 10-Q, and this Amendment does not modify or update the disclosures or financial statements in the Form 10-Q or otherwise reflect any events occurring after the original filing of the Form 10-Q. As a result, this Amendment should be read in conjunction with the Form 10-Q.

PART II -- OTHER INFORMATION

ITEM 1A. RISK FACTORS

The following risk factors and other information included in this quarterly report should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us also may impair our business operations. If any of the following risks occur, our business, financial condition, operating results and cash flows could be materially adversely affected.

Because our product candidates are still being developed, we will require substantial funds to continue; we cannot be certain that funds will be available and, if they are not available, we may have to take actions that could adversely affect your investment and may not be able to continue as a going concern.

While our refocused business strategy has reduced capital expenditures and other operating expenses, we will need to commit substantial funds to continue development of our product candidates and we may not be able to obtain sufficient funds on acceptable terms, or at all. If adequate funds are not available, we may have to raise additional funds in a manner that may dilute or otherwise adversely affect the rights of existing shareholders, curtail or cease operations, or file for bankruptcy protection in extreme circumstances. We have spent, and we expect to continue to spend, substantial funds in connection with:

- research and development relating to our product candidates and production technologies,
- various human clinical trials, and
- protection of our intellectual property.

We finance our operations primarily through our multiple revenue streams resulting from the licensing of our antibody technologies, discovery and development collaborations, product royalties and biodefense contracts, and sales of our common shares.

Based on our cash reserves and anticipated spending levels, revenue from collaborations including a XOMA 052 corporate partnership, licensing transactions or biodefense contracts, and other sources of funding we believe to be available, we believe that we have sufficient cash resources to meet our anticipated net cash needs through the next twelve months. Any significant revenue shortfalls, increases in planned spending on development programs or more rapid progress of development programs than anticipated, as well as the unavailability of anticipated sources of funding, could shorten this period. If adequate funds are not available, we will be required to delay, reduce the scope

of, or eliminate one or more of our product development programs and further reduce personnel-related costs. Progress or setbacks by potentially competing products may also affect our ability to raise new funding on acceptable terms. As a result, we do not know when or whether:

- operations will generate meaningful funds,
- additional agreements for product development funding can be reached,
- strategic alliances can be negotiated, or
- adequate additional financing will be available for us to finance our own development on acceptable terms, or at all.

Cash balances and operating cash flow are influenced primarily by the timing and level of payments by our licensees and development partners, as well as by our operating costs.

Global credit and financial market conditions may reduce our ability to access capital and cash and could negatively impact the value of our current portfolio of cash equivalents or short-term investments and our ability to meet our financing objectives.

Traditionally, we have funded a large portion of our research and development expenditures through raising capital in the equity markets. Recent events, including failures and bankruptcies among large commercial and investment banks, have led to considerable declines and uncertainties in these and other capital markets and may lead to new regulatory and other restrictions that may broadly affect the nature of these markets. These circumstances could severely restrict the raising of new capital by companies such as us in the future.

Volatility in the financial markets has also created liquidity problems in investments previously thought to bear a minimal risk. For example, money market fund investors, including us, have in the past been unable to retrieve the full amount of funds, even in highly-rated liquid money market accounts, upon maturity. Although as of September 30, 2010, we have received the full amount of proceeds from money market fund investments, an inability to retrieve funds from money market and similar short-term investments as they mature in the future could have a material and adverse impact on our business, results of operations and cash flows.

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since September 30, 2010 no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or short-term investments or our ability to meet our financing objectives.

Because all of our product candidates are still being developed, we have sustained losses in the past and we expect to sustain losses in the future.

We have experienced significant losses and, as of September 30, 2010, we had an accumulated deficit of \$835.6 million.

For the nine months ended September 30, 2010, we had a net loss of approximately \$51.0 million or \$2.87 per common share (basic and diluted). For the nine months ended September 30, 2009, we had a net loss of approximately \$2.4 million or \$0.24 per common share (basic and diluted).

Our ability to achieve profitability is dependent in large part on the success of our development programs, obtaining regulatory approval for our product candidates and entering into new agreements for product development, manufacturing and commercialization, all of which are uncertain. Our ability to fund our ongoing operations is dependent on the foregoing factors and on our ability to secure additional funds. Because our product candidates are still being developed, we do not know whether we will ever achieve sustained profitability or whether cash flow from future operations will be sufficient to meet our needs.

We may issue additional equity securities and thereby materially and adversely affect the price of our common shares.

We are authorized to issue, without shareholder approval, 1,000,000 preference shares, of which 2,959 were issued and outstanding as of October 28, 2010, which may give other shareholders dividend, conversion, voting, and liquidation rights, among other rights, which may be superior to the rights of holders of our common shares. In addition, we are authorized to issue, generally without shareholder approval, up to 46,666,666 common shares, of which 21,798,576 were issued and outstanding as of October 28, 2010. If we issue additional equity securities, the price of our common shares may be materially and adversely affected.

As announced in the third quarter of 2009, we entered into an At Market Issuance Sales Agreement, with Wm Smith & Co. (“Wm Smith”), under which we may sell up to 1.7 million of our common shares from time to time through Wm Smith, as our agent for the offer and sale of the common shares. Wm Smith could sell these common shares by any method permitted by law deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act of 1933, including but not limited to sales made directly on The NASDAQ Global Market, on any other existing trading market for the common shares or to or through a market maker. Wm Smith could also sell the common shares in privately negotiated transactions, subject to our approval. From the inception of this agreement through September 30, 2010, we sold a total of 1,112,132 common shares through Wm Smith for aggregate gross proceeds of \$10.7 million. From October 1, 2010 through October 27, 2010, 554,534 additional common shares were sold through Wm Smith, constituting all of the shares remaining available for sale under the agreement, for aggregate gross proceeds of \$1.5 million.

In addition, we completed an underwritten offering of 2.8 million units, with each unit consisting of one of our common shares and a warrant to purchase 0.45 of a common share, for gross proceeds of approximately \$21 million, before deducting underwriting discounts and commissions and estimated offering expenses of \$1.7 million. The investors purchased the units at a price of \$7.50 per unit. The warrants, which represent the right to acquire an aggregate of up to 1.26 million common shares, are exercisable beginning six months and one day after issuance and have a five-year term and an exercise price of \$10.50 per share.

On July 23, 2010, we entered into a common share purchase agreement with Azimuth Opportunity, Ltd. (“Azimuth”), pursuant to which we obtained a committed equity line of credit facility under which we could sell up to \$30 million of our registered common shares to Azimuth over a 12-month period, subject to certain conditions and limitations. In August of 2010, we sold a total of 3,421,407 common shares under this facility for aggregate proceeds of \$14.2 million, representing the maximum number of shares that could be sold under this facility.

On October 26, 2010, we entered into a new At Market Issuance Sales Agreement with Wm Smith and McNicoll, Lewis & Vlak LLC (the “Agents”), under which we may sell common shares from time to time through the Agents, as our agents for the offer and sale of the common shares, in an aggregate amount not to exceed the amount that can be sold under our registration statement on Form S-3 (File No. 333-148342) filed with the U.S. Securities and Exchange Commission on December 26, 2007. The Agents may sell the common shares by any method permitted by law deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act, including without limitation sales made directly on The NASDAQ Global Market, on any other existing trading market for the common shares or to or through a market maker. The Agents may also sell the common shares in privately negotiated transactions, subject to our prior approval.

The financial terms of future collaborative or licensing arrangements could result in dilution of our share value.

Funding from collaboration partners and others has in the past and may in the future involve issuance by us of our shares. Because we do not currently have any such arrangements, we cannot be certain how the purchase price of such shares, the relevant market price or premium, if any, will be determined or when such determinations will be made. Any such issuance could result in dilution in the value of our issued and outstanding shares.

Our share price may be volatile and there may not be an active trading market for our common shares.

There can be no assurance that the market price of our common shares will not decline below its present market price or that there will be an active trading market for our common shares. The market prices of biotechnology companies have been and are likely to continue to be highly volatile. Fluctuations in our operating results and general market conditions for biotechnology stocks could have a significant impact on the volatility of our common share price. We have experienced significant volatility in the price of our common shares. From January 1, 2010 through November 2, 2010, our share price has ranged from a high of \$11.850 to a low of \$2.310 . Factors contributing to such volatility include, but are not limited to:

- sales and estimated or forecasted sales of products for which we receive royalties,
- results of preclinical studies and clinical trials,
- information relating to the safety or efficacy of products or product candidates,
- developments regarding regulatory filings,
- announcements of new collaborations,
- failure to enter into collaborations,
- developments in existing collaborations,
- our funding requirements and the terms of our financing arrangements,

- technological innovations or new indications for our therapeutic products and product candidates,
- introduction of new products or technologies by us or our competitors,
- government regulations,
- developments in patent or other proprietary rights,
- the number of shares issued and outstanding,
- the number of shares trading on an average trading day,
- announcements regarding other participants in the biotechnology and pharmaceutical industries, and
- market speculation regarding any of the foregoing.



We face uncertain results of clinical trials of our potential products.

Our potential products, including XOMA 052 and XOMA 3AB, will require significant additional research and development, extensive preclinical studies and clinical trials and regulatory approval prior to any commercial sales. This process is lengthy and expensive, often taking a number of years. As clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals, the length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly. As a result, it is uncertain whether:

- our future filings will be delayed,
- our preclinical and clinical studies will be successful,
- we will be successful in generating viable product candidates to targets,
- we will be able to provide necessary additional data,
- results of future clinical trials will justify further development, or
- we will ultimately achieve regulatory approval for any of these product candidates.

For example, in 2003, we completed two Phase 1 trials of XOMA 629, a BPI-derived topical peptide compound targeting acne, evaluating the safety, skin irritation and pharmacokinetics. In January of 2004, we announced the initiation of Phase 2 clinical testing in patients with mild-to-moderate acne. In August of 2004, we announced the results of a Phase 2 trial with XOMA 629 gel. The results were inconclusive in terms of clinical benefit of XOMA 629 compared with vehicle gel. In 2007, after completing an internal evaluation of this program, we chose to reformulate and focus development efforts on the use of this reformulated product candidate in superficial skin infections, including impetigo and the eradication of staphylococcus aureus. In the fourth quarter of 2008, we decided to curtail all spending on XOMA 629 in response to current economic conditions and to focus our financial resources on XOMA 052.

The timing of the commencement, continuation and completion of clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, and shortages of available drug supply. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In addition, we will conduct clinical trials in foreign countries in the future which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign clinical research organizations, as well as expose us to risks associated with foreign currency transactions insofar as we might desire to use U.S. dollars to make contract payments denominated in the foreign currency where the trial is being conducted.

All of our product candidates are prone to the risks of failure inherent in drug development. Preclinical studies may not yield results that would satisfactorily support the filing of an IND (or a foreign equivalent) with respect to our product candidates. Even if these applications would be or have been filed with respect to our product candidates, the results of preclinical studies do not necessarily predict the results of clinical trials. Similarly, early-stage clinical trials in healthy volunteers do not predict the results of later-stage clinical trials, including the safety and efficacy profiles of any particular product candidates. In addition, there can be no assurance that the design of our clinical trials is focused on appropriate indications, patient populations, dosing regimens or other variables which will result in obtaining the

desired efficacy data to support regulatory approval to commercialize the drug. Preclinical and clinical data can be interpreted in different ways. Accordingly, FDA officials or officials from foreign regulatory authorities could interpret the data in different ways than we or our partners do which could delay, limit or prevent regulatory approval.

Administering any of our products or potential products may produce undesirable side effects, also known as adverse effects. Toxicities and adverse effects that we have observed in preclinical studies for some compounds in a particular research and development program may occur in preclinical studies or clinical trials of other compounds from the same program. Such toxicities or adverse effects could delay or prevent the filing of an IND (or a foreign equivalent) with respect to such products or potential products or cause us to cease clinical trials with respect to any drug candidate. In clinical trials, administering any of our products or product candidates to humans may produce adverse effects. These adverse effects could interrupt, delay or halt clinical trials of our products and product candidates and could result in the FDA or other regulatory authorities denying approval of our products or product candidates for any or all targeted indications. The FDA, other regulatory authorities, our partners or we may suspend or terminate clinical trials at any time. Even if one or more of our product candidates were approved for sale, the occurrence of even a limited number of toxicities or adverse effects when used in large populations may cause the FDA to impose restrictions on, or stop, the further marketing of such drugs. Indications of potential adverse effects or toxicities which may occur in clinical trials and which we believe are not significant during the course of such clinical trials may later turn out to actually constitute serious adverse effects or toxicities when a drug has been used in large populations or for extended periods of time. Any failure or significant delay in completing preclinical studies or clinical trials for our product candidates, or in receiving and maintaining regulatory approval for the sale of any drugs resulting from our product candidates, may severely harm our reputation and business.

Given that regulatory review is an interactive and continuous process, we maintain a policy of limiting announcements and comments upon the specific details of regulatory review of our product candidates, subject to our obligations under the securities laws, until definitive action is taken.

Our therapeutic product candidates have not received regulatory approval. If these product candidates do not receive regulatory approval, neither our third party collaborators nor we will be able to manufacture and market them.

Our product candidates, including XOMA 052 and XOMA 3AB, cannot be manufactured and marketed in the United States and other countries without required regulatory approvals. The United States government and governments of other countries extensively regulate many aspects of our product candidates, including:

- testing,
- manufacturing,
- promotion and marketing, and
- exporting.

In the United States, the Food and Drug Administration (“FDA”) regulates pharmaceutical products under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. At the present time, we believe that most of our product candidates will be regulated by the FDA as biologics. Initiation of clinical trials requires approval by health authorities. Clinical trials involve the administration of the investigational new drug to healthy volunteers or to patients under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with FDA and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practices and the European Clinical Trials Directive under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Other national, foreign and local regulations may also apply. The developer of the drug must provide information relating to the characterization and controls of the product before administration to the patients participating in the clinical trials. This requires developing approved assays of the product to test before administration to the patient and during the conduct of the trial. In addition, developers of pharmaceutical products must provide periodic data regarding clinical trials to the FDA and other health authorities, and these health authorities may issue a clinical hold upon a trial if they do not believe, or cannot confirm, that the trial can be conducted without unreasonable risk to the trial participants. We cannot assure you that U.S. and foreign health authorities will not issue a clinical hold with respect to any of our clinical trials in the future.

The results of the preclinical studies and clinical testing, together with chemistry, manufacturing and controls information, are submitted to the FDA and other health authorities in the form of a new drug application for a pharmaceutical product, and in the form of a BLA for a biological product, requesting approval to commence commercial sales. In responding to a new drug application or an antibody license application, the FDA or foreign health authorities may grant marketing approvals, request additional information or further research, or deny the application if it determines that the application does not satisfy its regulatory approval criteria. Regulatory approval of a new drug application, BLA, or supplement is never guaranteed, and the approval process can take several years and is extremely expensive. The FDA and foreign health authorities have substantial discretion in the drug and biologics approval processes. Despite the time and expense incurred, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical, clinical or manufacturing-related studies.

Changes in the regulatory approval policy during the development period, changes in, or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application may cause delays in the

approval or rejection of an application. State regulations may also affect our proposed products. The FDA has substantial discretion in both the product approval process and manufacturing facility approval process and, as a result of this discretion and uncertainties about outcomes of testing, we cannot predict at what point, or whether, the FDA will be satisfied with our or our collaborators' submissions or whether the FDA will raise questions which may be material and delay or preclude product approval or manufacturing facility approval. As we accumulate additional clinical data, we will submit it to the FDA, and such data may have a material impact on the FDA product approval process.

Even once approved, a product may be subject to additional testing or significant marketing restrictions, its approval may be withdrawn or it may be voluntarily taken off the market.

Even if the FDA, the European Commission or another regulatory agency approves a product candidate for marketing, the approval may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials, and the FDA, European Commission or other regulatory agency may subsequently withdraw approval based on these additional trials.

Even for approved products, the FDA, European Commission or other regulatory agency may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product.

Furthermore, a marketing approval of a product may be withdrawn by the FDA, the European Commission or another regulatory agency or such a product may be voluntarily withdrawn by the company marketing it based, for example, on subsequently-arising safety concerns. In February of 2009, the European Medicines Agency (“EMA”) announced that it had recommended suspension of the marketing authorization of RAPTIVA® in the European Union and that its Committee for Medicinal Products for Human Use (“CHMP”) had concluded that the benefits of RAPTIVA® no longer outweigh its risks because of safety concerns, including the occurrence of progressive multifocal leukoencephalopathy (“PML”) in patients taking the medicine. In the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA® from the U.S. market, based on the association of RAPTIVA® with an increased risk of PML.

The FDA, European Commission and other agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Certain of our technologies are relatively new and are in-licensed from third parties, so our capabilities using them are unproven and subject to additional risks.

We license technologies from third parties. These technologies include but are not limited to phage display technologies licensed to us in connection with our bacterial cell expression technology licensing program. However, our experience with some of these technologies remains relatively limited and, to varying degrees, we are still dependent on the licensing parties for training and technical support for these technologies. In addition, our use of these technologies is limited by certain contractual provisions in the licenses relating to them and, although we have obtained numerous licenses, intellectual property rights in the area of phage display are particularly complex. If the owners of the patent rights underlying the technologies we license do not properly maintain or enforce those patents, our competitive position and business prospects could be harmed. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce our licensed intellectual property. Our licensors may not successfully prosecute the patent applications to which we have licenses, or our licensors may fail to maintain existing patents. They may determine not to pursue litigation against other companies that are infringing these patents, or they may pursue such litigation less aggressively than we would. Our licensors may also seek to terminate our license, which could cause us to lose the right to use the licensed intellectual property and adversely affect our ability to commercialize our technologies, products or services.

We do not know whether there will be, or will continue to be, a viable market for the products in which we have an ownership or royalty interest.

Even if products in which we have an interest receive approval in the future, they may not be accepted in the marketplace. In addition, we or our collaborators or licensees may experience difficulties in launching new products, many of which are novel and based on technologies that are unfamiliar to the healthcare community. We have no

assurance that healthcare providers and patients will accept such products, if developed. For example, physicians and/or patients may not accept a product for a particular indication because it has been biologically derived (and not discovered and developed by more traditional means) or if no biologically derived products are currently in widespread use in that indication. Similarly, physicians may not accept a product if they believe other products to be more effective or are more comfortable prescribing other products.

Safety concerns may also arise in the course of on-going clinical trials or patient treatment as a result of adverse events or reactions. For example, in February of 2009, the EMEA announced that it had recommended suspension of the marketing authorization of RAPTIVA ® in the European Union and EMD Serono Inc., the company that marketed RAPTIVA ® in Canada (“EMD Serono”) announced that, in consultation with Health Canada, the Canadian health authority (“Health Canada”), it would suspend marketing of RAPTIVA ® in Canada. In March of 2009, Merck Serono Australia Pty Ltd, the company that marketed RAPTIVA ® in Australia (“Merck Serono Australia”), following a recommendation from the Therapeutic Goods Administration, the Australian health authority (“TGA”), announced that it was withdrawing RAPTIVA ® from the Australian market. In the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA ® from the U.S. market, based on the association of RAPTIVA ® with an increased risk of PML. As a result, sales of RAPTIVA ® ceased in the second quarter of 2009.

Furthermore, government agencies, as well as private organizations involved in healthcare, from time to time publish guidelines or recommendations to healthcare providers and patients. Such guidelines or recommendations can be very influential and may adversely affect the usage of any products we may develop directly (for example, by recommending a decreased dosage of a product in conjunction with a concomitant therapy or a government entity withdrawing its recommendation to screen blood donations for certain viruses) or indirectly (for example, by recommending a competitive product over our product). Consequently, we do not know if physicians or patients will adopt or use our products for their approved indications.

We or our third party collaborators or licensees may not have adequate manufacturing capacity sufficient to meet market demand.

If any of our product candidates are approved, because we have never commercially introduced any pharmaceutical products, we do not know whether the capacity of our existing manufacturing facilities can be increased to produce sufficient quantities of our products to meet market demand. Also, if we or our third party collaborators or licensees need additional manufacturing facilities to meet market demand, we cannot predict that we will successfully obtain those facilities because we do not know whether they will be available on acceptable terms. In addition, any manufacturing facilities acquired or used to meet market demand must meet the FDA's quality assurance guidelines.

Our agreements with third parties, many of which are significant to our business, expose us to numerous risks.

Our financial resources and our marketing experience and expertise are limited. Consequently, our ability to successfully develop products depends, to a large extent, upon securing the financial resources and/or marketing capabilities of third parties.

- In April of 1996, we entered into an agreement with Genentech whereby we agreed to co-develop Genentech's humanized monoclonal antibody product RAPTIVA®. In April of 1999, March of 2003, and January of 2005, the companies amended the agreement. In October of 2003, RAPTIVA® was approved by the FDA for the treatment of adults with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and, in September of 2004, Merck Serono announced the product's approval in the European Union. In January of 2005, we entered into a restructuring of our collaboration agreement with Genentech which ended our existing cost and profit sharing arrangement related to RAPTIVA® in the United States and entitled us to a royalty interest on worldwide net sales. In February of 2009, the EMEA announced that it had recommended suspension of the marketing authorization of RAPTIVA® in the European Union and EMD Serono announced that, in consultation with Health Canada, it would suspend marketing of RAPTIVA® in Canada. In March of 2009, Merck Serono Australia, following a recommendation from the TGA, announced that it was withdrawing RAPTIVA® from the Australian market. In the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA® from the U.S. market, based on the association of RAPTIVA® with an increased risk of PML. As a result, sales of RAPTIVA® ceased in the second quarter of 2009.
- In March of 2004, we announced we had agreed to collaborate with Chiron Corporation (now Novartis) for the development and commercialization of antibody products for the treatment of cancer. In April of 2005, we announced the initiation of clinical testing of the first product candidate out of the collaboration, HCD122, an anti-CD40 antibody, in patients with advanced chronic lymphocytic leukemia. In October of 2005, we announced the initiation of the second clinical trial of HCD122 in patients with multiple myeloma. In November of 2008, we announced the restructuring of this product development collaboration, which involves six development programs including the ongoing HCD122 program. In exchange for cash and debt reduction on our existing loan facility with Novartis, Novartis has control over the HCD122 program and the additional ongoing program, as well as the right to expand the development of these programs into additional indications outside of oncology. We may, in the future, receive milestones of up to \$14 million and double-digit royalty rates for two ongoing product programs, including HCD122. The agreement also provides us with options to develop or receive royalties on four additional programs.
- In March of 2005, we entered into a contract with the National Institute of Allergy and Infectious Diseases ("NIAID") to produce three monoclonal antibodies designed to protect United States citizens

against the harmful effects of botulinum neurotoxin used in bioterrorism. In July of 2006, we entered into an additional contract with NIAID for the development of an appropriate formulation for human administration of these three antibodies in a single injection. In September of 2008, we announced that we were awarded an additional contract with NIAID to support our on-going development of drug candidates toward clinical trials in the treatment of botulism poisoning.

We have licensed our bacterial cell expression technology, an enabling technology used to discover and screen, as well as develop and manufacture, recombinant antibodies and other proteins for commercial purposes, to over 50 companies. As of September 30, 2010, we were aware of two antibody products manufactured using this technology that have received FDA approval, Genentech's LUCENTIS® (ranibizumab injection) for treatment of neovascular wet age-related macular degeneration and UCB's CIMZIA® (certolizumab pegol) for treatment of Crohn's disease and rheumatoid arthritis. In the third quarter of 2009, we sold our LUCENTIS® royalty interest to Genentech. In the third quarter of 2010, we sold our CIMZIA® royalty interest to an undisclosed buyer.



Because our collaborators and licensees are independent third parties, they may be subject to different risks than we are and have significant discretion in determining the efforts and resources they will apply related to their agreements with us. If these collaborators and licensees do not successfully develop and market these products, we may not have the capabilities, resources or rights to do so on our own. We do not know whether our collaborators or licensees will successfully develop and market any of the products that are or may become the subject of one of our collaboration or licensing arrangements. In particular, each of these arrangements provides for funding solely by our collaborators or licensees. Furthermore, our contracts with NIAID contain numerous standard terms and conditions provided for in the applicable federal acquisition regulations and customary in many government contracts. Uncertainty exists as to whether we will be able to comply with these terms and conditions in a timely manner, if at all. In addition, we are uncertain as to the extent of NIAID's demands and the flexibility that will be granted to us in meeting those demands.

Even when we have a collaborative relationship, other circumstances may prevent it from resulting in successful development of marketable products.

- In September of 2004, we entered into a collaboration arrangement with Apton Corporation ("Apton") for the treatment of gastrointestinal and other gastrin-sensitive cancers using anti-gastrin monoclonal antibodies. In January of 2006, Apton announced that its common stock had been delisted from NASDAQ. In May of 2006, Apton filed for bankruptcy protection under Chapter 11, Title 11 of the United States Bankruptcy Code.
- In September of 2006, we entered into an agreement with Taligen Therapeutics, Inc. ("Taligen") which formalized an earlier letter agreement, which was signed in May of 2006, for the development and cGMP manufacture of a novel antibody fragment for the potential treatment of inflammatory diseases. In May of 2007, we and Taligen entered into a letter agreement which provided that we would not produce a cGMP batch at clinical scale pursuant to the terms of the agreement entered into in September of 2006. In addition, the letter agreement provided that we would conduct and complete the technical transfer of the process to Avecia Biologics Limited or its designated affiliate ("Avecia"). The letter agreement also provided that, subject to payment by Taligen of approximately \$1.7 million, we would grant to Avecia a non-exclusive, worldwide, paid-up, non-transferable, non-sublicensable, perpetual license under our owned project innovations. We received \$0.6 million as the first installment under the payment terms of the letter agreement but not the two additional payments totaling approximately \$1.1 million to which we were entitled upon fulfillment of certain obligations. In May of 2009, the matter was resolved by agreement of the parties in a manner that had no further impact on our financial position.

Although we continue to evaluate additional strategic alliances and potential partnerships, we do not know whether or when any such alliances or partnerships will be entered into.

Products and technologies of other companies may render some or all of our products and product candidates noncompetitive or obsolete.

Developments by others may render our products, product candidates, or technologies obsolete or uncompetitive. Technologies developed and utilized by the biotechnology and pharmaceutical industries are continuously and substantially changing. Competition in the areas of genetically engineered DNA-based and antibody-based technologies is intense and expected to increase in the future as a number of established biotechnology firms and large chemical and pharmaceutical companies advance in these fields. Many of these competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including that they may have:

- significantly greater financial resources,

- larger research and development and marketing staffs,
- larger production facilities,
- entered into arrangements with, or acquired, biotechnology companies to enhance their capabilities, or
- extensive experience in preclinical testing and human clinical trials.

These factors may enable others to develop products and processes competitive with or superior to our own or those of our collaborators. In addition, a significant amount of research in biotechnology is being carried out in universities and other non-profit research organizations. These entities are becoming increasingly interested in the commercial value of their work and may become more aggressive in seeking patent protection and licensing arrangements. Furthermore, many companies and universities tend not to announce or disclose important discoveries or development programs until their patent position is secure or, for other reasons, later; as a result, we may not be able to track development of competitive products, particularly at the early stages. Positive or negative developments in connection with a potentially competing product may have an adverse impact on our ability to raise additional funding on acceptable terms. For example, if another product is perceived to have a competitive advantage, or another product's failure is perceived to increase the likelihood that our product will fail, then investors may choose not to invest in us on terms we would accept or at all.

The examples below pertain to competitive events in the market which we review quarterly and are not intended to be representative of all existing competitive events. Without limiting the foregoing, we are aware that:

#### XOMA 052

We are conducting clinical testing of XOMA 052, a potent anti-inflammatory monoclonal antibody targeting IL-1 beta, in Type 2 diabetes patients and Behcet's disease patients. Other companies are developing other products based on the same or similar therapeutic targets as XOMA 052 and these products may prove more effective than XOMA 052. We are aware that:

- In June of 2009, Novartis announced it had received U.S. marketing approval for Ilaris ® (canakinumab), a fully-human monoclonal antibody targeting IL-1 beta, to treat children and adults with Cryopyrin-Associated Periodic Syndromes (“CAPS”). In October of 2009, Novartis announced that Ilaris ® had been approved in the European Union for CAPS. Canakinumab is also in clinical trials in Type 2 diabetes, chronic obstructive pulmonary disorder, certain forms of gout and systemic juvenile rheumatoid arthritis. In June of 2010, Novartis announced positive results of Phase 2 clinical trial of canakinumab in gout.
- Eli Lilly and Company (“Lilly”) is developing LY2189102, an investigational IL-1 beta antibody, for bi-weekly subcutaneous injection for the treatment of Type 2 diabetes. Lilly announced the initiation of a Phase 2 study in the third quarter of 2009 and has estimated completion of this study in November of 2010.
- In 2008, Biovitrum AB (now called Swedish Orphan Biovitrum, “Biovitrum”) obtained a worldwide exclusive license to Amgen Inc. (“Amgen”)’s Kineret ® (anakinra) for its current approved indication. Kineret ® is an IL-1 receptor antagonist (IL-1ra) currently marketed to treat rheumatoid arthritis and has been evaluated over the years in multiple IL-1 mediated diseases, including Type 2 diabetes and other indications we are considering for XOMA 052. In addition to other on-going studies, a proof-of-concept clinical trial in the United Kingdom investigating Kineret ® in patients with a certain type of myocardial infarction, or heart attack, has been completed. In August of 2010, Biovitrum announced that the FDA had granted orphan drug designation to Kineret ® for the treatment of CAPS.
- In February of 2008, Regeneron Pharmaceuticals, Inc. (“Regeneron”) announced it had received marketing approval from the FDA for ARCALYST ® (rilonacept) Injection for Subcutaneous Use, an interleukin-1 blocker or IL-1 Trap, for the treatment of CAPS, including Familial Cold Auto-inflammatory Syndrome and Muckle-Wells Syndrome in adults and children 12 and older. In September of 2009, Regeneron announced that rilonacept was approved in the European Union for CAPS. In June of 2010, Regeneron announced positive results of a Phase 3 clinical trial of rilonacept in gout. In October 2010, Regeneron disclosed that it expected to have initial data from two ongoing Phase 3 studies of rilonacept in gout by early 2011.
- Amgen has been developing AMG 108, a fully-human monoclonal antibody that targets inhibition of the action of IL-1. On April 28, 2008, Amgen discussed results from its recently completed Phase 2 study in rheumatoid arthritis. AMG 108 showed statistically significant improvement in the signs and symptoms of rheumatoid arthritis and was well tolerated. Amgen has announced it is focusing on other opportunities for the antibody.

In June of 2009, Cytos Biotechnology AG announced the initiation of an ascending dose Phase 1 study of CYT013-IL1bQb, a therapeutic vaccine targeting IL-1 beta, in Type 2 diabetes and that this study is expected to be completed in the first quarter of 2011.

XOMA 3AB

- In May of 2006, the U.S. Department of Health & Human Services awarded Cangene Corporation (“Cangene”) a five-year, \$362 million contract under Project Bioshield. The contract requires Cangene to manufacture and supply 200,000 doses of an equine heptavalent botulism anti-toxin to treat individuals who have been exposed to the toxins that cause botulism. In May of 2008, Cangene announced significant product delivery under this contract. In March of 2010, this contract was extended for an additional two years, until May of 2013.
- Emergent BioSolutions, Inc. (“Emergent”) is currently in development of a botulism immunoglobulin candidate that may compete with our anti-botulinum neurotoxin monoclonal antibodies.
- We are aware of additional companies that are pursuing biodefense-related antibody products. PharmAthene, Inc. and Human Genome Sciences, Inc. are developing anti-anthrax antibodies. Cangene and Emergent are developing anti-anthrax immune globulin products. These products may compete with our efforts in the areas of other monoclonal antibody-based biodefense products, and the manufacture of antibodies to supply strategic national stockpiles.

Manufacturing risks and inefficiencies may adversely affect our ability to manufacture products for ourselves or others.

To the extent we continue to provide manufacturing services for our own benefit or to third parties, we are subject to manufacturing risks. Additionally, unanticipated fluctuations in customer requirements have led and may continue to lead to manufacturing inefficiencies. We must utilize our manufacturing operations in compliance with regulatory requirements, in sufficient quantities and on a timely basis, while maintaining acceptable product quality and manufacturing costs. Additional resources and changes in our manufacturing processes may be required for each new product, product modification or customer or to meet changing regulatory or third party requirements, and this work may not be successfully or efficiently completed. In addition, to the extent we continue to provide manufacturing services, our fixed costs, such as facility costs, would be expected to increase, as would necessary capital investment in equipment and facilities.

Manufacturing and quality problems may arise in the future to the extent we continue to perform these services for our own benefit or for third parties. Consequently, our development goals or milestones may not be achieved in a timely manner or at a commercially reasonable cost, or at all. In addition, to the extent we continue to make investments to improve our manufacturing operations, our efforts may not yield the improvements that we expect.

Because many of the companies we do business with are also in the biotechnology sector, the volatility of that sector can affect us indirectly as well as directly.

As a biotechnology company that collaborates with other biotechnology companies, the same factors that affect us directly can also adversely impact us indirectly by affecting the ability of our collaborators, partners and others we do business with to meet their obligations to us and reduce our ability to realize the value of the consideration provided to us by these other companies.

For example, in connection with our licensing transactions relating to our bacterial cell expression technology, we have in the past and may in the future agree to accept equity securities of the licensee in payment of license fees. The future value of these or any other shares we receive is subject both to market risks affecting our ability to realize the value of these shares and more generally to the business and other risks to which the issuer of these shares may be subject.

As we do more business internationally, we will be subject to additional political, economic and regulatory uncertainties.

We may not be able to successfully operate in any foreign market. We believe that, because the pharmaceutical industry is global in nature, international activities will be a significant part of our future business activities and that, when and if we are able to generate income, a substantial portion of that income will be derived from product sales and other activities outside the United States. Foreign regulatory agencies often establish standards different from those in the United States, and an inability to obtain foreign regulatory approvals on a timely basis could put us at a competitive disadvantage or make it uneconomical to proceed with a product or product candidate's development. International operations and sales may be limited or disrupted by:

- imposition of government controls,
- export license requirements,
- political or economic instability,

- trade restrictions,
- changes in tariffs,
- restrictions on repatriating profits,
- exchange rate fluctuations,
- withholding and other taxation, and
- difficulties in staffing and managing international operations.

If we and our partners are unable to protect our intellectual property, in particular our patent protection for our principal products, product candidates and processes, and prevent its use by third parties, our ability to compete in the market will be harmed, and we may not realize our profit potential.

We rely on patent protection, as well as a combination of copyright, trade secret, and trademark laws to protect our proprietary technology and prevent others from duplicating our products or product candidates. However, these means may afford only limited protection and may not:

- prevent our competitors from duplicating our products;
- prevent our competitors from gaining access to our proprietary information and technology, or
- permit us to gain or maintain a competitive advantage.

Because of the length of time and the expense associated with bringing new products to the marketplace, we and our partners hold and are in the process of applying for a number of patents in the United States and abroad to protect our product candidates and important processes and also have obtained or have the right to obtain exclusive licenses to certain patents and applications filed by others. However, the mere issuance of a patent is not conclusive as to its validity or its enforceability. The United States Federal Courts or equivalent national courts or patent offices elsewhere may invalidate our patents or find them unenforceable. In addition, the laws of foreign countries may not protect our intellectual property rights effectively or to the same extent as the laws of the United States. If our intellectual property rights are not adequately protected, we may not be able to commercialize our technologies, products, or services, and our competitors could commercialize our technologies, which could result in a decrease in our sales and market share that would harm our business and operating results. Specifically, the patent position of biotechnology companies generally is highly uncertain and involves complex legal and factual questions. The legal standards governing the validity of biotechnology patents are in transition, and current defenses as to issued biotechnology patents may not be adequate in the future. Accordingly, there is uncertainty as to:

- whether any pending or future patent applications held by us will result in an issued patent, or that if patents are issued to us, that such patents will provide meaningful protection against competitors or competitive technologies,
- whether competitors will be able to design around our patents or develop and obtain patent protection for technologies, designs or methods that are more effective than those covered by our patents and patent applications, or
- the extent to which our product candidates could infringe on the intellectual property rights of others, which may lead to costly litigation, result in the payment of substantial damages or royalties, and/or prevent us from using technology that is essential to our business.

We have established an extensive portfolio of patents and applications, both United States and foreign, related to our BPI-related product candidates, including novel compositions, their manufacture, formulation, assay and use. We have also established a portfolio of patents, both United States and foreign, related to our bacterial cell expression technology, including claims to novel promoter sequences, secretion signal sequences, compositions and methods for expression and secretion of recombinant proteins from bacteria, including immunoglobulin gene products. Most of the more important European patents in our bacterial cell expression patent portfolio expired in July of 2008.

If certain patents issued to others are upheld or if certain patent applications filed by others issue and are upheld, we may require licenses from others in order to develop and commercialize certain potential products incorporating our

technology or we may become involved in litigation to determine the proprietary rights of others. These licenses, if required, may not be available on acceptable terms, and any such litigation may be costly and may have other adverse effects on our business, such as inhibiting our ability to compete in the marketplace and absorbing significant management time.

Due to the uncertainties regarding biotechnology patents, we also have relied and will continue to rely upon trade secrets, know-how and continuing technological advancement to develop and maintain our competitive position. All of our employees have signed confidentiality agreements under which they have agreed not to use or disclose any of our proprietary information. Research and development contracts and relationships between us and our scientific consultants and potential customers provide access to aspects of our know-how that are protected generally under confidentiality agreements. These confidentiality agreements may be breached or may not be enforced by a court. To the extent proprietary information is divulged to competitors or to the public generally, such disclosure may adversely affect our ability to develop or commercialize our products by giving others a competitive advantage or by undermining our patent position.



Litigation regarding intellectual property can be costly and expose us to risks of counterclaims against us.

We may be required to engage in litigation or other proceedings to protect our intellectual property. The cost to us of this litigation, even if resolved in our favor, could be substantial. Such litigation could also divert management's attention and resources. In addition, if this litigation is resolved against us, our patents may be declared invalid, and we could be held liable for significant damages. In addition, we may be subject to a claim that we are infringing another party's patent. If such claim is resolved against us, we or our collaborators may be enjoined from developing, manufacturing, selling or importing products, processes or services unless we obtain a license from the other party. Such license may not be available on reasonable terms, thus preventing us from using these products, processes or services and adversely affecting our revenue.

Even if we or our third party collaborators or licensees bring products to market, we may be unable to effectively price our products or obtain adequate reimbursement for sales of our products, which would prevent our products from becoming profitable.

If we or our third party collaborators or licensees succeed in bringing our product candidates to the market, they may not be considered cost-effective, and reimbursement to the patient may not be available or may not be sufficient to allow us to sell our products on a competitive basis. In both the United States and elsewhere, sales of medical products and treatments are dependent, in part, on the availability of reimbursement to the patient from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and services. Our business is affected by the efforts of government and third-party payors to contain or reduce the cost of healthcare through various means. In the United States, there have been and will continue to be a number of federal and state proposals to implement government controls on pricing. In addition, the emphasis on managed care in the United States has increased and will continue to increase the pressure on the pricing of pharmaceutical products. We cannot predict whether any legislative or regulatory proposals will be adopted or the effect these proposals or managed care efforts may have on our business.

Healthcare reform measures and other statutory or regulatory changes could adversely affect our business.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our business. In March of 2010, the U.S. Congress enacted and President Obama signed into law the Patient Protection and Affordable Care Act, which includes a number of healthcare reform provisions. The reforms imposed by the new law will significantly impact the pharmaceutical industry, most likely in the area of pharmaceutical product pricing; however, the full effects of new law cannot be known until these provisions are implemented and the relevant federal and state agencies issue applicable regulations or guidance.

The pharmaceutical and biotechnology industries are subject to extensive regulation, and from time to time legislative bodies and governmental agencies consider changes to such regulations that could have significant impact on industry participants. For example, in light of certain highly-publicized safety issues regarding certain drugs that had received marketing approval, the U.S. Congress has considered various proposals regarding drug safety, including some which would require additional safety studies and monitoring and could make drug development more costly. We are unable to predict what additional legislation or regulation, if any, relating to safety or other aspects of drug development may be enacted in the future or what effect such legislation or regulation would have on our business.

The business and financial condition of pharmaceutical and biotechnology companies are also affected by the efforts of governments, third-party payors and others to contain or reduce the costs of healthcare to consumers. In the United States and various foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the healthcare system, such as proposals relating to the

reimportation of drugs into the U.S. from other countries (where they are then sold at a lower price) and government control of prescription drug pricing. The pendency or approval of such proposals could result in a decrease in our share price or limit our ability to raise capital or to obtain strategic collaborations or licenses.

We are exposed to an increased risk of product liability claims, and a series of related cases is currently pending against us.

The testing, marketing and sales of medical products entails an inherent risk of allegations of product liability. In the event of one or more large, unforeseen awards of damages against us, our product liability insurance may not provide adequate coverage. A significant product liability claim for which we were not covered by insurance would have to be paid from cash or other assets. To the extent we have sufficient insurance coverage, such a claim would result in higher subsequent insurance rates. In addition, product liability claims can have various other ramifications including loss of future sales opportunities, increased costs associated with replacing products, and a negative impact on our goodwill and reputation, which could also adversely affect our business and operating results.

On April 9, 2009, a complaint was filed in the Superior Court of Alameda County, California, in a lawsuit captioned Hedrick et al. v. Genentech, Inc. et al , Case No. 09-446158. The complaint asserts claims against Genentech, us and others for alleged strict liability for failure to warn, strict product liability, negligence, breach of warranty, fraudulent concealment, wrongful death and other claims based on injuries alleged to have occurred as a result of three individuals' treatment with RAPTIVA ® . The complaint seeks unspecified compensatory and punitive damages. Since then, additional complaints have been filed in the same court, bringing the total number of pending cases to forty-nine. All of the complaints allege the same claims and seek the same types of damages based on injuries alleged to have occurred as a result of the plaintiffs' treatment with RAPTIVA ® . Even though Genentech has agreed to indemnify us, there can be no assurance that this or other products liability lawsuits will not result in liability to us or that our insurance or contractual arrangements will provide us with adequate protection against such liabilities.

On August 4, 2010, a petition was filed in the District Court of Dallas County, Texas in a case captioned McCall v. Genentech, Inc., et al. , No. 10-09544. The defendants filed a notice of removal to the United States District Court for the Northern District of Texas on September 3, 2010. The removed case is captioned McCall v. Genentech, Inc., et al. , No. 3:10-cv-01747-B. The petition asserts personal injury claims against Genentech, the Company, and others arising out of the plaintiff's treatment with RAPTIVA ®. The petition alleges claims based on negligence, strict liability, misrepresentation and suppression, conspiracy, and actual and constructive fraud. The petition seeks compensatory damages and punitive damages in an unspecified amount. Even though Genentech has agreed to indemnify us, there can be no assurance that this or other products liability lawsuits will not result in liability to us or that our insurance or contractual arrangements will provide us with adequate protection against such liabilities.

The loss of key personnel, including our Chief Executive Officer, could delay or prevent achieving our objectives.

Our research, product development and business efforts could be adversely affected by the loss of one or more key members of our scientific or management staff, particularly our executive officers: Steven B. Engle, our Chairman, Chief Executive Officer and President; Patrick J. Scannon, M.D., Ph.D., our Executive Vice President and Chief Medical Officer; Fred Kurland, our Vice President, Finance and Chief Financial Officer; and Christopher J. Margolin, our Vice President, General Counsel and Secretary. We currently have no key person insurance on any of our employees.

We may not realize the expected benefits of our initiatives to reduce costs across our operations, and we may incur significant charges or write-downs as part of these efforts.

We have pursued and may continue to pursue a number of initiatives to reduce costs across our operations. In January of 2009, we implemented a workforce reduction of approximately 42% in order to improve our cost structure. We recorded charges in 2009 of \$3.1 million for severance, other employee benefits and outplacement services related to the workforce reduction. In the second quarter of 2009, we vacated one of our leased buildings and recorded a restructuring charge of \$0.5 million primarily related to the net present value of the net future minimum lease payments, less the estimated future sublease income.

In addition, as a result of the workforce reduction, we temporarily vacated another building. As manufacturing demand increases in the future, we plan to resume operations at this facility. The net book value of fixed assets in the vacant building potentially subject to write-down is approximately \$3.6 million as of September 30, 2010. Although we have determined that there was no impairment of the assets as of September 30, 2010, there can be no assurance that we will not determine otherwise as of a future date and as a consequence write down these assets as impaired.

We may not realize some or all of the expected benefits of our current and future initiatives to reduce costs. In addition to restructuring or other charges, we may experience disruptions in our operations as a result of these initiatives and write-downs.

A U.S. holder of our common shares and warrants could be subject to material adverse U.S. federal income tax consequences if we were considered to be a PFIC at any time during the US holder's holding period.

A non-U.S. corporation generally will be a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes in any taxable year in which, after applying the relevant look-through rules with respect to the income and assets of its subsidiaries, either 75% or more of its gross income is "passive income" (generally including (without limitation) dividends, interest, annuities and certain royalties and rents not derived in the active conduct of a business) or the average value of its assets that produce passive income or are held for the production of passive income is at least 50% of the total value of its assets. In determining whether we meet the 50% test, cash is considered a passive asset and the total value of our assets generally will be treated as equal to the sum of the aggregate fair market value of

our outstanding common shares plus our liabilities. If we own at least 25% (by value) of the stock of another corporation, we will be treated, for purposes of the PFIC tests, as owning our proportionate share of the other corporation's assets and receiving our proportionate share of the other corporation's income.

We believe that we were not a PFIC for the 2009 taxable year. However, because PFIC status is determined annually and depends on the composition of a company's income and assets and the fair market value of its assets (including goodwill), which may be volatile in our industry, there can be no assurance that we will not be considered a PFIC for 2010 or any subsequent year. For example, taking into account our existing cash balances, if the value of our common shares were to decline materially, it is possible that we could become a PFIC in 2010 or a subsequent year. Additionally, due to the complexity of the PFIC provisions and the limited authority available to interpret such provisions, there can be no assurance that our determination regarding our PFIC status for any taxable year could not be successfully challenged by the Internal Revenue Service ("IRS").

If we were found to be a PFIC for any taxable year in which a U.S. holder (as defined below) held common shares or warrants, certain adverse U.S. federal income tax consequences could apply to such U.S. holder, including a recharacterization of any capital gain recognized on a sale or other disposition of common shares or warrants as ordinary income, ineligibility for any preferential tax rate otherwise applicable to any “qualified dividend income,” a material increase in the amount of tax that such U.S. holder would owe and the possible imposition of interest charges, an imposition of tax earlier than would otherwise be imposed and additional tax form filing requirements.

For purposes of this discussion, the term “U.S. holder” means a beneficial owner of common shares or warrants that is, for U.S. federal income tax purposes, (i) an individual who is a U.S. citizen or resident, (ii) a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (iii) an estate the income of which is includable in gross income for U.S. income tax purposes regardless of its source, or (iv) a trust, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. fiduciaries have the authority to control all substantial decisions of the trust, or if the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person. Special rules apply to a U.S. investor who owns our common shares or warrants through an entity treated as a partnership for U.S. federal income tax purposes.

A U.S. holder owning shares in a PFIC (or a corporation that might become a PFIC) might be able to mitigate the adverse tax consequences of PFIC status by making certain elections, including “qualified electing fund” (a “QEF”) or “mark-to-market” elections, if deemed appropriate based on guidance provided by the U.S. holder’s own tax advisor. However, it should be noted that (1) the beneficial effect of a QEF election or a mark-to-market election may be substantially diminished if such election is not made from the inception of a U.S. holder’s holding period (a “Year One Election”), (2) neither a QEF election nor a mark-to-market election can be made with respect to the warrants, (3) a Year One Election generally cannot be made for any common shares received upon exercise of the warrants (“Warrant Shares”) because the holding period of Warrant Shares is deemed, for QEF election and mark-to-market election purposes, to include the holding period of the underlying warrants but the QEF election or mark-to-market election will not be effective until the taxable year in which the underlying warrants are exercised, and (4) a QEF election or mark-to-market election is made on a shareholder-by-shareholder basis and, once made, can only be revoked with the consent of the IRS.

The PFIC rules are very complex, as are the requirements and effects of the various elections designed to mitigate the adverse consequences of the PFIC rules. A U.S. holder should consult its own tax advisor regarding the PFIC rules, including the foregoing limitations on the ability to make a QEF election or a mark-to-market election (or to qualify either such election as a Year One Election), the timing requirements with respect to the various elections and the irrevocability of certain elections (absent the consent of the IRS).

As a result of a recent legislative change, a U.S. holder generally will be required to file IRS Form 8621 if the U.S. holder holds our common shares or warrants in any taxable year in which we are classified as a PFIC (whether or not a QEF or mark-to-market election is made).

Our ability to use our net operating loss carry-forwards and other tax attributes will be substantially limited by Section 382 of the Internal Revenue Code.

Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”) generally limits the ability of a corporation that undergoes an “ownership change” to utilize its net operating loss carryforwards (“NOLs”) and certain other tax attributes against any taxable income in taxable periods after the ownership change. The amount of taxable income in each taxable year after the ownership change that may be offset by pre-change NOLs and certain other pre-change tax attributes is generally equal to the product of (a) the fair market value of the corporation’s outstanding shares immediately prior to the ownership change and (b) the long-term tax exempt rate (i.e., a rate of interest established by

the IRS that tracks the yield on long-term tax-exempt bonds and fluctuates from month to month). In general, an “ownership change” occurs whenever the percentage of the shares of a corporation owned, directly or indirectly, by “5-percent shareholders” (within the meaning of Section 382 of the Internal Revenue Code) increases by more than 50 percentage points over the lowest percentage of the share of such corporation owned, directly or indirectly, by such “5-percent shareholders” at any time over the preceding three years.

In 2009, we experienced an ownership change under Section 382, which subjects the amount of NOLs and other tax attributes that can be utilized to an annual limitation, which will substantially limit the future use of our pre-change NOLs and certain other pre-change tax attributes per year.

Recently proposed legislation, if enacted, could subject us to U.S. federal income taxation as if we were a U.S. corporation.

A bill recently introduced in the House of Representatives provides in certain instances that a corporation that changed its corporate domicile from the United States to a non-U.S. jurisdiction prior to the effective date of the “inversion” rules of Section 7874 of the Code would, for any taxable year beginning on or after the second anniversary of the bill’s enactment, be treated as a U.S. corporation for U.S. federal income taxes purposes if such corporation were managed and controlled primarily in the United States. If this bill were enacted in 2010 in its present form and we were to make no changes to our current management structure, we would likely be treated, beginning in 2013, as a U.S. corporation subject to U.S. federal income taxation on our worldwide income. There can be no assurance that the foregoing bill or another similar legislative proposal will not become law.

Because we are a relatively small biopharmaceutical company with limited resources, we may not be able to attract and retain qualified personnel.

Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified scientific and management personnel, particularly in areas requiring specific technical, scientific or medical expertise. We had approximately 225 employees as of November 2, 2010. We anticipate that we will require additional experienced executive, accounting, research and development, legal, administrative and other personnel in the future. There is intense competition for the services of these personnel, especially in California. Moreover, we expect that the high cost of living in the San Francisco Bay Area, where our headquarters and manufacturing facilities are located, may impair our ability to attract and retain employees in the future. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to implement our current initiatives or grow effectively.

Calamities, power shortages or power interruptions at our Berkeley headquarters and manufacturing facility could disrupt our business and adversely affect our operations, and could disrupt the businesses of our customers.

Our principal operations are located in Northern California, including our corporate headquarters and manufacturing facility in Berkeley, California. In addition, many of our collaborators and licensees are located in California. All of these locations are in areas of seismic activity near active earthquake faults. Any earthquake, terrorist attack, fire, power shortage or other calamity affecting our facilities or our customers’ facilities may disrupt our business and could have material adverse effect on our business and results of operations.

We may be subject to increased risks because we are a Bermuda company.

Alleged abuses by certain companies that have changed their legal domicile from jurisdictions within the United States to Bermuda have created an environment where, notwithstanding that we changed our legal domicile in a transaction that was approved by our shareholders and fully taxable to our company under United States law, we may be exposed to various prejudicial actions, including:

- “blacklisting” of our common shares by certain pension funds,
- legislation restricting certain types of transactions, and
- punitive tax legislation.

We do not know whether any of these things will happen, but if implemented one or more of them may have an adverse impact on our future operations or our share price.

It may be difficult to enforce a judgment obtained against us because we are a foreign entity.

We are a Bermuda company. All or a substantial portion of our assets, including substantially all of our intellectual property, may be located outside the United States. As a result, it may be difficult for shareholders and others to enforce in United States courts judgments obtained against us. We have irrevocably agreed that we may be served with process with respect to actions based on offers and sales of securities made hereby in the United States by serving Christopher J. Margolin, c/o XOMA Ltd., 2910 Seventh Street, Berkeley, California 94710, our United States agent appointed for that purpose. Uncertainty exists as to whether Bermuda courts would enforce judgments of United States courts obtained in actions against us or our directors and officers that are predicated upon the civil liability provisions of the United States securities laws or entertain original actions brought in Bermuda against us or such persons predicated upon the United States securities laws. There is no treaty in effect between the United States and Bermuda providing for such enforcement, and there are grounds upon which Bermuda courts may not enforce judgments of United States courts. Certain remedies available under the United States federal securities laws may not be allowed in Bermuda courts as contrary to that nation's policy.



Our shareholder rights agreement or bye-laws may prevent transactions that could be beneficial to our shareholders and may insulate our management from removal.

In February of 2003, we adopted a new shareholder rights agreement (to replace the shareholder rights agreement that had expired), which could make it considerably more difficult or costly for a person or group to acquire control of us in a transaction that our Board of Directors opposes.

Our bye-laws:

- require certain procedures to be followed and time periods to be met for any shareholder to propose matters to be considered at annual meetings of shareholders, including nominating directors for election at those meetings;
- authorize our Board of Directors to issue up to 1,000,000 preference shares without shareholder approval and to set the rights, preferences and other designations, including voting rights, of those shares as the Board of Directors may determine; and
- contain provisions, similar to those contained in the Delaware General Corporation Law that may make business combinations with interested shareholders more difficult.

These provisions of our shareholders rights agreement and our bye-laws, alone or in combination with each other, may discourage transactions involving actual or potential changes of control, including transactions that otherwise could involve payment of a premium over prevailing market prices to holders of common shares, could limit the ability of shareholders to approve transactions that they may deem to be in their best interests, and could make it considerably more difficult for a potential acquirer to replace management.

ITEM 6. EXHIBITS

Exhibit  
Number

10.24C	Second Amendment to Agreement dated September 15, 2008, between XOMA (US) LLC and National Institute of Allergy and Infectious Diseases (previously filed)
10.38	Royalty Purchase Agreement, dated as of August 12, 2010, by and among XOMA CDRA LLC, XOMA (US) LLC, XOMA Ltd., the buyer named therein (with certain confidential information omitted, which omitted information is the subject of a confidential treatment request and has been filed separately with the Securities and Exchange Commission) (previously filed)
31.1	Certification of Steven B. Engle, filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Fred Kurland, filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Steven B. Engle, furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Fred Kurland, furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.1	Press Release dated November 4, 2010, furnished herewith

SIGNATURES

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

XOMA Ltd.

Date: November 12, 2010

By:

/s/ STEVEN B. ENGLE  
Steven B. Engle  
Chairman, Chief Executive Officer and  
President  
(principal executive officer)

Date: November 12, 2010

By:

/s/ FRED KURLAND  
Fred Kurland  
Vice President, Finance and Chief Financial  
Officer  
(principal financial officer and chief  
accounting officer)