XOMA LTD /DE/ Form 10-K March 10, 2011

#### **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2010

OR

o 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)

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

Title of each class

Name of each exchange on which registered

Common Shares, U.S. \$0.0075 par value Preference Share Purchase Rights The NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No x

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 x 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes "No"

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large Accelerated Filer o Accelerated Filer x Non-Accelerated filer o Smaller 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 x

The aggregate market value of voting shares held by non-affiliates of the registrant is \$104,378,157 as of June 30, 2010

Number of Common Shares outstanding as of March 8, 2011: 29,510,963

#### DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Company's Proxy Statement for the Company's 2010 Annual General Meeting of Shareholders are		
incorporated by reference into Part III of this Report.		

## XOMA Ltd. 2010 FORM 10-K ANNUAL REPORT TABLE OF CONTENTS

-			
1)	Λ	D'I	, 1
_	៸᠆┪	пι	

Item 1.	<u>Business</u>	1
Item 1A.	Risk Factors	17
Item 1B.	<u>Unresolved Staff Comments</u>	33
Item 2.	<u>Properties</u>	33
Item 3.	Legal Proceedings	33
Item 4.	Reserved	34
	Supplementary Item: Executive Officers of the Registrant	34
PART II		
Item 5.	Market for Registrant's Common Equity, Related Shareholder Matters	
	and Issuer Purchases of Equity Securities	35
Item 6.	Selected Financial Data	36
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	38
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk	53
Item 8.	Financial Statements and Supplementary Data	53
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	53
Item 9A.	Controls and Procedures	54
Item 9B.	Other Information	55
PART III		
Item 10.	Directors, Executive Officers, and Corporate Governance	56
Item 11.	Executive Compensation	56
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters	56
Item 13.	Certain Relationships and Related Transactions, and Director	
rem 13.	Independence	56
Item 14.	Principal Accountant Fees and Services	56
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	57
<u>SIGNATURES</u>		58
INDEX TO FINANCIAL S	STATEMENTS	F-1
INDEA TO THINANCIAL S	11/11D/IID/IIO	1'-1
INDEX TO EXHIBITS		i

#### **Table of Contents**

#### PART I

Item 1. Business

Overview

XOMA Ltd. ("XOMA"), a Bermuda company, is a biopharmaceutical company focused on the discovery, development and manufacture of therapeutic antibodies designed to treat autoimmune, infectious, inflammatory and oncological diseases. Our proprietary development pipeline includes XOMA 052, an antibody that inhibits interleukin-1 beta ("IL-1 beta"), which is expected to advance into Phase 3 development for the treatment of Behcet's uveitis and is in Phase 2 clinical development for Type 2 diabetes with cardiovascular biomarkers; XOMA 3AB, a biodefense anti-botulism product candidate comprised of a combination, or cocktail, of antibodies; and preclinical antibody discovery programs in several indications, including autoimmune, cardio-metabolic, inflammatory, and oncological diseases. We have a fully integrated product development platform, extending from preclinical science and clinical development to scale-up development and manufacturing.

We have entered into a license and collaboration agreement with Les Laboratoires Servier ("Servier"), to jointly develop and commercialize XOMA 052 in multiple indications. XOMA 052 is designed to inhibit the pro-inflammatory cytokine IL-1 beta that is believed to be a primary trigger of pathologic inflammation in multiple diseases. Under the terms of the agreement, Servier has worldwide rights to diabetes and cardiovascular disease indications and rights outside the U.S. and Japan to Behcet's uveitis and other inflammatory disease and oncology indications. XOMA retains development and commercialization rights for Behcet's uveitis and other inflammatory disease and oncology indications in the U.S. and Japan, and has an option to reacquire rights to diabetes and cardiovascular disease indications from Servier in these territories. Should we exercise our option to reacquire rights to the diabetes and cardiovascular disease indications in the U.S. and Japan, we will be required to pay Servier an option fee and partially reimburse their incurred development expenses.

Our biodefense initiatives currently include a \$65 million multiple-year contract funded by the National Institute of Allergy and Infectious Diseases ("NIAID"), a part of the National Institutes of Health ("NIH"), to support our ongoing development of XOMA 3AB toward clinical trials in the treatment of botulism poisoning. XOMA also develops products with premier pharmaceutical companies including Novartis AG ("Novartis") and Takeda Pharmaceutical Company Limited ("Takeda").

We have a premier antibody discovery and development platform that incorporates a collection of antibody phage display libraries and proprietary Human Engineering<sup>TM</sup> ("HE<sup>TM</sup>"), affinity maturation, Bacterial Cell Expression ("BCE") and manufacturing technologies that enhance our ability and that of our collaboration partners to discover and develop new therapeutic antibodies. BCE is a key biotechnology for the discovery and manufacturing of antibodies and other proteins. To date, more than 50 pharmaceutical and biotechnology companies have signed BCE licenses, and a number of licensed product candidates are in clinical development. We continue to develop and commercialize additional antibody-related technologies including proprietary display technologies to enable antibody discovery and optimization. Our technologies have contributed to the success of the marketed antibody products LUCENTIS® (ranibizumab injection), for wet age-related macular degeneration and macular edema following retinal vein occlusion, and CIMZIA® (certolizumab pegol), for rheumatoid arthritis and Crohn's disease.

#### Strategy

We are advancing a pipeline of biologic products using our proven expertise, technologies and capabilities from antibody discovery through product development. We seek to expand our pipeline by developing proprietary products and technologies, providing contract services to government agencies responsible for biodefense and entering into

licensing and collaborative arrangements with pharmaceutical and biotechnology companies. The principal elements of our strategy are to:

•Focus on advancing XOMA 052, our lead product candidate. Using our proprietary antibody technologies, capabilities and expertise, we discovered XOMA 052, an antibody that inhibits IL-1 beta. XOMA 052 has the potential to address the underlying inflammatory causes of a wide range of unmet medical needs by targeting IL-1 beta, a cytokine that triggers inflammatory pathways in the body. In 2010, we completed a successful Phase 2 proof-of-concept trial of XOMA 052 in Behcet's uveitis and initiated two Phase 2 clinical trials in Type 2 diabetes patients and one Phase 2 trial in Type 1 diabetes patients.

In January of 2011, we announced interim results from three months' treatment with XOMA 052 or placebo in the 74 patient Phase 2a Type 2 diabetes trial, showing that XOMA 052 was well-tolerated and demonstrated evidence of biological activity. We expect to report top line, six month results from the Phase 2b Type 2 diabetes trial, in which 420 patients were enrolled, in the first quarter of 2011, and results from the full six months' treatment in the Phase 2a trial in the second quarter of 2011.

#### **Table of Contents**

In 2010, we also completed and announced positive results from an open-label pilot study of XOMA 052 in patients with uveitis of Behcet's disease who were suffering from vision-threatening exacerbations despite maximal doses of immunosuppressive medicines. XOMA 052 has been designated as an orphan drug for the treatment of Behcet's disease by the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA").

In December of 2010, we entered into an agreement with Servier to jointly develop and commercialize XOMA 052. This collaboration agreement substantially increases our cash resources while reducing future cash requirements, provides the funding to move XOMA 052 into Phase 3 development in 2011 in Behcet's uveitis, and supports further development in diabetes and cardiovascular diseases.

- •Continue building our biodefense business. To date, we have been awarded three contracts, totaling nearly \$100 million, from NIAID, to support our ongoing development of XOMA 3AB and additional product candidates toward clinical trials in the treatment of botulism poisoning. In addition, our biodefense programs include two subcontracts with SRI International totaling \$4.3 million, funded through NIAID, for the development of antibodies to neutralize H1N1 and H5N1 influenza viruses and the virus that causes severe acute respiratory syndrome ("SARS"). We will continue to seek further opportunities to work with government and other institutions.
- Advancing our proprietary preclinical pipeline candidates. We will continue to develop our proprietary preclinical pipeline, which includes candidates in development for autoimmune, cardio-metabolic, inflammatory, and oncological diseases.
- •Generate collaboration and licensing revenue. We have generated significant revenue from collaborations and licensing related to our proprietary technologies, including our phage display libraries, BCE, HE<sup>TM</sup>, and Targeted Affinity Enhancement ("TAE<sup>TM</sup>") technologies. Historically, we have established technology collaborations with several companies to provide access to multiple proprietary antibody discovery and optimization technologies. In addition, we have licensed our BCE technology to more than 50 companies in exchange for license, milestone and other fees, royalties and complementary technologies, and a number of licensed product candidates are in clinical development. We believe we can continue to generate significant revenue from our proprietary technologies in the future.

#### **Proprietary Products**

As part of our strategy, we are focusing our technology and resources on advancing our emerging proprietary pipeline. Below is a summary of our proprietary products:

•XOMA 052 is a potent monoclonal antibody with the potential to improve the treatment of patients with a wide variety of inflammatory diseases. XOMA 052 binds strongly to IL-1 beta, a pro-inflammatory cytokine involved in the development of Behcet's uveitis, Type 2 diabetes, cardiovascular disease, rheumatoid arthritis, gout and other diseases. By binding to IL-1 beta, XOMA 052 inhibits the activation of the IL-1 receptor, thereby preventing the cellular signaling events that produce inflammation. XOMA 052 is a humanized IgG2 antibody. Based on its binding properties, specificity for IL-1 beta and half-life in the body, XOMA 052 may provide convenient dosing of once per month or less frequently.

During 2010, we completed patient enrollment in the Phase 2a and Phase 2b clinical trials of XOMA 052 in Type 2 diabetes patients. The primary goal of the 74 patient Phase 2a trial was to gain additional XOMA 052 safety information in Type 2 diabetes patients on a background of stable metformin monotherapy. The patients were randomized at approximately a 3:1 ratio to receive three months of treatment with either XOMA 052 at a single dose level or placebo, respectively, after which patients in the XOMA 052 group received an additional three months of treatment at the same, a higher or a lower dose of XOMA 052. In January of 2011, we announced an interim review of

3-month data from the Phase 2a trial where XOMA 052 was shown to be well-tolerated with no significant differences in adverse events, lab abnormalities or vital signs between the XOMA 052 and placebo groups and no drug-related serious adverse events. At the time of this 3-month review, evidence of biological activity was observed including a reduction in C-reactive protein levels and a modest reduction in hemoglobin A1c ("HbA1c") levels. C-reactive protein is a biomarker of cardiovascular risk, and HbA1c is a measure indirectly reflecting blood glucose levels as averaged over a period estimated to be 90 to 120 days. Separately, we anticipate reporting top line, six month results from the Phase 2b trial by the end of the first quarter of 2011. The primary goal of the 420 patient Phase 2b trial was to further evaluate the use of multiple dose regimens on the safety, pharmacodynamics and efficacy of XOMA 052 in cardiometabolic and other diseases, and based on positive results to select doses for pivotal Phase 3 studies.

#### **Table of Contents**

Also during 2010, XOMA announced positive results from a Phase 2 proof-of-concept clinical trial evaluating XOMA 052 in Behcet's uveitis, a vision-threatening complication of Behcet's disease, demonstrating rapid improvement in vision-threatening disease exacerbations in all seven treated patients despite discontinuation of immunosuppressive drugs such as cyclosporine and/or azathioprine. Follow-up results demonstrated that each of the five patients re-treated with XOMA 052 after they experienced a new uveitis exacerbation responded again to XOMA 052 treatment and maintained their response for several months. The drug was well-tolerated in this trial, and no drug-related adverse events were reported.

In August of 2010, we obtained FDA orphan drug status for XOMA 052 for the treatment of Behcet's disease. The designation offers a number of potential incentives, which may include, among others, a seven-year period of U.S. marketing exclusivity from the date of marketing authorization, written guidance on the non-clinical and clinical studies needed to obtain marketing approval, and tax credits for certain clinical research. In October of 2010, XOMA 052 was granted orphan drug status for the treatment of Behcet's disease by the EMA. The designation generally provides EU market exclusivity for up to ten years following approval for the given indication. Other potential benefits include protocol assistance, direct access to centralized marketing authorization procedures and financial incentives.

•XOMA 3AB is a multi-antibody product designed to neutralize the most potent of the botulinum toxins, Type A, which causes paralysis and is a bioterrorism threat. Our anti-botulism program was recently expanded to include additional product candidates and is the first of its kind to combine multiple human antibodies to target a broad spectrum of the most toxic botulinum toxins, including the three most toxic serotypes of botulism, Types A, B and E. The antibodies are designed to bind to each toxin and enhance the clearance of the toxin from the body. The use of multiple antibodies increases the likelihood of clearing the harmful toxins by providing specific protection against each toxin type. In contrast to existing agents that treat botulism, XOMA uses advanced human monoclonal antibody technologies in an effort to achieve superior safety, potency and efficacy, and avoid life-threatening immune reactions associated with animal-derived products.

XOMA 3AB is currently in preclinical studies to assess safety through funding provided by NIAID. We have a history of successfully providing contract services to the U.S. government for the development of anti-botulinum neurotoxin antibodies.

• Preclinical Product Pipeline: We are pursuing additional opportunities to further broaden our preclinical product pipeline. These include internal discovery programs, product development collaborations with other pharmaceutical and biotechnology companies and evaluation of product in-licensing, in-kind product trades and acquisition opportunities.

### Partnership Products

Historically, XOMA has provided contract research and development services for world-class organizations, such as Novartis, Takeda, and Schering Plough Research Institute, a division of Schering Corporation, now a subsidiary of Merck & Co. (referred to herein as "Merck/Schering-Plough"), in pursuit of new antibody products. In more recent years, we have been evolving our business focus from a service provider model to a proprietary product development model. However, we will continue to capitalize on collaborative partnership arrangements as opportunities arise. Below is a list of activities in 2010 through such collaborations:

• Therapeutic Antibodies with Takeda: Since 2006, Takeda has been a collaboration partner for therapeutic monoclonal antibody discovery and development against multiple targets selected by them. In February of 2009, we expanded our existing collaboration to provide Takeda with access to multiple antibody technologies, including a suite of research and development technologies and integrated information and data management systems. In the

first quarter of 2010, we received a \$1.0 million payment from Takeda for achieving a pre-established, pre-clinical milestone under our collaboration agreement and may receive potential milestones and royalties on sales of antibody products in the future.

- •Therapeutic Antibodies with Novartis: In November of 2008, we restructured our product development collaboration with Novartis. Under the restructured agreement, Novartis received control over the two ongoing programs under the original product development collaboration entered into in 2004 with Novartis (then Chiron Corporation). In exchange, we recognized \$13.7 million in revenue in 2008 and may, in the future, receive milestones and double-digit royalty rates for the programs and options to develop or receive royalties from four additional programs.
- Therapeutic Antibodies with Merck/Schering-Plough: Merck/Schering-Plough has been a collaboration partner since 2006 for therapeutic monoclonal antibody discovery and development against multiple targets selected by them. In January of 2011, we successfully completed the services to Merck/Schering-Plough and the collaboration agreement in now complete.

#### **Table of Contents**

Technology Licenses and Royalties

**Technology Licenses** 

Below is a summary of certain proprietary technologies owned by us and available for licensing to other companies:

- •Antibody discovery technologies: XOMA uses human antibody phage display libraries in its discovery of therapeutic candidates, and we offer access to multiple libraries, including novel libraries developed internally, as part of our collaboration business. We believe that access to multiple libraries offers a number of benefits to XOMA and its collaboration partners, because it enables use of libraries best suited to the needs of a particular discovery project to increase the probability of technical and business success in finding rare and unique functional antibodies directed to targets of interest.
- Bacterial Cell Expression: The production or expression of antibodies using bacteria is an enabling technology for the discovery and selection, as well as the development and manufacture, of recombinant protein pharmaceuticals, including diagnostic and therapeutic antibodies for commercial purposes. Genetically engineered bacteria are used in the recombinant expression of target proteins for biopharmaceutical research and development. Reasons include the relative simplicity of gene expression in bacteria as well as many years of experience culturing such species as E. coli in laboratories and manufacturing facilities. XOMA scientists have developed bacterial expression technologies for producing antibodies and other recombinant protein products.

We have granted more than 50 licenses to biotechnology and pharmaceutical companies to use our patented and proprietary technologies relating to bacterial expression of recombinant pharmaceutical products. Bacterial antibody expression is also a key technology used in multiple systems for high-throughput screening of antibody domains. Expression of antibodies by phage display technology, for example, depends upon the expression and secretion of antibody domains from bacteria as properly folded, functional proteins.

Many licensees of our bacterial cell expression technology have developed, or are in the process of developing, antibodies for which we may be entitled to future milestone payments and royalties on product sales. Under the terms of our license agreement with Pfizer, Inc. ("Pfizer"), signed in 2007, we received an up-front cash payment of \$30 million and from 2008 through 2010 we received milestone payments relating to five undisclosed product candidates, including a payment of \$0.5 million for the initiation of a Phase 3 clinical trial. We may also be eligible for additional milestone payments aggregating up to \$6.4 million relating to these five product candidates and low single-digit royalties on future sales of all products subject to this license. In addition, we may receive potential milestone payments aggregating up to \$1.7 million for each additional qualifying product candidate. Our right to milestone payments expires on the later of the expiration of the last-to-expire licensed patent or the tenth anniversary of the effective date. Our right to royalties expires upon the expiration of the last-to-expire licensed patent.

Current licensees include but are not limited to the following companies:

Active Biotech AB	Centocor Ortho Biotech (now a member of Johnson & Johnson)	MorphoSys AG
Affimed Therapeutics AG	Crucell Holland B.V. (now a member of Johnson & Johnson)	Novartis AG

Affitech AS	Dompe, s.p.a.	Pfizer Inc.
Alexion Pharmaceuticals, Inc.	Dyax Corp.	Takeda Pharmaceutical Company Ltd.
Applied Molecular Evolution, Inc. (now a subsidiary of Eli Lilly and Company)	Eli Lilly and Company	The Medical Research Council
Avecia Limited	Genentech, Inc. (now a member of the Roche Group)	UCB S.A.
Aventis Pharma Deutschland GmbH (Hoechst) (now Sanofi-Aventis)	Invitrogen Corporation	Verenium Corporation
Bayer Healthcare AG	Merck & Co., Inc.	Wyeth Pharmaceuticals Division (now a member of Pfizer Inc.)
BioInvent International AB	Mitsubishi Tanabe Pharma Corporation	ZymoGenetics, Inc. (now a member of Bristol-Myers Squibb Company)

#### **Table of Contents**

These licenses are sometimes associated with broader agreements which may include expanded license rights, cell line development and process development.

- Human Engineering<sup>TM</sup>: HE<sup>TM</sup> is a proprietary technology that allows modification of non-human monoclonal antibodies to reduce or eliminate detectable immunogenicity and make them suitable for medical purposes in humans. The technology uses a unique method developed by us, based on analysis of the conserved structure-function relationships among antibodies. The method defines which residues in a non-human variable region are candidates to be modified. The result is a HE<sup>TM</sup> antibody with preserved antigen binding, structure and function, and with eliminated or greatly reduced immunogenicity. Human Engineering<sup>TM</sup> technology is used in development of XOMA 052 and certain other antibody products.
- Targeted Affinity Enhancement<sup>TM</sup>: TAE<sup>TM</sup> is a proprietary technology involving the assessment and guided substitution of amino acids in antibody variable regions, enabling efficient optimization of antibody binding affinity and selectivity modulation. TAE<sup>TM</sup> generates a comprehensive map of the effects of amino acid mutations likely to impact binding. The technology is utilized by XOMA scientists and has been licensed to a number of our collaborators.

We also have access to certain intellectual property rights and services that augment our existing integrated antibody technology platform and development capabilities and further compress product development timelines. This broad antibody technology platform and expertise is available for building our antibody product pipeline as well as those of our collaborators.

#### **Royalties**

In August of 2010, XOMA sold its royalty interest in CIMZIA® (certolizumab pegol) to an undisclosed buyer for gross proceeds of \$4.0 million. Prior to the sale, XOMA earned low single digit royalties on sales of CIMZIA® in the U.S. and Canada from UCB Celltech, a branch of UCB S.A. ("UCB"). Royalties earned from these sales were \$0.5 million in 2010, \$0.5 million in 2009 and \$0.1 million in 2008. CIMZIA®, an anti-tumor necrosis factor product, was approved by the FDA in April of 2008 for the treatment of moderate-to-severe Crohn's disease in adults who have not responded to conventional therapies. In addition, CIMZIA® was approved for the treatment of moderate-to-severe rheumatoid arthritis in adults by the FDA in May of 2009 and in Canada in September of 2009. UCB is responsible for the marketing and sales effort in support of this product. We will no longer receive royalties on sales of CIMZIA®.

### **Table of Contents**

### Proprietary Product Summary:

The following table describes important information related to the proprietary products we are currently developing:

Program XOMA 052	Description HE <sup>TM</sup> antibody to IL-1 beta	Indication Behcet's uveitis, Type diabetes, Type 1 diabetes and cardiovascular disease	Status  Thase 2 for Behcet's uveitis, Type 2 diabetes, Type 1 diabetes and cardiovascular disease	Developer Proprietary (in collaboration with Servier)
XOMA 3AB	Therapeutic antibodies to multiple botulinum neurotoxins	Botulism poisoning	Preclinical	Proprietary (NIAID-funded)
Multiple preclinical programs	Fully human monoclonal antibodies to undisclosed disease targets	Inflammatory, autoimmune, infectious and oncological diseases	Preclinical s	Proprietary

### Partnership Product Summary:

The following table describes important information related to certain products that we are currently developing or have developed in the past, for which we may earn royalties on product sales in the future:

Program	Description	Indication	Status	Developer
HCD 122 and LFA 102	2Fully human antibody to CD40 and other monoclonal antibodies to undisclosed disease targets	Hematologic tumors and other undisclosed diseases	Phase 1 and 2 and Phase 1	Novartis
Therapeutic antibodies	Fully human monoclonal antibodies to undisclosed disease targets	Undisclosed	Preclinical	Takeda (fully-funded)
Therapeutic antibodies	Fully human monoclonal antibodies to undisclosed disease targets	Non-small cell lung cancer	Phase 2	AVEO (fully-funded)

### **Licensed Product Summary:**

The following table describes important information related to certain products developed under licenses with us, for which we earn or may earn royalties on product sales in the future:

Program	Description	Indication	Status	Developer
Various products in	Various monoclonal	Undisclosed diseases	Various phases of	Pfizer
development by Pfizer	antibodies to		clinical and preclinical	
	undisclosed disease		development	
	targets			
	-	Undisclosed diseases		Various licensees

Various products in development by other licensees Various mone antibodies to undisclosed described by the development by other licensees various mone antibodies to undisclosed described by the development by other licensees various mone antibodies to undisclosed described by the development by other licensees various mone antibodies to undisclosed development by other licensees various mone antibodies to undisclosed development by other licensees various mone antibodies to undisclosed development by other licensees various mone antibodies to undisclosed development by other licensees various mone antibodies to undisclosed development by other licensees various mone antibodies to undisclosed development by other licensees various mone antibodies to undisclosed development by the licensees various mone antibodies to undisclosed development by the licensees various mone and the license various mone and the license

Various monoclonal antibodies to undisclosed disease targets Various phases of clinical and preclinical development

#### **Table of Contents**

Financial and Legal Arrangements of Product Collaborations, Licensing and Other Arrangements

Collaboration and Licensing Agreements

Servier

We have entered into a license and collaboration agreement with Servier, to jointly develop and commercialize XOMA 052 in multiple indications, which provides for a non-refundable upfront payment of \$15 million that was received by us in January of 2011. Under the terms of the agreement, Servier has worldwide rights to diabetes and cardiovascular disease indications and rights outside the U.S. and Japan to Behcet's uveitis and other inflammatory and oncology indications. XOMA retains development and commercialization rights for Behcet's uveitis and other inflammatory disease and oncology indications in the U.S. and Japan, and has an option to reacquire rights to diabetes and cardiovascular disease indications from Servier in these territories (the "Cardiometabolic Indications Option"). Should we exercise the Cardiometabolic Indications Option, we will be required to pay Servier an option fee and partially reimburse their incurred development expenses.

Under this agreement, Servier will fully fund activities to advance the global clinical development and future commercialization of XOMA 052 in diabetes and cardiovascular related diseases. Also, Servier will fund \$50 million of future XOMA 052 global clinical development and chemistry and manufacturing controls ("CMC") expenses and 50% of further expenses for the Behcet's uveitis indication. We will also be responsible for manufacturing XOMA 052 throughout clinical development and launch.

In addition, under the agreement, we are eligible to receive a combination of Euro- and US Dollar ("USD")-denominated, development and sales milestones for multiple indications aggregating to a potential maximum of approximately \$470 million when converted using the December 31, 2010 Euro to USD exchange rate (the "12/31/10 Exchange Rate"), if XOMA reacquires diabetes and cardiovascular rights in the U.S. and Japan. If XOMA does not reacquire these rights, then the milestone payments aggregate to a potential maximum of approximately \$770 million converted using the 12/31/10 Exchange Rate. Milestone payments for which XOMA will be eligible under the agreement include \$20 million upon initiation of the first Phase 3 clinical trial for XOMA 052 by Servier in its licensed territory in Type 2 diabetes. Servier's obligation to pay development and commercialization milestones will continue for so long as Servier is developing or selling products under the agreement.

We are also eligible to receive royalties on XOMA 052 sales, which are tiered based on sales levels and range from a mid-single digit to up to a mid-teens percentage rate. Our right to royalties with respect to a particular product and country will continue for so long as such product is sold in such country.

The collaboration will be carried out and managed by committees mutually established by the parties. In general, in the event of any disputes, each party will have decision-making authority over matters relating to its areas of responsibility and territory, but neither party will have unilateral decision-making rights if the decision would have a material adverse impact on the other party's rights in its territory. The agreement contains customary termination rights relating to matters such as material breach by either party, safety issues and patents. Servier also has a unilateral right to terminate the agreement on a country-by-country basis or in its entirety on 6 months' notice.

We have also entered into a loan agreement with Servier, which provides for an advance of up to €15 million, which converts to approximately \$20 million using the 12/31/10 Exchange Rate. The loan was fully funded in January of 2011. This loan is secured by an interest in our intellectual property rights to all XOMA 052 indications worldwide, excluding the U.S. and Japan territories. The loan has a final maturity date in 2016; however, after a specified period prior to final maturity, the loan is required to be repaid (i) at Servier's option, by applying up to a significant percentage of any milestone or royalty payments owed by Servier under our collaboration agreement and (ii) using a

significant percentage of any upfront, milestone or royalty payments we receive from any third party collaboration or development partner for rights to XOMA 052 in the U.S. and/or Japan. In addition, the loan becomes immediately due and payable upon certain customary events of default. Refer to Item 7: Management's Discussion and Analysis of Financial Condition and Results of Operations: Subsequent Events for further information regarding our loan agreement with Servier.

#### **NIAID**

In March of 2005, we were awarded a \$15 million competitive bid contract from NIAID to develop three anti-botulinum neurotoxin monoclonal antibodies. Under this contract, we created production cell lines using our proprietary antibody expression systems, built Master and Manufacturer's Working Cell Banks, developed production processes and produced initial quantities of the three antibodies. The contract was performed over an 18-month period and was fully funded with federal funds from NIAID under Contract No. HHSN266200500004C ("NIAID 1"). Final acceptance of the project was received in October of 2006.

#### **Table of Contents**

In July of 2006, we were awarded a \$16.3 million NIAID contract under Contract No. HHSN266200600008C/N01-Al-60008 ("NIAID 2") to produce monoclonal antibodies for the treatment of botulism to protect United States citizens against the harmful effects of botulinum neurotoxins used in bioterrorism. Under this contract, we created and produced XOMA 3A, an innovative injectable product comprised of three anti-type A botulinum neurotoxin monoclonal antibodies. This work was complete in the third quarter of 2010.

In September of 2008, we were awarded a third NIAID contract for \$65 million under Contract No. HHSN272200800028C ("NIAID 3") to continue development of our anti-botulinum antibody product candidates, including XOMA 3AB and additional product candidates. As part of the contract, we are developing, evaluating and producing the clinical supplies to support an IND filing with the FDA and conduct preclinical studies required to support human clinical trials.

#### SRI International

In the third quarter of 2009, we began work on two biodefense subcontract awards from SRI International, including a \$2.1 million award to develop novel antibody drugs against the virus that causes SARS and a \$2.2 million award to develop a novel antibody, known as F10, that has been shown to neutralize group 1 influenza A viruses, including the H1N1 and H5N1 strains. The subcontract awards are funded through NIAID.

#### Takeda

In November of 2006, we entered into a fully funded collaboration agreement with Takeda for therapeutic monoclonal antibody discovery and development under which we agreed to discover and optimize therapeutic antibodies against multiple targets selected by Takeda. Takeda agreed to make up-front, annual maintenance and milestone payments to us, fund our research and development and manufacturing activities for preclinical and early clinical studies and pay royalties on sales of products resulting from the collaboration. Takeda is responsible for clinical trials and commercialization of drugs after an IND submission and is granted the right to manufacture once a product enters into Phase 2 clinical trials. In the first quarter of 2010, a discovery and development program with Takeda under this collaboration was discontinued following the analysis of research data. The termination resulted in the recognition of the remaining unamortized balance in deferred revenue of \$1.1 million in the first quarter of 2010, as no continuing performance obligations exist. Separately, we received a \$1.0 million payment from Takeda for achieving a pre-established, preclinical milestone under the only currently active discovery and development program with Takeda. We recognized this milestone payment in revenue in the first quarter of 2010. We have completed a technology transfer and do not expect to perform any further contract research and development services under this program.

Under the terms of this agreement, we may receive milestone payments aggregating up to \$20.75 million relating to one undisclosed product candidate and low single-digit royalties on future sales of all products subject to this license. In addition, in the event Takeda were to develop additional future qualifying product candidates under the terms of our agreement, we would be eligible for milestone payments aggregating up to \$20.75 million for each such qualifying product candidate. Our right to milestone payments expires on the later of the receipt of payment from Takeda of the last amount to be paid under the agreement or the cessation of all research and development activities with respect to all program antibodies, collaboration targets and/or collaboration products. Our right to royalties expires on the later of 13.5 years from the first commercial sale of each royalty-bearing discovery product or the expiration of the last-to-expire licensed patent.

In February of 2009 we expanded our existing collaboration to provide Takeda with access to multiple antibody technologies, including a suite of research and development technologies and integrated information and data management systems. We may receive milestones of up to \$3.25 million per discovery product candidate and low

single-digit royalties on future sales of all antibody products subject to this license. Our right to milestone payments expires on the later of the receipt of payment from Takeda of the last amount to be paid under the agreement or the cessation of all research and development activities with respect to all program antibodies, collaboration targets and/or collaboration products. Our right to royalties expires on the later of 10 years from the first commercial sale of such royalty-bearing discovery product, or the expiration of the last-to-expire licensed patent.

#### **Novartis**

In November of 2008, we restructured our product development collaboration with Novartis, which involves six development programs including the HCD122 program. HCD122, which is a fully human anti-CD40 antagonist antibody, intended as a treatment for B-cell mediated diseases, including malignancies and autoimmune diseases, is currently recruiting patients for a Phase 1/2 lymphoma trial. The antibody has a dual mechanism of action that involves inhibition of CD40-ligand mediated growth and survival while recruiting immune effector cells to kill CD40-expressing tumor cells through a process known as antibody-dependent cellular cytotoxicity (ADCC). CD40, a member of the tumor necrosis factor, or TNF, family of antigens, is a cell surface antigen expressed in B-cell malignancies and involved in a broad variety of immune and inflammatory responses.

#### **Table of Contents**

Under the restructured agreement, Novartis made a payment to us of \$6.2 million in cash; reduced our existing debt by \$7.5 million; will fully fund all future research and development expenses; may pay potential milestones of up to \$14 million and royalty rates ranging from 10% to 20% for two ongoing product programs, HCD122 and LFA 102; and has provided us with options to develop or receive royalties on four additional programs. In exchange, Novartis has control over the HCD122 and LFA 102 programs, as well as the right to expand the development of these programs into additional indications outside of oncology. As part of the agreement, Novartis paid us for all project costs incurred after July 1, 2008. Our right to milestone payments expires at such time as no collaboration product or former collaboration product is being developed or commercialized anywhere in the world and no royalty-style payments on these products are due. Our right to royalty-style payments expires on the later of the expiration of any licensed patent covering each product or 20 years from the launch of each product that is produced from a cell line provided to Novartis by XOMA.

The collaboration between XOMA and Novartis (then Chiron Corporation) began in 2004 with the signing of an exclusive, worldwide, multi-product agreement to develop and commercialize multiple antibody products for the treatment of cancer. We shared expenses and revenue, generally on a 70-30 basis, with our share being 30 percent. Financial terms included initial payments to us in 2004 totaling \$10 million and a note agreement, secured by our interest in the collaboration, to fund up to 75 percent of our share of expenses beginning in 2005. The secured note agreement with Novartis, which was executed in May of 2005, is due and payable in full in June of 2015. At December 31, 2010, the outstanding principal balance under this note agreement totaled \$13.7 million and, pursuant to the terms of the arrangement as restructured in November of 2008, we will not make any additional borrowings on the Novartis note. In the first quarter of 2007, the mutual obligations of XOMA and Novartis to work together on an exclusive basis in oncology expired, except with respect to existing collaborative product development projects.

In December of 2008, we entered into a Manufacturing and Technology Transfer Agreement with Novartis, effective July 1, 2008. Under this agreement, XOMA was engaged by Novartis to perform research and development, process development, manufacturing and technology transfer activities with respect to the ongoing product programs now controlled by Novartis under the restructured product development collaboration. The work performed by XOMA under this agreement, which was fully funded by Novartis, was completed in the third quarter of 2009.

#### Arana

In September of 2009, we entered into an antibody discovery collaboration with Arana Therapeutics Limited ("Arana"), a wholly-owned subsidiary of Cephalon, Inc., involving multiple proprietary XOMA antibody research and development technologies, including a new antibody phage display library and a suite of integrated information and data management systems. Arana agreed to pay us a fee of \$6.0 million, of which we received \$4.0 million in the third quarter of 2009 and \$2.0 million in the third quarter of 2010. Also, we may be entitled to future milestone payments, aggregating up to \$3.0 million per product, and low single-digit royalties on product sales. Our right to milestone payments expires on the later of the receipt of payment from Arana of the last amount to be paid under the agreement, the cessation by Arana of the use of all research and development technologies or the cessation by Arana of the exercise of the patent rights granted to them. Our right to royalties expires five years from the first commercial sale of each royalty-bearing product.

#### Kaketsuken

In October of 2009, we entered into an antibody discovery collaboration with The Chemo-Sero-Therapeutic Research Institute, a Japanese research foundation known as Kaketsuken, involving multiple proprietary XOMA antibody research and development technologies, including a new antibody phage display library and a suite of integrated information and data management systems. Kaketsuken agreed to pay us a fee of \$8.0 million, of which we received \$6.0 million in the fourth quarter of 2009 and \$2.0 million in the fourth quarter of 2010. Also, we may be entitled to

future milestone payments, aggregating up to \$0.2 million per product, and low single-digit royalties on product sales. Our right to milestone payments expires upon the receipt of payment from Kaketsuken of the last amount to be paid pursuant to the agreement. Our right to royalties expires 15 years from the first commercial sale of each royalty-bearing product.

Merck/Schering-Plough/AVEO Pharmaceuticals, Inc. ("AVEO")

In April of 2006, we entered into an agreement with AVEO to utilize our HE<sup>TM</sup> technology to humanize AV-299, AVEO's novel anti-HGF antibody, under which AVEO paid us an up-front license fee and development milestones. In addition, we will receive royalties on sales of products resulting from the agreement. Under this agreement we created four Human Engineering<sup>TM</sup> versions of the original AV-299, all of which met design goals and from which AVEO selected one as its lead development candidate. In September of 2006, as a result of the successful humanization of AV-299, we entered into a second agreement with AVEO to manufacture and supply AV-299 in support of early clinical trials. Under the agreement, we created AV-299 production cell lines, conducted process and assay development, and performed Good Manufacturing Practices ("cGMP") manufacturing activities. AVEO retains all development and commercialization rights to AV-299 and may be required to pay XOMA annual maintenance fees, additional development milestone payments aggregating up to \$6.3 million and low single-digit royalties on product sales in the future. Our right to milestone payments expires upon full satisfaction of all financial obligations of AVEO pursuant to the agreement. Our right to royalties expires on the later of 15 years from the first commercial sale of each royalty-bearing product or the expiration of the last-to-expire licensed patent. In the third quarter of 2010, the Company received a \$0.8 million milestone payment related to AVEO's initiation of a Phase 2 clinical trial to evaluate AV-299 for the treatment of non-small cell lung cancer. The Company recognized this milestone payment as revenue in the third quarter of 2010.

#### **Table of Contents**

In April of 2007, Merck/Schering-Plough entered into a research, development and license agreement with AVEO concerning AV-299 and other anti-HGF molecules. In connection with the aforementioned license agreement, AVEO assigned its entire right, title and interest in, to and under its manufacturing agreement with XOMA to Merck/Schering-Plough. In the third quarter of 2010, AVEO regained its worldwide rights from Merck/Schering-Plough to develop and commercialize AV-299 and other anti-HGF molecules.

### Merck/Schering-Plough

In May of 2006, we entered into a fully funded collaboration agreement with Merck/Schering-Plough for therapeutic monoclonal antibody discovery and development. Under the agreement, Merck/Schering-Plough made up-front, annual maintenance and milestone payments to us, funded our research and development activities related to the agreement and would have paid royalties on sales of products resulting from the collaboration. During the collaboration, we discovered therapeutic antibodies against multiple targets selected by Merck/Schering-Plough using multiple human antibody phage display libraries, optimized antibodies through affinity maturation or other protein engineering, used our proprietary HE<sup>TM</sup> technology to humanize antibody candidates generated by hybridoma techniques, performed preclinical studies to support regulatory filings, developed cell lines and production processes and produced antibodies for initial clinical trials. Merck/Schering-Plough selected the first target at the inception of the agreement and, in December of 2006, exercised its right to initiate the additional discovery and development programs. In January of 2011, we successfully completed the services to Merck/Schering-Plough and the collaboration agreement in now complete.

#### **UCB**

Celltech Therapeutics Ltd., now UCB Celltech, a branch of UCB, utilized our bacterial cell expression technology under license in the development of CIMZIA® for the treatment of moderate-to-severe Crohn's disease in adults who have not responded to conventional therapies and for the treatment of moderate-to-severe rheumatoid arthritis in adults. The license provides for a low-single digit royalty on sales of CIMZIA® in countries where our bacterial cell expression technology is patented, which includes the U.S. and Canada, until the expiration of the last-to-expire licensed patent. In August of 2010, we sold our royalty interest in CIMZIA® to an undisclosed buyer for gross proceeds of \$4.0 million. We will no longer receive royalties on sales of CIMZIA®.

#### Genentech

In April of 1996, we entered into a collaboration agreement with Genentech, Inc., a wholly-owned member of the Roche Group (referred to herein as "Genentech") for the development of RAPTIVA®. In March of 2003, we entered into amended agreements which called for us to share in the development costs and called for Genentech to finance our share of development costs via a convertible subordinated loan. Under the loan agreement, upon FDA approval of the product, which occurred in October of 2003, we elected to pay \$29.6 million of the development loan in convertible preference shares, which are convertible into approximately 0.3 million common shares at a price of \$116.25 per common share.

In January of 2005, we restructured our arrangement with Genentech on RAPTIVA® under which we were entitled to receive mid-single digit royalties on worldwide sales of RAPTIVA® in all indications. The previous cost and profit sharing arrangement for RAPTIVA® in the U.S. was discontinued and Genentech was responsible for all operating and development costs associated with the product. In the first half of 2009, RAPTIVA® was withdrawn from the commercial drug markets and royalties ceased.

Genentech utilized our bacterial cell expression technology under license in the development of LUCENTIS® for the treatment of neovascular wet age-related macular degeneration. LUCENTIS® was approved by the FDA in June of

2006 and in the European Union in January of 2007. We were entitled to receive a low-single digit royalty on worldwide sales of LUCENTIS®. In the third quarter of 2009, we sold our LUCENTIS® royalty interest to Genentech for \$25 million, including royalty revenue from the second quarter of 2009. We will not receive any further royalties from sales of LUCENTIS®.

Financing Agreements

**Underwritten Offering** 

#### **Table of Contents**

In February of 2010, 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. As of December 31, 2010 all of these warrants were outstanding.

### Registered Direct Offerings

In May of 2009, we entered into a definitive agreement with an institutional investor to sell 784,313 units, with each unit consisting of one of our common shares and a warrant to purchase 0.50 of a common share, for gross proceeds of approximately \$10 million, before deducting placement agent fees and estimated offering expenses of \$0.8 million, in a registered direct offering. The investor purchased the units at a price of \$12.75 per unit. The warrants, which represent the right to acquire an aggregate of up to 392,157 common shares, were exercisable at any time on or after May 15, 2009 and prior to May 20, 2014 at an exercise price of \$15.30 per share. In February of 2010, the holders of these warrants agreed to amend the terms of their warrants to remove the provisions that would have required a reduction of the warrant exercise price and an increase in the number of shares issuable on exercise of the warrants each time we sold common shares at a price less than the exercise price of such warrants (the "Eliminated Adjustment Provisions") and the exercise price of these warrants was reduced from \$15.30 per share to \$0.015 per share. In the first quarter of 2010, the holders of these warrants exercised all warrants, acquiring 392,157 common shares for an aggregate exercise price of \$5,882.

In June of 2009, we entered into a definitive agreement with certain institutional investors to sell 695,652 units, with each unit consisting of one of our common shares and a warrant to purchase 0.50 of a common share, for gross proceeds of approximately \$12 million, before deducting placement agent fees and estimated offering expenses of \$0.8 million, in a second registered direct offering. The investor purchased the units at a price of \$17.25 per unit. The warrants, which represent the right to acquire an aggregate of up to 347,826 common shares, are exercisable at any time on or prior to December 10, 2014 at an exercise price of \$19.50 per share. In February of 2010, the holders of these warrants agreed to amend the terms of their warrants to remove the Eliminated Adjustment Provisions and we made a cash payment of \$4.5 million to these warrant holders, which was recorded in other income (expense). The exercise price of these warrants remained unchanged at \$19.50 per share. As of December 31, 2010 all of these warrants were outstanding.

#### **ATM Agreements**

In the third quarter of 2009, we entered into an At Market Issuance Sales Agreement (the "2009 ATM Agreement"), under which we could sell up to 1.7 million of our common shares from time to time through Wm Smith & Co. ("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. We paid Wm Smith a commission equal to 3% of the gross proceeds of all common shares sold through it as sales agent under the 2009 ATM Agreement but in no event less than \$0.02 per share. Shares sold under the 2009 ATM Agreement were sold pursuant to a prospectus which formed a part of our registration statement on Form S-3 (File No. 333-148342) (the "Existing Registration Statement") filed with the U.S. Securities and Exchange Commission (the "SEC") on December 26, 2007 and declared effective by the SEC on May 29, 2008. From the inception of the 2009 ATM Agreement through October of 2010, the Company sold a total of 1.7 million common shares through Wm Smith, constituting all of the shares available for sale under the agreement, for aggregate gross proceeds of \$12.2 million, including 1.4 million common shares sold in 2010 for aggregate gross proceeds of \$9.3 million. Total offering expenses related to these sales were \$0.4 million.

In the third quarter of 2010, we entered into an At Market Issuance Sales Agreement (the "2010 ATM 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 the Existing Registration Statement. 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. We will pay the Agents, collectively, a commission equal to 3% of the gross proceeds of the sales price of all common shares sold through them as sales agents under the 2010 ATM Agreement. From the inception of the 2010 ATM Agreement through December 31, 2010, we sold a total of 6.7 million common shares under this agreement for aggregate gross proceeds of \$29.7 million. Total offering expenses related to these sales were \$0.9 million. Subsequent to December 31, 2010 through March 8, 2011, we have sold an additional 796,898 common shares through the Agents pursuant to the 2010 ATM Agreement for aggregate gross proceeds of \$4.3 million. Total offering expenses related to these sales were \$0.1 million.

Equity Line of Credit

#### **Table of Contents**

In July of 2010, we entered into a common share purchase agreement (the "Purchase Agreement") with Azimuth Opportunity Ltd. ("Azimuth"), pursuant to which we obtained a committed equity line of credit facility (the "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. The Purchase Agreement provided that we could determine, in our sole discretion, the timing, dollar amount and floor price per share of each draw down under the Facility, subject to certain conditions and limitations and that the number and price of shares sold in each draw down were generally to be determined by a contractual formula designed to approximate fair market value, less a discount. The Purchase Agreement also provided that from time to time and in our sole discretion, we could grant Azimuth the right to exercise one or more options to purchase additional common shares during each draw down pricing period for the amount of shares based upon the maximum option dollar amount and the option threshold price specified by us. We also agreed to issue 111,111 common shares to Azimuth upon execution of the agreement relating to the Facility, in consideration of Azimuth's execution and delivery of that agreement. Shares under the Facility and the shares we agreed to issue to Azimuth upon execution of the agreement relating to the Facility were sold pursuant to a prospectus which forms a part of a registration statement declared effective by the SEC on May 29, 2008. In August of 2010, we sold a total of 3,421,407 common shares under the Facility for aggregate gross proceeds of \$14.2 million, representing the maximum number of shares that could be sold under the Facility. As a result, the Facility is no longer in effect, and no additional shares can be issued thereunder.

#### Research and Development

Our research and development expenses currently include costs of personnel, supplies, facilities and equipment, consultants, third party costs and other expenses related to preclinical and clinical testing. In 2010, our research and development expenses were \$77.4 million compared with \$58.1 million in 2009 and \$82.6 million in 2008.

Our research and development activities can be divided into those related to our internal projects and those related to collaborative and contract arrangements, which are reimbursed by our customers. In 2010, research and development expenses related to internal projects were \$58.1 million compared with \$42.2 million in 2009 and \$58.5 million in 2008. In 2010, research and development expenses related to collaborative and contract arrangements were \$19.3 million compared with \$15.9 million in 2009 and \$24.1 million in 2008. Refer to Item 7: Management's Discussion and Analysis of Financial Condition and Results of Operations- Research and Development Expenses for further information regarding our research and development expenses.

### Competition

The biotechnology and pharmaceutical industries are subject to continuous and substantial technological change. Competition in the areas of recombinant DNA-based and antibody-based technologies is intense and expected to increase as new technologies emerge and established biotechnology firms and large chemical and pharmaceutical companies continue to advance in the field. A number of these large pharmaceutical and chemical companies have enhanced their capabilities by entering into arrangements with or acquiring biotechnology companies or entering into business combinations with other large pharmaceutical companies. Many of these companies have significantly greater financial resources, larger research and development and marketing staffs and larger production facilities than ours. Moreover, certain of these companies have extensive experience in undertaking preclinical testing and human clinical trials. These factors may enable other companies to develop products and processes competitive with or superior to ours. 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. There can be no assurance that developments by others will not

render our products or technologies obsolete or uncompetitive.

Without limiting the foregoing, we are aware of the following competitors for the products and candidates shown in the table below. This table is not intended to be representative of all existing competitors in the market:

Product/Candidate	Competitors
XOMA 052	Biovitrum AB
	Eli Lilly and Company
	MedImmune
	Novartis AG
	Regeneron Pharmaceuticals,
	Inc.
XOMA 3AB	Cangene Corporation
	Emergent BioSolutions, Inc.

#### **Table of Contents**

#### Regulatory

Our products are subject to comprehensive preclinical and clinical testing requirements and to approval processes by the FDA and by similar authorities in other countries. Our products are primarily regulated on a product-by-product basis under the United States Food, Drug and Cosmetic Act and Section 351(a) of the Public Health Service Act. Most of our human therapeutic products are or will be classified as biologic products. Approval of a biologic for commercialization requires licensure of the product and the manufacturing facilities. The review of therapeutic biologic products is carried out by the FDA's Center for Drug Evaluation and Research, the body that also reviews drug products.

The FDA regulatory process is carried out in several phases. Prior to beginning human clinical testing of a proposed new biologic product, an IND is filed with the FDA. This document contains scientific information on the proposed product, including results of testing of the product in animal and laboratory models. Also included is information on manufacturing the product and studies on toxicity in animals and a clinical protocol outlining the initial investigation in humans.

The initial stage of clinical testing, Phase 1, ordinarily encompasses safety, pharmacokinetic and pharmacodynamic evaluations. Phase 2 testing encompasses investigation in specific disease states designed to provide preliminary efficacy data and additional information on safety. Phase 3 studies are designed to further establish clinical safety and efficacy and to provide information allowing proper labeling of the product following approval. Phase 3 studies are most commonly multi-center, randomized, placebo-controlled trials in which rigorous statistical methodology is applied to clinical results. Other designs may also be appropriate in specific circumstances.

Following completion of clinical trials, a BLA is submitted to the FDA to request marketing approval. Internal FDA committees are formed that evaluate the application, including scientific background information, animal and laboratory efficacy studies, toxicology, manufacturing facility and clinical data. During the review process, a dialogue between the FDA and the applicant is established in which FDA questions are raised and additional information is submitted. During the final stages of the approval process, the FDA generally requests presentation of clinical or other data before an FDA advisory committee, at which point, some or all of such data may become available. Also, during the later stages of review, the FDA conducts an inspection of the manufacturing facility to establish that the product is made in conformity with good manufacturing practice. If all outstanding issues are satisfactorily resolved and labeling established, the FDA issues a license for the product and for the manufacturing facility, thereby authorizing commercial distribution.

The FDA has substantial discretion in both the product approval process and the manufacturing approval process. It is not possible to predict at what point, or whether, the FDA will be satisfied with our submissions or whether the FDA will raise questions which may delay or preclude product approval or manufacturing facility approval. As additional clinical data is accumulated, it will be submitted to the FDA and may have a material impact on the FDA product approval process. Given that regulatory review is an interactive and continuous process, we have adopted a policy of limiting announcements and comments upon the specific details of the ongoing regulatory review of our products, subject to our obligations under the securities laws, until definitive action is taken. There can be no assurance any of the products we have under development will be developed successfully, obtain the requisite regulatory approval or be successfully manufactured or marketed.

In Europe, most of our human therapeutic products are or will be classified as biological medicinal products which are assessed through a centralized procedure by the EMA. The EMA coordinates the evaluation and supervision of medicinal products throughout the European Union and the European Economic Area. The assessment of the Marketing Authorization Application ("MA") is carried out by a Rapporteur and a Co-Rapporteur appointed by the Committee for Medicinal Products for Human Use ("CHMP"), which is the expert scientific committee of the EMEA.

The Rapporteur and Co-Rapporteur are drawn from the CHMP membership representing member states of the European Union. In addition to their responsibility for undertaking scientific assessments of an application for a MA, the Rapporteur and the Co-Rapporteur liaise with the applicant on behalf of the CHMP in an effort to provide answers to queries raised by the CHMP. Their assessment report(s) is circulated to and considered by the full CHMP membership, leading to the production ultimately of a CHMP opinion which is transmitted to the applicant and the European Commission. The final decision on the grant of a MA is made by the European Commission as the licensing authority of the European Community ("Community"). Under Community law, a positive decision issued by the European Commission represents the grant of a MA. Such an authorization allows a medicinal product to be placed on the European market. Upon the grant of an MA in the European Union, certain member states require pricing approval before the product can be placed into commercial distribution.

#### **Table of Contents**

Under Community law, the applicant may request grant of a MA under exceptional circumstances if comprehensive data on the efficacy and safety of the drug, under normal conditions of use cannot be provided because its intended indications are encountered so rarely (such as in the case of a medicinal product intended for treating an orphan disease) that comprehensive evidence cannot reasonably be collected, the present state of scientific knowledge will not allow comprehensive information to be collected, or it would be against generally accepted medical ethics to collect comprehensive information. The Rapporteur, Co-Rapporteur and the other CHMP members will assess the justification/data submitted for exceptional circumstances as part of the overall assessment of the benefit/risk of the application. It is up to the CHMP, during the review, to ultimately decide on whether grant of a MA under exceptional circumstances is justified on the evidence before them. Approval under exceptional circumstances is subject to a requirement for specific procedures related to safety and results of its use and is reviewed annually to reassess the risk-benefit balance of the product. Once approval is granted, the product can be marketed under the single European MA in all member states of the European Union and the European Economic Area. Consistent with the single MA, the labeling for Europe is identical throughout all member states except that all labeling must be translated into the local language of the country of intended importation and in relation to the content of the so called "blue box" on the outer packaging in which locally required information may be inserted.

Orphan drugs are those intended for use in rare diseases or conditions. As a result of the high cost of development and the low return on investment for rare diseases, governments provide regulatory and commercial incentives for the development of drugs for small disease populations. In the United States, the term "rare disease or condition" means any disease or condition which affects less than 200,000 persons in the United States. Applications for United States orphan drug status are evaluated and granted by the Office of Orphan Products Development ("OOPD") of the FDA. In the United States, orphan drugs are subject to the standard regulatory process for marketing approval but are exempt from the payment of user fees for licensure, receive market exclusivity for a period of seven years and some tax benefits, and are eligible for OOPD grants. In Europe, orphan medicinal products are those intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the Community. The EMA's Committee for Orphan Medicinal Products ("COMP") reviews applications seeking orphan designation. If the European Commission agrees with a positive assessment made by COMP, then the product will receive a positive designation through adoption of a decision by the European Commission. Orphan medicinal products are exempt from fees for protocol assistance and scientific advice from the Scientific Advice Working Party during development, reduction or exemption of MA and other fees, and ten-year market exclusivity upon granting of a MA in respect of the approved clinical indication. Moreover, manufacturers may be eligible for grants or other financial incentives from the Community and Member States programs.

#### Patents and Trade Secrets

Patent and trade secret protection is important to our business and our future will depend in part on our ability to obtain patents, maintain trade secret protection and operate without infringing on the proprietary rights of others. As a result of our ongoing activities, we hold and have filed applications for a number of patents in the United States and internationally to protect our products and important processes. We also have obtained or have the right to obtain exclusive licenses to certain patents and applications filed by others. However, the patent position of biotechnology companies generally is highly uncertain and no consistent policy regarding the breadth of allowed claims has emerged from the actions of the U.S. Patent and Trademark Office ("Patent Office") with respect to biotechnology patents. Accordingly, no assurance can be given that our patents will afford protection against competitors with similar technologies, or others will not obtain patents claiming aspects similar to those covered by our patent applications.

We have issued patents in the U.S. and Europe for XOMA 052. U.S. Patent Nos. 7,531,166 and 7,582,742 cover XOMA 052 and other antibodies and antibody fragments with similar binding properties for IL-1 beta, as well as nucleic acids, expression vectors and production cell lines for the manufacture of such antibodies and antibody fragments. The patents provide exclusivity in the U.S. into 2027 and 2026, respectively. In addition, in April of 2010,

the U.S. Patent and Trademark Office issued U.S. Patent No. 7,695,718 covering methods of treating Type 2 diabetes with high affinity antibodies and antibody fragments that bind to IL-1 beta, including XOMA 052, and Patent No. 7,695,717 covering methods of treating IL-1 related inflammatory diseases, including rheumatoid arthritis and osteoarthritis, with XOMA 052 and other antibodies and antibody fragments with similar binding properties for human interleukin-1 beta (IL-1 beta). These patents provide coverage into 2027 and 2026, respectively. Further, in November of 2010, the U.S. Patent and Trademark Office issued U.S. Patent No. 7,829,093 relating to methods of treating diabetes mellitus Type 1 with XOMA 052 or other IL-1 beta antibodies having similar binding properties, and U.S. Patent No. 7,829,094 relating to methods of treating a cancer with XOMA 052 or other IL-1beta antibodies having similar binding properties, with the cancer being selected from multiple myeloma, acute myelogenous leukemia and chronic myelogenous leukemia. These patents provide coverage to 2026. Additionally, U.S. Patents Nos. 7,744,865 and 7,744,866 were issued June 29, 2010, covering additional IL-1 beta antibodies and antibody fragments into 2026. Also, the European Patent Office granted a patent for XOMA 052, as well as nucleic acids, expression vectors and production cell lines for the manufacture of XOMA 052. The patent provides exclusivity in Europe into 2026.

We have established a portfolio of patents related to our bacterial expression technology, including claims to novel promoter sequences, secretion signal sequences, compositions, methods for expression and secretion of recombinant proteins from bacteria, including immunoglobulin gene products, and improved methods and cells for expression of recombinant protein products. U.S. Patent Nos. 5,576,195 and 5,846,818 are related to DNA encoding a pectate lyase signal sequence, recombinant vectors, host cells and methods for production and externalization of recombinant proteins. U.S. Patent Nos. 5,595,898, 5,698,435 and 5,618,920 address secretable immunoglobulin chains, DNA encoding the chains and methods for their recombinant production. U.S. Patent Nos. 5,693,493, 5,698,417 and 6,204,023 relate to methods for recombinant production/secretion of functional immunoglobulin molecules. U.S. Patent Nos. 7,094,579 and 7,396,661 relate to eukaryotic signal sequences and their use in methods for prokaryotic expression of recombinant proteins. U.S. Patent No. 6,803,210 relates to improved bacterial host cells that are deficient in one or more of the active transport systems for an inducer of an inducible promoter, such as arabinose for an araB promoter, and methods for the use of such cells for the production of recombinant proteins. Most of the more important European patents in this portfolio expired in July of 2008 or earlier.

#### **Table of Contents**

We have also established a portfolio of patent applications related to our mammalian expression technology, including U.S. Patent No. 7,192,737, related to methods for increasing the expression of recombinant polypeptides using expression vectors containing multiple copies of a transcription unit encoding a polypeptide of interest.

We have established a portfolio of patents and applications related to our Human Engineering<sup>TM</sup> technology, including U.S. Patent No. 5,766,886, directed to methods of modifying antibody variable domains to reduce immunogenicity. Related patents and applications are directed to antibodies engineered according to our patented methods. We believe that our patented Human Engineering<sup>TM</sup> technology provides an attractive alternative to other humanization technologies.

If certain patents issued to others are upheld or if certain patent applications filed by others issue and are upheld, we may require certain licenses from others in order to develop and commercialize certain potential products incorporating our technology. There can be no assurance that such licenses, if required, will be available on acceptable terms.

Where appropriate, we also rely on trade secrets to protect aspects of our technology. However, trade secrets are difficult to protect. We protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants and collaborators. These parties may breach these agreements, and we may not have adequate remedies for any breach. Our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that we or our consultants or collaborators use intellectual property owned by others, we may have disputes with our collaborators or consultants or other third parties as to the rights in related or resulting know-how and inventions.

#### **International Operations**

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.

A number of risks are inherent in international operations. Foreign regulatory agencies often establish standards different from those in the United States. An inability to obtain foreign regulatory approvals on a timely basis could have an adverse effect on our international business, financial condition and results of operations. International operations may be limited or disrupted by the imposition of government controls, export license requirements, political or economic instability, trade restrictions, changes in tariffs, restrictions on repatriating profits, taxation or difficulties in staffing and managing international operations. In addition, our business, financial condition and results of operations may be adversely affected by fluctuations in currency exchange rates. There can be no assurance that we will be able to successfully operate in any foreign market.

Financial information regarding the geographic areas in which we operate is included in Note 13 to the Financial Statements: Concentration of Risk, Segment and Geographic Information.

#### Concentration of Risk

In 2010, NIAID, UCB, and Takeda each accounted for more than 10% of our total revenue, none of which represents a related party to XOMA. These key customers accounted for 87% of our total revenue in 2010 and NIAID was responsible for 23% of the accounts receivable balance at December 31, 2010. Servier accounted for an additional 72% of the accounts receivable balance at December 31, 2010. The loss of one or more of these customers could have a material adverse effect on our business and financial condition.

In 2009, Takeda and Genentech each accounted for more than 10% of our total revenue, none of which represents a related party to XOMA. These key customers accounted for 65% of our total revenue in 2009, but were not responsible for any of the accounts receivable balance at December 31, 2009. NIAID, Arana, and Kaketsuken accounted for 90% of the accounts receivable balance at December 31, 2009. In 2008, Genentech, Novartis, and Merck/Schering-Plough each provided more than 10% of our total revenue, none of which represent a related party to XOMA.

Organization

#### **Table of Contents**

We were incorporated in Delaware in 1981 and became a Bermuda company effective December 31, 1998, when we completed a shareholder-approved corporate reorganization, changing our legal domicile from Delaware to Bermuda and our name to XOMA Ltd. When referring to a time or period before December 31, 1998, or when the context so requires, the terms "Company" and "XOMA" refer to XOMA Corporation, a Delaware corporation and the predecessor of XOMA Ltd.

#### **Employees**

As of March 8, 2011, we employed approximately 230 full-time employees, none of which are unionized, at our facilities, principally in Berkeley, California. Our employees are primarily engaged in clinical, process development, research and product development, and in executive, business development, finance and administrative positions. We consider our employee relations to be excellent.

#### **Available Information**

For information on XOMA's investment prospects and risks, please contact Investor Relations and Corporate Communications at (510) 204-7200 or by sending an e-mail message to investorrelations@xoma.com. Our principal executive offices are located at 2910 Seventh Street, Berkeley, California 94710, U.S.A. Our telephone number is (510) 204-7200.

The following information can be found on our website at http://www.xoma.com or can be obtained free of charge by contacting our Investor Relations Department:

- •Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports will be available as soon as reasonably practicable after such material is electronically filed with the United States Securities and Exchange Commission ("SEC"). All reports we file with the SEC can also be obtained free of charge via EDGAR through the SEC's website at http://www.sec.gov.
- •Our policies related to corporate governance, including our Code of Ethics applying to our directors, officers and employees (including our principal executive officer and principal financial and accounting officer) that we have adopted to meet the requirements set forth in the rules and regulations of the SEC and its corporate governance principles are available.
- The charters of the Audit, Compensation and Nominating & Governance Committees of our Board of Directors are available.

We intend to satisfy the applicable disclosure requirements regarding amendments to, or waivers from, provisions of our Code of Ethics by posting such information on our website.

#### **Table of Contents**

Item 1A. Risk Factors

The following risk factors and other information included in this annual 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 operations.

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. In September of 2009, we sold our royalty interest in LUCENTIS® to Genentech, Inc., a wholly-owned member of the Roche Group (referred to herein as "Genentech") for gross proceeds of \$25 million, including royalty revenue from the second quarter of 2009. These proceeds, along with other funds, were used to fully repay our loan from Goldman Sachs Specialty Lending Holdings, Inc. ("Goldman Sachs"). As a result, we no longer have a royalty interest in LUCENTIS®. In 2008, we received \$8.8 million of revenue from this royalty interest. In August of 2010, we sold our royalty interest in CIMZIA® to an undisclosed buyer for gross proceeds of \$4.0 million, including royalty revenue from the second quarter of 2010. As a result, we no longer have a royalty interest in CIMZIA®. We received revenue from this royalty interest of \$0.5 million in 2010, \$0.5 million in 2009 and \$0.1 million in 2008.

Based on our cash reserves and anticipated spending levels, revenue from collaborations including our XOMA 052 collaboration agreement with Les Laboratoires Servier ("Servier"), biodefense contracts and licensing transactions 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 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 December 31, 2010, we have received the full amount of proceeds from money market fund investments, an inability to retrieve funds from money market fund investments as they mature in the future could have a material and adverse impact on our business, results of operations and cash flows.

#### **Table of Contents**

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 December 31, 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 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 December 31, 2010, we had an accumulated deficit of \$853.3 million.

For the year ended December 31, 2010, we had a net loss of approximately \$68.8 million or \$3.69 per common share (basic and diluted). For the year ended December 31, 2009, we had net income of approximately \$0.6 million or \$0.05 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 March 8, 2011, 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 28,491,318 were issued and outstanding as of December 31, 2010 and 29,510,963 were issued and outstanding as of March 8, 2011. If we issue additional equity securities, the price of our common shares may be materially and adversely affected.

In the third quarter of 2009, we had entered into an At Market Issuance Sales Agreement (the "2009 ATM Agreement"), with Wm Smith & Co. ("Wm Smith"), under which we could sell up to 1.7 million of our common shares from time to time through Wm Smith, as the 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 October 27, 2010, we sold a total of 1,666,666 common shares through Wm Smith, constituting all of the shares available for sale under the agreement, for aggregate gross proceeds of \$12.2 million.

On February 5, 2010, 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 an At Market Issuance Sales Agreement (the "2010 ATM 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 (the "SEC") on December 26, 2007 and declared effective by the SEC on May 29, 2008. 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. From the inception of the 2010 ATM Agreement through December 31, 2010, we sold a total of 6.7 million common shares under this agreement for aggregate gross proceeds of \$29.7 million. Subsequent to December 31, 2010 through March 8, 2011, we have sold an additional 796,898 common shares through Wm Smith for aggregate gross proceeds of \$4.3 million.

#### **Table of Contents**

On February 4, 2011, we entered into an At Market Issuance Sales Agreement (the "2011 ATM Agreement"), with McNicoll, Lewis & Vlak LLC ("MLV"), under which we may sell common shares from time to time through the MLV, as our agent 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. 333-172197) filed with the SEC on February 11, 2011, once such registration statement has been declared effective by the SEC. MLV 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. MLV 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 March 8, 2011, our share price has ranged from a high of \$12.60 to a low of \$2.24. 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,

#### **Table of Contents**

- announcements regarding other participants in the biotechnology and pharmaceutical industries, and
  - market speculation regarding any of the foregoing.

If we are unable to continue meet the requirements for continued listing on The NASDAQ Global Market, then we may be de-listed. In March of 2010, we received a Staff Determination letter from The NASDAQ Stock Market LLC ("NASDAQ") indicating that we had not regained compliance with the minimum \$1.00 per share requirement for continued inclusion on The NASDAQ Global Market, pursuant to NASDAQ Listing Rule 5450(a)(1). On August 18, 2010, we effected a reverse split of our common shares in order to regain compliance.

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, Food and Drug Administration ("FDA") officials or officials from foreign regulatory authorities could interpret the data in different ways than we or our development partners do which could delay, limit or prevent regulatory approval.

#### **Table of Contents**

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 development 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 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.

#### **Table of Contents**

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 other 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.

#### **Table of Contents**

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 EMA 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 and LFA 102 programs. In exchange for cash and debt reduction on our existing loan facility with Novartis, Novartis has control over the HCD122 and LFA 102 programs, as well as the right to expand the development of these programs into additional indications outside of oncology.
- 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.
- •In December of 2010, we entered into a license and collaboration agreement with Servier, to jointly develop and commercialize XOMA 052 in multiple indications. Under the terms of the agreement, Servier has worldwide rights to diabetes and cardiovascular disease indications and rights outside the U.S. and Japan to Behcet's uveitis and other inflammatory and oncology indications. XOMA retains development and commercialization rights for Behcet's uveitis and other inflammatory disease and oncology indications in the U.S. and Japan, and has an option to reacquire rights to diabetes and cardiovascular disease indications from Servier in these territories. Should we exercise this option, we will be required to pay Servier an option fee and partially reimburse their incurred development expenses. The agreement contains customary termination rights relating to matters such as material breach by either party, safety issues and patents. Servier also has a unilateral right to terminate the agreement on a country-by-country basis or in its entirety on 6 months' notice.
- •In December of 2010, we also entered into a loan agreement with Servier, which provides for an advance of up to €15 million and was fully funded in January of 2011. This loan is secured by an interest in our intellectual property rights to all XOMA 052 indications worldwide, excluding the U.S. and Japan territories. The loan has a final maturity date in 2016; however, after a specified period prior to final maturity, the loan is required to be repaid (i) at Servier's option, by applying up to a significant percentage of any milestone or royalty payments owed by Servier under our collaboration agreement and (ii) using a significant percentage of any upfront, milestone or royalty payments we receive from any third party collaboration or development partner for rights to XOMA 052 in the U.S. and/or Japan. In addition, the loan becomes immediately due and payable upon certain customary events of default.

### **Table of Contents**

• 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 December 31, 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, and different criteria for, 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 we, our collaborators or licensees will successfully develop and market any of the products that are or may become the subject of any of our collaboration or licensing arrangements. In some cases these arrangements provide for funding solely by our collaborators or licensees, and in other cases, such as our arrangement with Servier, all of the funding for certain projects and a significant portion of the funding for other projects is to be provided by our collaborator or licensee. In addition, third party arrangements such as ours also increase uncertainties in the related decision-making processes and resulting progress under the arrangements, as we and our collaborators or licensees may reach different conclusions, or support different paths forward, based on the same information, particularly when large amounts of technical data are involved. 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 Aphton Corporation ("Aphton") for the treatment of gastrointestinal and other gastrin-sensitive cancers using anti-gastrin monoclonal antibodies. In January of 2006, Aphton announced that its common stock had been delisted from NASDAQ. In May of 2006, Aphton 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,

### **Table of Contents**

- 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.

#### **XOMA 052**

We, in collaboration with Servier, are conducting clinical testing of XOMA 052, a potent anti-inflammatory monoclonal antibody targeting IL-1 beta, in Behcet's uveitis patients, Type 2 diabetes patients and cardiovascular 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 January of 2011, Novartis announced that it had filed for EMA approval of Ilaris® for the treatment and prevention of 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 March 2011, Regeneron disclosed that it intends to file a supplemental BLA for ARCALYST® for the prevention and treatment of gout.

• 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. In January of 2011, MedImmune, the worldwide biologics unit for AstraZeneca PLC, announced that Amgen granted it rights to develop AMG 108 worldwide except Japan.

#### **Table of Contents**

•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

We are also developing XOMA 3AB, a combination, or cocktail, of antibodies designed to neutralize the most potent of botulinum toxins. Other companies are developing other products targeting botulism poisoning and these products may prove more effective than XOMA 3AB. We are aware that:

- 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, which if significant could lead to an impairment on our long-lived assets or restructuring activities. 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 biotech 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:

#### **Table of Contents**

•	imposition of	government	controls
•	IIIIDOSIUOII OI	2010111111011	commons.

- 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 collaboration and development 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.

#### **Table of Contents**

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. Assuming the new law survives recent calls for its repeal, the reforms imposed by the new law would 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.

#### **Table of Contents**

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 fifty-eight. 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 in connection with these matters, 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 parties have fully briefed the Plaintiff's Motion to Remand and are awaiting a final ruling from the Court. The petition asserts personal injury claims against Genentech, us, 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 in connection with this matter, 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 January 7, 2011, a complaint was filed in the United States District Court for the Northern District of Texas in a case captioned Massa v. Genentech, Inc., et al., No. 4:11CV70. The Complaint alleges the same claims against Genentech, us and others and seeks the same types of damages as the complaints filed in the Superior Court of Alameda County, California referenced above. Even though Genentech has agreed to indemnify us in connection with this matter, 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; Fred Kurland, our Vice President, Finance and Chief Financial Officer; Patrick J. Scannon, M.D., Ph.D., our Executive Vice President and Chief Medical Officer; and Christopher J. Margolin, our Vice President, General Counsel and Secretary. We currently have no key person insurance on any of our employees.

A U.S. holder of our common shares or 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 U.S. holder's holding period.

#### **Table of Contents**

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 2010 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 2011 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 2011 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 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 p