XOMA LTD /DE/
Form 10-K
March 11, 2009
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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, 2008

OR

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

For the transition period from to

Commission File No. 0-14710

XOMA Ltd.

(Exact name of registrant as specified in its charter)

Bermuda	**52-2154066**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2910 Seventh Street, Berkeley, California 94710	**(510) 204-7200**
(Address of principal executive offices, including zip code)	**(Telephone Number)**

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

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

Common Shares, U.S. $0.0005 par value

Preference Share Purchase Rights

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ 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 ¨ 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 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. x

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 ¨ Accelerated Filer x Non-Accelerated filer ¨ Smaller reporting company ¨

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 $223,028,144 as of June 30, 2008

Number of Common Shares outstanding as of March 6, 2009: 142,244,227

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Company s Proxy Statement for the Company s 2009 Annual General Meeting of Shareholders are incorporated by reference into Part III of this Report.

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XOMA Ltd.

2008 FORM 10-K ANNUAL REPORT

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PART I

Item 1. Business

Overview

XOMA Ltd. (XOMA or the Company), a Bermuda company, is a leading biopharmaceutical company focused on the discovery, development and manufacture of therapeutic antibodies and other agents designed to treat inflammatory, autoimmune, infectious and oncological diseases. XOMA uses its expertise, technologies and capabilities to build a product pipeline that includes multiple proprietary and collaborative development programs. The Company s lead product candidate is XOMA 052, a potent monoclonal antibody with the potential to improve the treatment of patients with a wide variety of diseases in which inflammation is either the cause or plays a significant role.

XOMA has multiple revenue streams and generates revenues from product royalties, technology licenses, development collaborations and biodefense contracts. The Company receives royalties on three approved products, RAPTIVA®, which is marketed globally for the treatment of chronic moderate-to-severe plaque psoriasis, LUCENTIS®, which is marketed globally for the treatment of neovascular (wet) age-related macular degeneration, and CIMZIA®, which is approved in the U.S. and Switzerland for the treatment of Crohn s disease. XOMA has established on-going technology licensing programs for certain of its proprietary technologies, which have attracted numerous significant licensees including Pfizer Inc. (Pfizer). The Company s development collaborations include arrangements with Takeda Pharmaceutical Company Limited (Takeda), Schering-Plough Research Institute (SPRI) and Novartis AG (Novartis). XOMA s biodefense initiatives currently include a $65 million multiple-year contract with the National Institute of Allergy and Infectious Diseases (NIAID) to support XOMA s ongoing development of drug candidates toward clinical trials in the treatment of botulism poisoning.

The Company has a premier antibody discovery and development platform that includes six commercial antibody phage display libraries and XOMA s proprietary Human Engineering and bacterial cell expression technologies. Our Human Engineering technology was used in development of XOMA 052 and certain other antibody products. Bacterial cell expression technology is a key biotechnology for the discovery and manufacture of antibodies and other proteins. Thus far, more than 50 pharmaceutical and biotechnology companies have signed bacterial cell expression licenses with XOMA.

Strategy

We are advancing a pipeline of biotherapeutic 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, collaborating with pharmaceutical and biotechnology companies and providing contract services to government agencies responsible for biodefense. We fund a portion of our development activities through multiple revenue streams, including product royalties, technology licenses, collaborations and biodefense contracts. The principal elements of our strategy are to:

Focus on advancing our proprietary pipeline, including XOMA 052, our lead product candidate. Using our proprietary antibody technologies, capabilities and expertise, we discovered XOMA 052, a potent monoclonal antibody that targets the pro-inflammatory cytokine, Interleukin-1 beta (IL-1 beta). XOMA 052 is designed to reduce inflammation as an underlying cause of diabetes by targeting IL-1 beta, which triggers inflammatory pathways in the body. We believe XOMA 052 has the potential to treat many diseases in which inflammation is either the cause or plays a significant role. Because many of these diseases represent unmet medical needs, this potential increases the product s likelihood of successful development. In 2007, we began Phase 1 clinical studies of XOMA 052 in patients with Type 2 diabetes. We have been approached by several companies offering to collaborate on our testing and development of XOMA 052 for the treatment of diabetes and will seek to enter into such a collaboration by the end of 2009. We are also evaluating XOMA 052 for the treatment of rheumatoid arthritis in a Phase 2a clinical trial initiated in the first quarter of 2009. Additionally, we also plan to continue advancing our internal drug discovery efforts with multiple preclinical programs to generate new product candidates.

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*Increase licensing revenues from existing and future proprietary technologies***.** We have a history of generating significant revenue from our proprietary technologies, including our bacterial cell expression technology, which we have licensed to more than 50 companies in exchange for license, milestone and other fees, royalties and complementary technologies. We believe that we can continue to generate significant revenue from our bacterial cell expression and other proprietary technologies in the future.

Prioritize application of available resources. In response to current economic conditions, we have reviewed our research and development priorities in light of the positive interim XOMA 052 clinical study results discussed below and the need to establish a sustainable level of research and development investment. We have decided to focus our resources on XOMA 052 and curtail spending on certain other product candidates in our proprietary pipeline, including XOMA 629, which is a topical anti-bacterial formulation of a peptide derived from bactericidal/permeability-increasing protein (BPI), a key part of the protective human immune system. XOMA was developing XOMA 629 as a possible treatment for superficial skin infections, including impetigo and the eradication of staphylococcus aureus, including methicillin-resistant staphylococcus aureus (MRSA), but has curtailed all spending on XOMA 629 in response to current economic conditions.

In January of 2009, XOMA announced a workforce reduction of approximately 42 percent, or 144 employees, a majority of which were employed in manufacturing and related support functions. This decision was made based on the challenging economic conditions and a decline in forecasted contract manufacturing demand in 2009. We expect an annualized reduction of approximately $27 million in cash expenditures when changes are completed in the second quarter of 2009. Upon completion of the workforce reduction on March 17, 2009, we expect to have approximately 200 employees to develop XOMA 052, develop and license proprietary products and technology, and continue fully funded antibody discovery and development activities in collaboration with our pharmaceutical partners and under biodefense contracts with the U.S. government. We will maintain our pilot scale manufacturing plant. XOMA expects to record a charge in the first quarter of 2009 of approximately $3 million for severance and other costs related to the workforce reduction.

Proprietary Products

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

XOMA 052 is a potent Human Engineering 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 that is involved in the development of diabetes, rheumatoid arthritis and other diseases. By binding IL-1 beta, the drug inhibits the activation of the IL-1 receptor, thereby preventing the cellular signaling events that produce inflammation. XOMA 052 is a humanized IgG2 antibody with a half-life of 22 days. Based on its binding properties, specificity to IL-1 beta and half-life, XOMA 052 may provide convenient dosing of once per month or longer.

We are currently conducting two Phase 1 clinical trials in Type 2 diabetes patients, one in the U.S. and one in Europe. In September of 2008, we announced interim data from the Phase 1 clinical trials which indicate support for a novel anti-inflammatory approach to Type 2 diabetes treatment that may preserve insulin-producing cells. Although these Phase 1 studies were designed to test drug safety and pharmacokinetics, rather than efficacy, we believe these studies are important additions to other published medical research indicating that decreasing inflammation may reduce disease progression in diabetes. We plan to advance our Phase 1 clinical testing of XOMA 052 in Type 2 diabetes and initiate a major Phase 2 Type 2 diabetes study in the third quarter of 2009.

In addition to our Phase 1 clinical trials in Type 2 diabetes patients, we initiated a Phase 2a pharmacokinetic study of XOMA 052 in rheumatoid arthritis in the first quarter of 2009. Depending on resources and timing, we may initiate additional small XOMA 052 proof-of-concept trials in other indications in 2009.

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XOMA 3AB is an antibody drug candidate designed for the treatment of botulism poisoning, a potentially deadly muscle paralyzing disease. Our anti-botulism program 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 botulinum drugs, 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 antibodies. We have a history of successfully providing contract services to the U.S. government for the development of anti-botulinum neurotoxin antibodies. In September of 2008, we were awarded a $65 million multiple-year contract funded with federal funds from NIAID, a part of the National Institutes of Health (Contract No. HHSN272200800028C), to support ongoing development of drug candidates for the treatment of botulism poisoning. This contract is the third that NIAID has awarded us for the development of botulinum antitoxins and brings the program s total awards to nearly $100 million.

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 evaluations of product in-licensing, in-kind product trades and acquisition opportunities.

Partnership Products

XOMA partners with world-class organizations in research and development of new antibody products. Below is a list of current activities through such collaborations:

Therapeutic Antibodies with Novartis: Novartis is a global pharmaceutical company which reported net sales of $41.5 billion in 2008. In December of 2008, we entered into a Manufacturing and Technology Transfer Agreement with Novartis, effective July 1, 2008. Under this agreement, XOMA has been 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.

Therapeutic Antibodies with SPRI: SPRI is part of the Schering-Plough Corporation, a global pharmaceutical company which reported net sales of $18.5 billion in 2008. SPRI has been a partner since 2006 for therapeutic monoclonal antibody discovery and development against multiple targets selected by them, and we are currently conducting multiple discovery programs through this partnership.

Therapeutic Antibodies with Takeda: Takeda is a global pharmaceutical company which reported net sales of approximately $13.9 billion for its fiscal year ended March of 2008. Since 2006, Takeda has been a partner for therapeutic monoclonal antibody discovery and development against multiple targets selected by them. In September of 2008, we initiated new therapeutic antibody programs under our existing antibody discovery and development collaboration with Takeda. The new programs add to the multiple discovery and development programs already being advanced through the collaboration. In addition, 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. As part of the expanded collaboration, we received a $29.0 million expansion fee, before taxes and other costs, and we may receive potential milestones and royalties on sales of antibody products in the future.

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Royalties and Technology Licenses

Royalties

XOMA earns mid- and low-single digit royalties on the following three marketed antibody products:

RAPTIVA® (efalizumab) with Genentech, Inc. (Genentech): RAPTIVA® is a humanized therapeutic monoclonal antibody developed to treat immune system disorders. RAPTIVA® is the first biologic therapy designed to provide long-term control of chronic moderate-to-severe plaque psoriasis and can be self-administered by patients as a single, once-weekly subcutaneous injection. RAPTIVA® was approved by the U.S. Food and Drug Administration (FDA) in October of 2003 and in the European Union in September of 2004, where it is marketed by Merck Serono S.A. (Merck Serono , formerly Serono S.A.). According to Genentech, United States sales of RAPTIVA® during 2008 were $108 million, compared with $107 million and $90 million during 2007 and 2006, respectively. According to Merck Serono, sales of RAPTIVA® outside of the U.S. during 2008 were approximately $134 million, compared with $106 million and $70 million during 2007 and 2006, respectively. In 2008, we earned royalties of $12.2 million from worldwide sales of RAPTIVA®, compared with $10.6 million and $8.2 million during 2007 and 2006, respectively.

In October of 2008, the FDA announced that it had approved labeling changes, including a Boxed Warning, to highlight the risks of life-threatening infections, including progressive multifocal leukoencephalopathy (PML), with the use of RAPTIVA®. In November of 2008, Genentech announced that it had issued a Dear Healthcare Provider letter to inform dermatologists and neurologists of a second case of PML which resulted in the death of a 73-year old patient who had received RAPTIVA® for approximately four years. In February of 2009, the European Medicines Agency (EMEA) announced that it has recommended suspension of the marketing authorization of RAPTIVA® in the European Union and that its Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of RAPTIVA® no longer outweigh its risks and EMD Serono Inc., the company that markets RAPTIVA® in Canada (EMD Serono), announced that, in consultation with Health Canada, the Canadian health authority (Health Canada), it will suspend marketing of RAPTIVA® in Canada. Also in February of 2009, the FDA issued a public health advisory concerning three confirmed reports, and one possible report, of PML in patients using RAPTIVA®. Genentech has stated that it is working with the FDA to determine appropriate next steps, which may include significant restrictions in the use of, or suspension or withdrawal of regulatory approval for, RAPTIVA®.

LUCENTIS® (ranibizumab injection) by Genentech: LUCENTIS® is an antibody fragment against Vascular Endothelial Growth Factor for the treatment of neovascular (wet) age-related macular degeneration, which causes central vision loss in the elderly, brought on by deterioration of the macula, a collection of specialized cells located on the retina. LUCENTIS® was approved by the FDA in June of 2006 and in the European Union in January of 2007, where it is distributed by Novartis. It is the first marketed therapeutic product manufactured under a license using our bacterial cell expression technology. According to Genentech, U.S. sales of LUCENTIS® were $875 million during 2008 compared with $815 million and $380 million during 2007 and 2006, respectively. According to Novartis, sales of LUCENTIS® outside the United States were $886 million in 2008 compared with $393 million and $27 million during 2007 and 2006, respectively. In 2008, we earned royalties of $8.8 million from worldwide sales of LUCENTIS®, compared with $6.0 million and $2.0 million during 2007 and 2006, respectively.

In January of 2009, Novartis announced that LUCENTIS® was approved in Japan for the treatment of neovascular (wet) age-related macular degeneration.

CIMZIA® (certolizumab pegol) by UCB Celltech, a branch of UCB S.A. (UCB): CIMZIA® is an anti-TNF (Tumor Necrosis Factor) alpha antibody fragment. CIMZIA® was approved by the FDA in April of 2008 and in Switzerland in September of 2007 for the treatment of moderate-to-severe Crohn s disease in adults who have not responded to conventional therapies. UCB is responsible for the

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marketing and sales effort in support of this product in the U.S. and Switzerland. According to UCB, worldwide sales of CIMZIA® were approximately $13 million during 2008. Royalties earned in 2008 from sales of CIMZIA® were immaterial.

In January of 2009, UCB announced that the FDA had issued a Complete Response Letter relating to the Biologics License Application (BLA) of CIMZIA® for the treatment of rheumatoid arthritis. As a prerequisite for approval of CIMZIA®, UCB announced in February of 2009 that the FDA requires further analysis of existing data and a new safety update and that no additional studies are needed to fulfill the FDA s request. UCB is working with the FDA to fulfill its request and anticipates a full response will be submitted in the second quarter of 2009.

Technology Licenses

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

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. In support of our own biopharmaceutical development efforts, XOMA scientists have developed bacterial expression technologies for producing antibodies and other recombinant protein products.

We have granted over 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.

Under the terms of our license agreement with Pfizer, signed in 2007, we received an up-front, non-dilutive cash payment of $30.0 million and, in 2008, we received two milestone payments relating to two different products, including a payment of $0.5 million for the initiation of a Phase 3 clinical trial. We are also eligible for additional milestone, royalty and other fees on future sales of all products subject to this license.

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

Affimed Therapeutics AG	Crucell Holland B.V.	Novartis AG
Affitech AS	Dompe, s.p.a.	Pfizer, Inc.
Alexion Pharmaceuticals, Inc.	Dyax Corp.	Schering-Plough Corporation
Applied Molecular Evolution, Inc. (AME)	E.I. duPont de Nemours and Company	Takeda Pharmaceutical Company Ltd.
Avecia Limited	Eli Lilly and Company	The Medical Research Council
Aventis Pharma Deutschland GmbH (Hoechst)	Genentech, Inc.	UCB S.A.
Bayer Healthcare AG	Genzyme Corporation	Unilever plc
BioInvent International AB	Invitrogen Corporation	Verenium Corporation
Biosite Incorporated	Merck & Co., Inc.	Wyeth Pharmaceuticals Division
Centocor, Inc.	MorphoSys AG	ZymoGenetics, Inc.

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

Human Engineering. Human Engineering 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 Human Engineering antibody with preserved antigen binding, structure and function, and with eliminated or greatly reduced immunogenicity. Human Engineering technology was used in development of XOMA 052 and certain other antibody products.

Antibody discovery technologies. XOMA uses six commercial human antibody phage display libraries in its discovery of therapeutic candidates, and we offer access to numerous libraries as part of our collaboration business. We believe that access to multiple libraries offers a number of benefits to XOMA and its 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.

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.

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Proprietary Product Summary:

The following table describes important information related to certain products on which we may earn royalties or that we are currently developing:

Program	Description	Indication	Status	Collaborator/Developer
XOMA 052	HE antibody to IL-1ß	Type 2 diabetes, rheumatoid arthritis, systemic juvenile idiopathic arthritis, and gout	Phase 1 for T2D Phase 1 for RA	Proprietary
XOMA 3AB	Therapeutic antibodies to multiple botulinum neurotoxins	Botulism poisoning	Preclinical	Proprietary (NIAID-funded)
Multiple Therapeutic Antibodies	Fully human monoclonal antibodies to undisclosed disease targets	Undisclosed	Preclinical	Takeda (fully funded)
Multiple Therapeutic Antibodies	Fully human monoclonal antibodies to undisclosed disease targets	Undisclosed	Preclinical	Schering-Plough Research Institute (fully funded)
HCD 122 and other Therapeutic Antibodies	Fully human antibody to CD40 and other monoclonal antibodies to undisclosed disease targets	B-cell cancers and other undisclosed diseases	Phase 1 and Preclinical	Novartis (fully funded)
RAPTIVA®	Humanized anti-CD11a monoclonal antibody	Moderate-to-severe plaque psoriasis	Marketed in U.S. and elsewhere, XOMA earns royalties	Genentech (marketed product)
LUCENTIS®	Humanized antibody fragment against Vascular Endothelial Growth Factor	Neovascular (wet) age-related macular degeneration	Marketed in U.S., Europe and elsewhere, XOMA earns royalties	Genentech (marketed product)
CIMZIA®	Anti-TNF alpha antibody fragment	Crohn s disease and rhematoid arthritis	Marketed in U.S. and Switzerland for Crohn s disease, XOMA earns royalties	UCB (marketed product)

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Product Available for Out-Licensing

In an effort to focus our resources on our XOMA 052 program, we have designated XOMA 629 as available for out-licensing. XOMA 629 is a topical anti-bacterial formulation of a peptide derived from BPI, a key part of the protective human immune system. XOMA was developing XOMA 629 as a possible treatment for superficial skin infections, including impetigo and the eradication of staphylococcus aureus, including MRSA.

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

Current Agreements

Genentech

In April of 1996, we entered into a collaboration agreement with 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 to receive a 25% share of future U.S. operating profits and losses and a royalty on sales outside the U.S. The amended agreements also called for Genentech to finance our share of development costs up until first FDA marketing approval via a convertible subordinated loan, and our share of pre-launch marketing and sales costs via an additional commercial loan facility. 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 3.8 million common shares at a price of $7.75 per common share. The commercial loan was repaid in cash in two installments in 2004.

In January of 2005, we announced a restructuring of our arrangement with Genentech on RAPTIVA®. Under the restructured arrangement, we are 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 is responsible for all operating and development costs associated with the product. In addition, the outstanding balance on our development loan was extinguished.

In December of 1998, we licensed our bacterial cell expression technology to Genentech, which utilized it 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, the European Union in January of 2007 and Japan in January of 2009. We are entitled to receive a low-single digit royalty on worldwide sales of LUCENTIS®.

UCB

In December of 1998, we licensed our bacterial cell expression technology to Celltech Therapeutics Ltd., now UCB Celltech, a branch of UCB, which utilized it 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 rheumatoid arthritis. CIMZIA® was approved by the FDA in April of 2008 and in Switzerland in September of 2007 for the treatment of Crohn s disease. The FDA is currently considering UCB s application to market CIMZIA® for the treatment of rheumatoid arthritis. We are entitled to receive a low-single digit royalty on worldwide sales of CIMZIA®.

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 in Phase 1 and Phase 2 clinical trials in several indications. The investigational drug is in a Phase 1b-2a clinical trial for the treatment of lymphoma and a Phase 1 clinical trial for the treatment of multiple myeloma. 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.

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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 $14.0 million and double-digit royalty rates for two ongoing product programs, including HCD122; and has provided us with options to develop or receive royalties on four additional programs. In exchange, Novartis has control over the HCD122 program and the additional ongoing program, as well as the right to expand the development of these programs into additional indications outside of oncology. As part of the agreement, Novartis has paid us for all project costs incurred after July 1, 2008.

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 revenues, generally on a 70-30 basis, with our share being 30 percent. Financial terms included initial payments to us in 2004 totaling $10.0 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. 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 has been 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 is fully funded by Novartis.

Schering-Plough

In May of 2006, we entered into a fully funded collaboration agreement with the SPRI division of Schering-Plough Corporation for therapeutic monoclonal antibody discovery and development. Under the agreement, SPRI will make up-front, annual maintenance and milestone payments to us, fund our research and development activities related to the agreement and pay royalties on sales of products resulting from the collaboration. During the collaboration, we will discover therapeutic antibodies against multiple targets selected by SPRI using multiple human antibody phage display libraries, may optimize antibodies through affinity maturation or other protein engineering, may use our proprietary Human Engineering technology to humanize antibody candidates generated by hybridoma techniques, perform preclinical studies to support regulatory filings, develop cell lines and production processes and produce antibodies for initial clinical trials. SPRI 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.

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

In April of 2006, we entered into an agreement with AVEO to utilize our Human Engineering 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 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 is responsible to pay XOMA annual maintenance fees, additional development milestones and royalties if certain targets are met.

In April of 2007, Schering-Plough Corporation, acting through its SPRI division, 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 has assigned its entire right, title and interest in, to and under its manufacturing agreement with XOMA to SPRI.

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Takeda

In November of 2006, we entered into a fully funded collaboration agreement with Takeda for therapeutic monoclonal antibody discovery and development. Under the agreement, we will discover and optimize therapeutic antibodies against multiple targets selected by Takeda. Takeda will 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 will be responsible for clinical trials and commercialization of drugs after an Investigational New Drug (IND) submission and is granted the right to manufacture once a product enters into Phase 2 clinical trials.

In September of 2008, we initiated new therapeutic antibody programs under our existing collaboration with Takeda. The new programs add to the multiple discovery and development programs already being advanced through the collaboration.

In addition, 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 received a $29.0 million expansion fee, of which $23.2 million was received in cash in February of 2009 and the remainder was witheld for payment to the Japanese taxing authority. In addition, we expect to pay approximately $1.5 million of additional expenses to Takeda related to the agreement. We may receive potential milestones and royalties on sales of antibody products in the future.

NIAID

In March of 2005, we were awarded a $15.0 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 100% funded with federal funds from NIAID under Contract No. HHSN266200500004C. Final acceptance of the project was received in October of 2006.

In July of 2006, we were awarded a $16.3 million contract funded with federal funds from NIAID under Contract No. HHSN266200600008C/N01-Al-60008 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 have created and produced an innovative injectable product comprised of three anti-type A botulinum neurotoxin monoclonal antibodies to support entry into Phase 1 safety human clinical trials. The work is being performed on a cost plus fixed fee basis, per the terms of the contract, over a three-year period.

In September of 2008, we were awarded a third contract for $65 million funded with federal funds from NIAID under Contract No. HHSN272200800028C to continue development of our anti-botulinum antibody product candidates, including XOMA 3AB and additional product candidates. As part of the new contract, we will develop, evaluate and produce the clinical supplies to support an IND filing with the FDA and conduct preclinical studies required to support human clinical trials.

Recently Terminated Agreements

Lexicon

In November of 2008, we terminated our collaboration agreement with Lexicon Pharmaceuticals, Inc. (Lexicon), which was entered into in June of 2005 to jointly develop and commercialize antibody drugs for certain targets discovered by Lexicon. The collaboration was designed to combine Lexicon s target discovery and biotherapeutics capabilities with our antibody generation, process development and manufacturing expertise to accelerate the development and commercialization of novel therapeutic antibodies.

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Incyte

In July of 2008, our license agreement with Incyte Corporation (Incyte) expired including the remaining 125,000 warrants held by Incyte to purchase our common shares at $6.00 per share. This agreement was entered into in July of 1998 whereby we obtained an exclusive (even as to Incyte), freely sublicenseable, worldwide license to all of Incyte s patent rights relating to BPI. In exchange, we agreed to pay Incyte a royalty on sales of BPI products covered by the license, up to a maximum of $11.5 million and we made a $1.5 million advance royalty payment, one-half in cash and one-half in our common shares.

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 2008, our research and development expenses were $82.6 million compared with $66.2 million in 2007 and $52.1 million in 2006.

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 2008, research and development expenses related to internal projects were $58.5 million compared with $45.8 million in 2007 and $32.0 million in 2006. In 2008, research and development expenses related to collaborative and contract arrangements were $24.1 million compared with $20.4 million in 2007 and $20.1 million in 2006. Refer to *Item 7: 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.

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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	Amgen, Inc. Novartis AG Biovitrum AB Regeneron Pharmaceuticals, Inc.
XOMA 3AB	Cangene Corporation Emergent BioSolutions, Inc.
RAPTIVA®	Amgen, Inc. with Wyeth Pharmaceuticals Abbott Laboratories Johnson & Johnson Astellas Pharma US, Inc.
LUCENTIS®	Pfizer, Inc. with OSI Pharmaceuticals, Inc. Novartis AG with QLT Inc.
CIMZIA®	Johnson & Johnson Abbott Laboratories

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

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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 EMEA. The EMEA 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 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.

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.

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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 EMEA 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 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 No. 5,028,530 directed to expression vehicles containing an araB promoter, host cells and processes for regulated expression of recombinant proteins expired in July of 2008. 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.

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 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 technology provides an attractive alternative to other humanization technologies.

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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 1 to the Financial Statements: Segment and Geographic Information*.

Concentration of Risk

In 2008, Genentech, Novartis and SPRI each provided more than 10% of our total revenues, none of which represent a related party to XOMA. These key customers accounted for 81% of our total revenues in 2008 and represented 64% of the accounts receivable balance at December 31, 2008. NIAID accounted for an additional 28% of the accounts receivable balance at December 31, 2008. The loss of one or more of these customers could have a material adverse effect on our business and financial condition.

In 2007, Pfizer, Genentech, SPRI and NIAID each provided more than 10% of our total revenues, none of which represent a related party to XOMA. These key customers accounted for approximately 99% of our accounts receivable balance at December 31, 2007. In 2006, Genentech and NIAID each provided more than 10% of our total revenues. These key customers accounted for approximately 39% of the accounts receivable balance at December 31, 2006. SPRI accounted for an additional 45% of the accounts receivable balance at December 31, 2006.

Organization

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.

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Employees