

GENENTECH INC
Form DEFA14A
November 17, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934

Filed by the Registrant

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Check the appropriate box:

Preliminary Proxy Statement

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Definitive Proxy Statement

Definitive Additional Materials

Soliciting Material Pursuant to §240.14a-12

Genentech, Inc.

(Name of Registrant as Specified in its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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#1

Genentech: An Overview

Genentech: An Overview

Patrick Yang, Executive Vice President

Manufacturing, Genentech

November 17, 2006

#2

Meeting Agenda

Introduction to Genentech

Pat Yang

Manufacturing

Next steps

Pat Yang

Q&A

All

#3

Manufacturing
Manufacturing

Genentech is a world leader in biotech manufacturing, with more FDA-approved manufacturing capacity for the production of biotech medicines than any other company

Four facilities: South San Francisco, CA; Vacaville, CA and Oceanside, CA and Porriño, Spain

We believe we have the right plans in place to meet the growing demand for our products:

Oceanside facility purchased from Biogen Idec in 2005

Option to purchase facility in Singapore

Working with Lonza, Wyeth and Novartis

Process yield improvements for Rituxan and Avastin

New capacity coming online for bulk and filling/packaging

#4

Q4 '06, announced Lonza will acquire our 40,000 liter facility in Porriño, Spain; Lonza will continue production of Avastin for Genentech for 3 years

We anticipate closing the transaction before the end of 2006
Porriño, Spain

(Lonza Biologics)
Status
Enhancement Project
Facility

Anticipate construction, qualification and
licensure of our new plant in Vacaville,
California in 2H '09 (additional 200,000 liters)
Vacaville, CA
CCP2
Genentech Bulk
Manufacturing
Oceanside, CA
NIMO

Anticipate
FDA licensure to produce
commercial Avastin in 1H '07 (90,000 liters)
Contract
Manufacturing
Wyeth BioPharma
Andover,
MA

Received
FDA licensure to produce Herceptin
Q3 '06
Process
Improvements
Rituxan

Anticipate
approval of higher titer Rituxan
process in Vacaville by the end of 2006
(+50%)
Avastin

Anticipate
approval of higher titer Avastin
process in South San Francisco by the end of
2006 (+50%)
Near-term Key Capacity Enhancement
Projects
Near-term Key Capacity Enhancement
Projects
As of November 9, 2006

#5
Novartis
Pharmaceuticals
Huningue, France

Began manufacturing all future worldwide
supply of Xolair
Wyeth BioPhmara
Andover, MA

Received FDA licensure to produce

Herceptin
Lonza Biologics
Porrino, Spain

Announced Lonza will acquire our 40,000 liter facility in Porriño, Spain; facility will continue production of Avastin for 3 years
Lonza Biologics
Singapore

Entered into long-term supply agreement with Lonza to manufacture Genentech products at their 80,000-liter facility in Singapore; We have an exclusive option to purchase the Singapore facility in the future
2006 Key Contract Manufacturing Accomplishments
2006 Key Contract Manufacturing Accomplishments

Our strategies include expanding or acquiring facilities and engaging contract manufacturers that produce Genentech's products on our behalf
As of November 9, 2006

#6

Completed qualification runs of Avastin at Oceanside

Expect FDA licensure to produce Avastin 1H 07

Purchased state-of-the-art finish/fill facility in Hillsboro, Oregon

Expect facility to be licensed and operational in 2010

Expect FDA approval of high titer processes for Rituxan (in Vacaville) and Avastin (in SSF)

Signed two new product supply agreements with Roche

Other 2006 Manufacturing Accomplishments

Other 2006 Manufacturing Accomplishments

As of November 9, 2006

#7

Genentech's Oceanside Facilities

Genentech's Oceanside Facilities

Manufacturing Facility

Manufacturing Facility

NIMO

Commercial Facility

NICO

Clinical Facility

Purchased

Purchased

June 2005

February 2006

Potential Capacity

Potential Capacity

90,000 liters

5,500 liters

of Employees

of Employees

Approximately 530 employees as
of September 30, 2006

Plan to employ approximately 30
employees by the end of 2006

Status

Status

Q3 '06 completed qualification
runs
of Avastin

Expect FDA licensure
to produce
Avastin
in 1H '07

Expect to be operational by
Q1 '07
QuickTime and a
MPEG-4 Video decompressor
are needed to see this picture.

#8

-

Potential to purchase Lonza Singapore Facility

610,000 Liters

Option

to

Purchase

from

2007

-

2010

Q4 06 Genentech obtained an exclusive option to purchase the Lonza Singapore facility during the period from 2007 to 2012

Licensure to produce Avastin is expected in 2010

80,000 liters

Lonza Singapore Facility

Q4 06,
announced

Lonza

will

acquire

our

40,000

liter

facility

in

Porriño,

Spain;

Lonza

will

continue

production

of

Avastin

for

Genentech for 3 years.

We anticipate closing the transaction before the end of 2006.

Lonza Biologics, Porriño, Spain

Comments

Other

Comments

Potential Capacity

Genentech Bulk Manufacturing Facility

240,000 Liters

Current Total Capacity in Use

-

Potential addition of Vacaville, CA

530,000 Liters

Potential Capacity in 1H 09

-

Potential addition of Oceanside, CA

330,000 Liters

Potential Capacity in 1H 07

Comments

Contract Manufacturing (Bulk)

Expect FDA licensure in 2H 09

200,000 (8x25,000L)

Vacaville, CA (CCP2)

In July 2006, Roche signed two new product supply agreements which supplement and supersede existing product supply agreements.

Roche
has
agreed
to
purchase
specified
amounts
of
Herceptin,
Avastin
and
Rituxan
through
2008
and
to
purchase
specified
amounts
of
Herceptin
and
Avastin
through
2012.

Previously, Roche had assumed most of their own ex-US Herceptin supply and was planning on assuming all their ex-US Avastin supply.

Genentech has and will continue to supply all of Roche's ex-U.S. Rituxan supply.
Roche, Penzberg, Germany

Received FDA licensure in Q1 '06 to produce bulk substance Xolair (will produce all future worldwide supply). As of
Genentech
will
acquire
bulk
supply
of
Xolair
from
Novartis
and
compensate
them
on
a
cost
plus
mark
up
basis.

Novartis Pharmaceuticals, Huningue, France

Received

FDA

licensure

in

Q3 06

to

produce

Herceptin;

expect

Wyeth

to

produce

25%

of

Herceptin

over

the

next

several

years.

Genentech

will

produce

the

remainder

in

Vacaville.

Wyeth BioPharma, Andover, MA

Received FDA licensure in Q3 05 to produce Rituxan; expect Lonza to produce ~50% of Rituxan over the next se

Genentech will produce the remainder in our other facilities.

Q3 06 we completed qualification runs of Avastin

Expect

FDA

licensure

to

produce

Avastin

in

1H 07

First licensed in 2000. Licensed to produce Avastin, Herceptin, Rituxan, Xolair.

First licensed in 1985. Licensed to produce Activase, Avastin, Cathflo Activase, Herceptin,

Lucentis, Nutropin, Nutropin AQ, Pulmozyme, Raptiva, Rituxan, and TNKase.

Comments

Lonza Biologics, Portsmouth, NH

90,000 (6x15,000L)

Oceanside, CA (NIMO)

144,000 (12x12,000L)

Vacaville, CA (CCP1)

96,000 (8x12,000L)

South San Francisco, CA
Current Capacity
Genentech Bulk Manufacturing Facility
Manufacturing Capacity
Manufacturing Capacity
As of November 9, 2006

#9
0
50,000
100,000
150,000
200,000
250,000
300,000
350,000
400,000
450,000
500,000
550,000
600,000
650,000
1999

2000

2001

2002

2003

2004

2005

2006

1H'07

2008

2H'09

2010

*Chinese Hamster Ovary Cell Culture

Note:

In

Q4 '06,

Genentech

has

entered

into

an

agreement

with

Lonza

to

purchase

Genentech's

Porrino,

Spain

manufacturing

facility.

Concurrently,

we

entered

into

a

supply

agreement

for

the

manufacture

of

certain

Genentech

products

at

Lonza's

facility

currently

under

construction

in
Singapore,
with
Genentech
also
receiving
the
right
to
exercise
an
exclusive
option
to
purchase
the
Lonza
Singapore
facility
during
the
period
from
2007
to
2012.
The
transactions
are
subject
to
various
closing
conditions..

As of November 9, 2006

Genentech Commercial Cell Culture*

Bioreactor Capacity

Genentech Commercial Cell Culture*

Bioreactor Capacity

Current Commercial Capacity

South San Francisco, CA and Vacaville, CA (CCP1)

#10

What Does This Mean For You?

What Does This Mean For You?

We encourage continued focus on your current efforts to bring important new medicines to patients, as this is in everyone's best interest

While we fully expect the deal to go through, we aren't there yet

Your current management continues to run the company until close

Once the GNE and Tanox transition teams are up and running, more detailed information will be available on next steps, key milestones, etc.

Most importantly, we recognize that this is an uncertain time for Tanox employees. Consistent with our values, our intent is to treat Tanox employees with the same respect & integrity that we treat our own employees

#11

Transition Process Will Be Organized Around Four Areas

Transition Process Will Be Organized Around Four Areas

EC / Legal

EC

Product

Portfolio

Committee

Research

Review

Committee

EC / PROP

Executive Team

Decision

maker

Feb. 28, 2007*

Feb. 28, 2007*

Jan. 31, 2007*

Feb 28, 2007*

3.Recomm

end-ation

Feb 10, 2007*

Feb. 10, 2007*

Jan. 31, 2007*

Jan 31, 2007*

2.

Evaluation

Number of

contracts; Rights

and obligations of

each

Number of

employees by

functional area

Number and

value of R&D

programs

Number, location,

and capability of

facility

1.

Assessmen

t

Contracts

HR

Change

management

R&D

Programs

Facilities/

Property

Process Summary

* All dates are tentative

#12

Decisions Yet to be Determined

Decisions Yet to be Determined

Future plans for Tanox's pipeline

Future plans for Tanox's sites

Future status of employees

Who will be retained

How/when decisions will be made after close;
however, our intent is for decisions to be made
as quickly and with as much transparency as
possible

Where retained employees will be located

Details of post-close integration and timeline

#13

Next Steps

Next Steps

Today:

Small functional meetings with Genentech and Tanox management

Next few months:

Additional site visits to establish post-close integration plans

Deal not closed until at least Q1 '07; Tanox remains an independent company until the deal closes. It is important to stay focused and keep moving projects forward during this time:

Tanox shareholder vote

Hart-Scott-Rodino submission and review

Review of deal by Federal Trade Commission

Transition team established

#14
Genentech Transition Team
Ashraf Hanna,
Team Leader
Mark Asbury
Leigh Morgan
Charles Calderaro
Sean Bohlen
Andy Chan
Neil
Cohen
Contracts
R&D
HR
Facilities/
Property
Communi
cation
Ray Sanchez-
Pescadore,

Project Manager
Brian Muma

#15

Forward Looking
Statement
Forward Looking
Statement

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, among other things, our expectations regarding the closing of the acquisition and the integration of the operations of Tanox, our belief that we have the right plans in place to meet future demand for our products, our belief regarding the future growth and profitability of Xolair and anti-IgE inhibition products, our future product development plans (including anti-IL 13 Mab for asthma, anti-Factor D Mab for dry AMD and anti-CD4 for HIV), our expectations regarding the timing of our evaluations and decisions for transition plans, and the timing of and actual severance payment amounts for Tanox employees; planned manufacturing expansions and our manufacturing capacity, including expected timeframes for FDA filings and approval for licensure of manufacturing facilities and expected timeframe for facilities to become operational; and FDA approvals of yield improvements. Actual results could differ materially. Among other things, the transaction and its timing could be affected or prevented by failure of certain closing conditions to occur, including FTC or other regulatory actions or delays; integration of the Tanox business (including the timing of our decisions regarding such integration) could be affected by failures in our due diligence review of the Tanox business and failure to retain certain key employees; growth and profitability of our asthma and anti-IgE business (including Xolair) could be affected by adverse market conditions, increased competition, delay or failure of clinical programs, and safety or manufacturing issues; future development plans may be affected by changes in our corporate strategy, increased competition, regulatory actions or delays, unsuccessful clinical trials or third party intellectual property rights; Xolair clinical trials could be affected by a number of factors including unexpected safety, efficacy or manufacturing issues, additional time requirements for data analysis and FDA actions or delays; achieving sales revenue consistent with internal forecasts, unexpected expenses such as litigation or legal settlement expenses, changes in tax rules, adverse market conditions, increased competition, regulatory actions or delays; the severance described in this presentation will be subject to other terms and conditions set forth in the severance plan established by Genentech (including the execution of a release by each eligible employee); and the expected FDA filings and licensure timeframes, planned manufacturing expansions, manufacturing capacity, timeframes for FDA approvals of yield improvements and timeframe when manufacturing facilities will become operational could be affected by a number of factors including FDA or other regulatory actions or delays, failure to receive FDA approval and other delays or manufacturing issues. Please refer to Genentech's periodic reports filed with the Securities and Exchange Commission. Such reports contain and identify important factors that could cause actual results to differ materially from those contained in our forward-looking statements. All such risk factors, including those found in our most recent Form 10-Q, are incorporated by reference into this transcript. We undertake no obligation to update or revise any forward-looking statements in the future.

#16
Thank You
Thank You

#17
Q&A Session
Q&A Session

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, among other things, our expectations regarding the closing of the acquisition and the integration of the operations of Tanox, our future product development plans with regard to Tanox's pipeline, our expectations regarding the timing of our evaluations and decisions for transition plans, planned manufacturing expansions and our manufacturing capacity, including expected timeframes for FDA filings and approval for licensure of manufacturing facilities and expected timeframe for facilities to become operational; and FDA approvals of yield improvements. Actual results could differ materially. Among other things, the transaction and its timing could be affected or prevented by failure of certain closing conditions to occur, including FTC or other regulatory actions or delays; integration of the Tanox business (including the timing of our decisions regarding such integration) could be affected by failures in our due diligence review of the Tanox business and failure to retain certain key employees; future development plans may be affected by changes in our corporate strategy, increased competition, regulatory actions or delays, unsuccessful clinical trials or third party intellectual property rights; and the expected FDA filings and licensure timeframes, planned manufacturing expansions, manufacturing capacity, timeframes for FDA approvals of yield improvements and timeframe when manufacturing facilities will become operational could be affected by a number of factors including FDA or other regulatory actions or delays, failure to receive FDA approval and other delays or manufacturing issues. Please refer to Genentech's periodic reports filed with the Securities and Exchange Commission. Such reports contain and identify important factors that could cause actual results to differ materially from those contained in our forward-looking statements. All such risk factors, including those found in our most recent Form 10-Q filed with the Securities and Exchange Commission, are incorporated by reference into this transcript. We undertake no obligation to update or revise any forward-looking statements in this presentation in the future.