

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

IMCLONE SYSTEMS INC/DE
Form SC 13D/A
March 06, 2002

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 13D

(Amendment No. 2)

Under the Securities Exchange Act of 1934

ImClone Systems Incorporated
(Name of Issuer)

Common Stock, Par Value \$0.001 Per Share
(Title of Class of Securities)

45245W109
(CUSIP Number)

Bristol-Myers Squibb Company
345 Park Avenue
New York, New York 10154
(212) 546-4000
Attn: General Counsel

(Name, Address and Telephone Number of Person Authorized to Receive Notices and Communications)

March 5, 2002
(Date of Event which Requires Filing of this Statement)

If the filing person has previously filed a statement on Schedule 13G to report the acquisition that is the subject of this Schedule 13D, and is filing this schedule because of Sections 240.13d-1(e), 240.13d-1(f) or 240.13d-1(g), check the following box [].

NOTE: Schedules filed in paper format shall include a signed original and five copies of the schedule, including all exhibits. Sections 240.13d-7(b) for other parties to whom copies are to be sent.

* The remainder of this cover page shall be filled out for a reporting person's initial filing on this form with respect to the subject class of securities, and for any subsequent amendment containing information which would alter disclosures provided in a prior cover page.

The information required on the remainder of this cover page shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934 ("Act") or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act.

(Continued on following page(s))

CUSIP No. 45245W109

1 Names of Reporting Persons

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

Identification Nos. of Above Persons (entities only)
Bristol-Myers Squibb Company
22-0790350

Check the Appropriate Box if a Member of a Group

2 (a)

(b)

3 SEC Use Only

4 Source of Funds
BK, OO

5 Check if Disclosure of Legal Proceedings is Required
Pursuant to Items 2(d) or 2(e)

6 Citizenship or Place of Organization
Delaware

7 Sole Voting Power
14,392,003

Number of Shares
Beneficially
Owned by Each
Reporting
Person with

8 Shared Voting Power
- 0 -

9 Sole Dispositive Power
14,392,003

10 Shared Dispositive Power
- 0 -

11 Aggregate Amount Beneficially Owned by Each Reporting Person
14,392,003

12 Check Box if the Aggregate Amount in Row (11) Excludes
Certain Shares

13 Percent of Class Represented
by Amount in Row (11)
19.9%

14 Type of Reporting Person
CO

2

1 Names of Reporting Persons
Identification Nos. of Above Persons (entities only)
Bristol-Myers Squibb Biologics Company
22-3828046

Check the Appropriate Box if a Member of a Group

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

2	(a) <input checked="" type="checkbox"/>	
	(b) <input type="checkbox"/>	
<hr/>		
3	SEC Use Only	
<hr/>		
4	Source of Funds BK, OO	
<hr/>		
5	Check if Disclosure of Legal Proceedings is Required Pursuant to Items 2(d) or 2(e) <input type="checkbox"/>	
<hr/>		
6	Citizenship or Place of Organization Delaware	
<hr/>		
	7	Sole Voting Power 14,392,003
	<hr/>	
	8	Shared Voting Power - 0 -
	<hr/>	
	9	Sole Dispositive Power 14,392,003
	<hr/>	
	10	Shared Dispositive Power - 0 -
<hr/>		
11	Aggregate Amount Beneficially Owned by Each Reporting Person 14,392,003	
<hr/>		
12	Check Box if the Aggregate Amount in Row (11) Excludes Certain Shares <input type="checkbox"/>	
<hr/>		
13	Percent of Class Represented by Amount in Row (11) 19.9%	
<hr/>		
14	Type of Reporting Person CO	
<hr/>		

Item 1. Security and Issuer.

Item 1 is hereby amended, in pertinent part, by the following:

This Amendment No. 2 to Schedule 13D relating to the Common Stock, par value \$.001 per share, of ImClone Systems Incorporated ("ImClone") is being filed on behalf of the undersigned to further amend their disclosure with respect to Section 13(d) of the Act and the rules and regulations thereunder. Such disclosure constituted part of the undersigned's Schedule TO previously filed on September 28, 2001, as amended by filings made on October 12, 2001, October 26, 2001, October 29, 2001 and November 1, 2001. Such disclosure was also amended by Amendment No. 1 to Schedule 13D filed by the undersigned on February 6, 2002 ("Amendment No. 1").

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

Item 4. Purpose of the Transaction.

Item 4 is hereby amended, in pertinent part, by the following:

As set forth in Amendment No. 1, on February 5, 2002, Bristol-Myers Squibb Company (the "Company") proposed to restructure certain terms of its commercial arrangement with ImClone in connection with the Company's evaluation of its relationship with ImClone. On March 5, 2002, the Company and ImClone announced that they had agreed to restructure certain provisions of the Development, Promotion, Distribution and Supply Agreement, dated as of September 19, 2001, by and among ImClone, the Company and E.R. Squibb & Sons, LLC (the "Distribution Agreement"). The amendment to the Distribution Agreement in respect of such restructuring is attached hereto as Exhibit A and is incorporated herein by reference. In addition, the joint press release of the Company and ImClone in respect of such restructuring is attached hereto as Exhibit B and is incorporated herein by reference.

Item 7. Material to be Filed as Exhibits.

Exhibit A Amendment No. 1, dated March 5, 2002, to the Development, Promotion, Distribution and Supply Agreement, dated as of September 19, 2001, by and among ImClone Systems Incorporated, Bristol-Myers Squibb Company and E.R. Squibb & Sons, LLC.*

Exhibit B Joint press release of Bristol-Myers Squibb Company and ImClone Systems Incorporated, dated March 5, 2002.

* Certain portions of this agreement have been omitted pursuant to an application for confidential treatment filed with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

4

Signature

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

Date: March 6, 2002

BRISTOL-MYERS SQUIBB COMPANY

by: /s/ Frederick S. Schiff

Name: Frederick S. Schiff
Title: Senior Vice President and Chief
Financial Officer

BRISTOL-MYERS SQUIBB BIOLOGICS COMPANY

by: /s/ Sandra Leung

Name: Sandra Leung
Title: Vice President and Secretary

5

[NOTE: CERTAIN PORTIONS OF THIS DOCUMENT HAVE BEEN MARKED TO INDICATE THAT CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR SUCH PORTIONS BY BRISTOL-MYERS SQUIBB COMPANY, BRISTOL-MYERS SQUIBB BIOLOGICS COMPANY AND IMCLONE SYSTEMS INCORPORATED. THESE PORTIONS HAVE BEEN MARKED WITH TWO ASTERISKS ENCLOSED IN THE BRACKETS (I.E., [**]). THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

EXHIBIT A

AMENDMENT NO. 1 TO DEVELOPMENT, PROMOTION,
DISTRIBUTION AND SUPPLY AGREEMENT

AMENDMENT NO. 1 dated as of March 5, 2002 (this "Amendment"), by and among E. R. SQUIBB & SONS, LLC, a limited liability company organized and existing under the laws of the State of Delaware, having offices located at Route 206 and Province Line Road, Princeton, New Jersey ("ERS"), BRISTOL-MYERS SQUIBB COMPANY, a corporation organized and existing under the laws of the State of Delaware, having offices located at Route 206 and Province Line Road, Princeton, New Jersey ("BMS") and IMCLONE SYSTEMS INCORPORATED, a corporation organized under the laws of the State of Delaware, having offices located at 180 Varick Street, New York, New York 10014 (the "Company").

PRELIMINARY STATEMENTS

A. ERS, BMS and the Company are parties to the Development, Promotion, Distribution and Supply Agreement dated as of September 19, 2001 (the "Commercial Agreement") pursuant to which the Parties have agreed to collaborate on the development and commercialization of Products in the Territory.

B. On October 30, 2001, pursuant to the Commercial Agreement, the Company submitted a biologics license application for a Product under Section 351 of the Public Health Service Act. On December 28, 2001, the FDA notified the Company that it would refuse to file such biologics license application (the "Refusal to File").

C. In light of the Refusal to File and subsequent discussions with the FDA, the Parties have agreed to amend the Commercial Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the foregoing preliminary statements and the mutual agreements and covenants set forth herein, the Parties hereby agree as follows:

1. DEFINITIONS.

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

1.1 Definitions in the Commercial Agreement. Capitalized terms used but not defined in this Amendment (including the Preliminary Statements set forth above) shall have the meanings set forth in the Commercial Agreement. References in the Commercial Agreement to "this Agreement" shall be deemed to refer to the Commercial Agreement as amended by this Amendment. Notwithstanding the foregoing, the date of the Commercial Agreement, as amended hereby, shall in all instances remain September 19, 2001, and references to "the date hereof", "the date of this Agreement" and "the Effective Date" in the Commercial Agreement shall continue to refer to September 19, 2001.

2. MANAGEMENT.

2.1 Clinical and Regulatory Oversight. The Parties agree that Andrew Bodnar ("Bodnar") shall, for so long as he is willing to serve, be entitled to oversee the implementation of the Clinical Development Plan and the process for seeking Registration of Products pursuant to the Commercial Agreement. Bodnar shall be entitled to attend meetings of any Committee, and any Committee may from time to time consult with Bodnar with respect to any matter relating to the Clinical Development Plan or Registration of the Product; provided that Bodnar shall not have any powers, rights or responsibilities of a member of a Committee (except to the extent he otherwise has such powers, rights or responsibilities in his capacity as a member of such Committee), and Bodnar's authority shall be subject to the authority of the Committees and the other provisions of the Commercial Agreement. Bodnar shall also be entitled to attend any meetings between the Company and the FDA with respect to a Product.

6

Confidential treatment requested by Bristol-Myers Squibb Company, Bristol-Myers Squibb Biologics Company and ImClone Systems Incorporated.

3. CLINICAL DEVELOPMENT PLAN/CLINICAL BUDGET

3.1 Product Development Committee Meeting.

(a) As soon as reasonably practicable after the date hereof, the PDC shall meet to amend and modify the Clinical Development Plan pursuant to the Commercial Agreement to reflect the current strategy of the Parties with respect to Registration of the Product. Such amended and modified Clinical Development Plan (the "Modified Clinical Plan") shall include the matters referred to in Section 4.3(b) of the Commercial Agreement, and shall be a "Clinical Development Plan" within the meaning of Section 1.20 of the Commercial Agreement.

(b) At the meeting referred to in Section 3.1(a), the PDC shall also modify the Clinical Budget relating to the Registrational Studies pursuant to the Commercial Agreement to reflect the Modified Clinical Plan; provided that such modified Clinical Budget (the "Modified Clinical Budget") shall (i) be equal in the aggregate to the Clinical Budget in effect as of the date hereof (the "Existing Clinical Budget") and (ii) in respect of any year prior to 2005, not be less than 80% of the budget for such year under the Existing Clinical Budget. Unless and until the Modified Clinical Budget is approved in accordance with the Commercial Agreement, the Existing Clinical Budget shall remain in effect.

3.2 Joint Manufacturing Committee Meeting. As soon as reasonably practicable after the meeting referred to in Section 3.1(a), the JMC shall

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

meet to amend Exhibit 8.12 (B) (i) to the Commercial Agreement to reflect the Modified Clinical Budget.

4. PAYMENTS.

4.1 Payments to the Company.

(a) As partial consideration to the Company for the rights granted to ERS under the Commercial Agreement and for entering into this Amendment, ERS shall pay to the Company a non-refundable and non-creditable payment of \$140,000,000 on March 7, 2002 in immediately available funds by wire transfer to an account specified by the Company.

(b) Section 6.2 of the Commercial Agreement is amended by deleting paragraph (a) thereof in its entirety and replacing it with the following:

"(a) As further consideration to the Company for the rights granted to ERS under this Agreement, ERS shall pay to the Company the following non-refundable and non-creditable payments on the date or upon the occurrence of the events, as the case may be, set forth below:

Date/Event -----	Payment -----
March 5, 2003	\$60,000,000
Upon receipt of written Registration in the US from the FDA with respect to any indication for a Product (the "First Indication").	\$250,000,000

Confidential treatment requested by Bristol-Myers Squibb Company, Bristol-Myers Squibb Biologics Company and ImClone Systems Incorporated.

Date/Event -----	Payment -----
Upon receipt of written Registration in the US from the FDA with respect to any indication relating to a different tumor type from the First Indication (the "Second Indication").	\$250,000,000

The Party who receives notice of Registration from the FDA shall be responsible for promptly informing the other Parties when such event occurs. The payments required with respect to receipt of Registration pursuant to this Section 6.2(a) shall be paid within 30 days (by wire transfer in immediately available funds to an account specified by the Company) after the earlier to occur of: (i) ERS receiving notice of the Registration from the FDA or (ii) the Company notifying ERS of such Registration. The Parties understand that the First Indication and the Second Indication may be included

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

in the same Registration; provided that any indication or series of indications relating to the same tumor type (e.g., colorectal cancer) shall, for all purposes under this Section 6.2, constitute one indication and no subsequent indication in respect of the tumor type for which the First Indication was received shall be considered a Second Indication."

4.2 Distribution Fees.

(a) Section 6 of the Commercial Agreement is amended by deleting Sections 6.3 and 6.4 in their entirety and replacing them with the following:

"Section 6.3 Distribution Fees for North America. As further consideration to the Company for the rights granted to ERS in North America under this Agreement, ERS shall pay to the Company a Distribution Fee for North America equal to 39% of Net Sales in North America during each calendar year (or portion thereof)."

(b) Section 6 of the Commercial Agreement is further amended by renumbering Section 6.5 as "Section 6.4" and Section 6.6 as "Section 6.5".

(c) Section 16.2 of the Commercial Agreement is amended by deleting ", subject to Section 6.4" from the first sentence thereof.

5. PROJECTIONS.

5.1 Base Case Projections. Exhibit 1.13 to the Commercial Agreement is deleted in its entirety and replaced by Exhibit 1.13 to this Amendment.

5.2 Low Case Projections. Exhibit 1.68 to the Commercial Agreement is deleted in its entirety and replaced by Exhibit 1.68 to this Amendment.

5.3 Marketing Budget. Exhibits 5.2(A) and 5.2(B) to the Commercial Agreement are deleted in their entirety and replaced by Exhibits 5.2(A) and 5.2(B) to this Amendment.

8

Confidential treatment requested by Bristol-Myers Squibb Company, Bristol-Myers Squibb Biologics Company and ImClone Systems Incorporated.

5.4 Commercial API Supply. Exhibit 8.12(B)(ii) to the Commercial Agreement is deleted in its entirety and replaced by Exhibit 8.12(B)(ii) to this Amendment.

5.5 Non-Registrational Clinical Budget. The portion of Exhibit 4.3(A) to the Commercial Agreement related to Non-Registrational Studies is deleted in its entirety and replaced by Exhibit 4.3(A) to this Amendment.

6. REPRESENTATIONS AND WARRANTIES.

Each Party represents and warrants to each of the other Parties, as of the date of this Amendment, that:

(a) such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Amendment and to carry out

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

the provisions hereof;

(b) such Party has taken all corporate action necessary to authorize the execution and delivery of this Amendment and the performance of its obligations under this Amendment and has full power and authority to enter into this Amendment and perform its obligations under this Amendment; and

(c) this Amendment has been duly executed by such Party and constitutes a valid and legally binding obligation of such Party, enforceable in accordance with its terms, subject to and limited by: (i) applicable bankruptcy, insolvency, reorganization, moratorium, and other laws generally applicable to creditors' rights; and (ii) judicial discretion in the availability of equitable relief.

7. MISCELLANEOUS.

7.1 Prior Events. Each Party hereby acknowledges and agrees that a requirement by the FDA that the Company (i) reformat and reanalyze the clinical data from the two clinical studies (Nos.9923 and 0141) conducted by the Company in connection with the Registration Application submitted to the FDA on October 30, 2001 and (ii) submit data from clinical study No. 007 currently being conducted by Merck KGaA in Europe for the use of the Product to treat refractory colorectal cancer to support a resubmission of the Registration Application, does not constitute, in and of itself without further FDA requirements, a "material delay" under Section 4.8 of the Commercial Agreement or give rise, as of the date hereof, to "a significant concern regarding a regulatory or patient safety issue that would seriously impact the long term viability of all Products" under Section 13.3 of the Commercial Agreement; provided that this Section 7.1 does not, and shall in no circumstances be construed as, an admission of the occurrence of, or as an indication of what may constitute or be considered in the determination of the existence of, a "material delay" under Section 4.8 of the Commercial Agreement or such a "significant concern" under Section 13.3 of the Commercial Agreement.

7.2 Manufacturing Facility. As soon as reasonably practicable after the date hereof, the Company shall resume construction of the BB-50 plant (the "Plant"), and use its commercially reasonable efforts to pursue diligently the construction of the Plant, substantially in accordance with the plans and specifications previously provided to BMS. The Company shall use its commercially reasonable efforts to complete such construction by [**].

7.3 Press Release. Immediately following execution of this Amendment, the Parties shall issue a joint press release in the form previously agreed by the Parties.

7.4 Rights. Except as specifically set forth herein, the Commercial Agreement shall remain unchanged and in full force and effect. The Parties acknowledge and agree that there are no

Confidential treatment requested by Bristol-Myers Squibb Company, Bristol-Myers Squibb Biologics Company and ImClone Systems Incorporated.

amendments, modifications or waivers in respect of the Commercial Agreement other than those specifically set forth in this Amendment.

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

7.5 Governing Law. This Amendment shall be governed by and interpreted in accordance with the laws of the State of New York without regard to conflicts of law principles.

7.6 Descriptive Headings. The descriptive headings of this Amendment are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Amendment.

7.7 Counterparts. This Amendment may be executed simultaneously in any number of counterparts, any one of which need not contain the signature of more than one Party but all such counterparts taken together shall constitute one and the same agreement.

10

Confidential treatment requested by Bristol-Myers Squibb Company, Bristol-Myers Squibb Biologics Company and ImClone Systems Incorporated.

IN WITNESS WHEREOF, each of the Parties has caused this Amendment to be executed by its duly authorized representative as of the day and year first above written.

IMCLONE SYSTEMS INCORPORATED

By: /s/ Samuel D. Waksal

Name: Samuel D. Waksal

Title: President and Chief Executive Officer

E. R. SQUIBB & SONS, LLC

By: /s/ John L. McGoldrick

Name: John L. McGoldrick

Title: Vice President

BRISTOL-MYERS SQUIBB COMPANY

By: /s/ Sandra Leung

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

Name: Sandra Leung

Title: Secretary

11

Confidential treatment requested by Bristol-Myers Squibb Company,
Bristol-Myers Squibb Biologics Company and ImClone Systems Incorporated.

Exhibit 1.13 -- Base Case Projections

United States and Japan C225 Sales

(\$MM)

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
--	------	------	------	------	------	------	------	------	------	------	------	------

Base Case

U.S. Sales	-	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
------------	---	------	------	------	------	------	------	------	------	------	------	------

Japan Sales	-	-	-	-	-	[**]	[**]	[**]	[**]	[**]	[**]	[**]
-------------	---	---	---	---	---	------	------	------	------	------	------	------

Total C225 Sales	-	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
------------------	---	------	------	------	------	------	------	------	------	------	------	------

Confidential treatment requested by Bristol-Myers Squibb Company,
Bristol-Myers Squibb Biologics Company and ImClone Systems Incorporated.

Exhibit 1.68 -- Low Case Projections

United States and Japan C225 Sales

(\$MM)

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
--	------	------	------	------	------	------	------	------	------	------	------	------

Low Case

U.S. Sales	-	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
------------	---	------	------	------	------	------	------	------	------	------	------	------

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

 Japan Sales - - - - - [**] [**] [**] [**] [**] [**] [

 Total C225 Sales - [**] [**] [**] [**] [**] [**] [**] [**] [**] [**] [

=====

Confidential treatment requested by Bristol-Myers Squibb Company,
 Bristol-Myers Squibb Biologics Company and ImClone Systems Incorporated.

 Exhibit 5.2A -- Marketing Budget
 2001-2004
 (\$MM)

	2001	2002	2003	2004
Total A&P Expense	[**]	[**]	[**]	[**]
U.S.	[**]	[**]	[**]	[**]
Japan	-	-	-	-

 Distribution & Other Fees - - [**] [**]

Total Sales Force	-	-	[**]	[**]
U.S.	-	-	[**]	[**]
Japan	-	-	-	-
# Reps			[**]	[**]

=====

Confidential treatment requested by Bristol-Myers Squibb Company,
 Bristol-Myers Squibb Biologics Company and ImClone Systems Incorporated.

 Exhibit 5.2B -- Indicative Marketing Budget
 2005-2017
 (\$MM)

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Total A&P Expense	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

U.S.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Japan	-	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Distribution & Other Fees	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Total Sales Force	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
U.S.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Japan	-	-	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

Confidential treatment requested by Bristol-Myers Squibb Company, Bristol-Myers Squibb Biologics Company and ImClone Systems Incorporated.

Exhibit 8.12B (ii)

United States and Japan C225 Commercial Volume
Kilograms

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Base Case											
United States - Lonza	[**]	[**]	-	-	-	-	-	-	-	-	-
United States - IMCL	-	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Japan - Lonza	-	-	-	-	-	-	-	-	-	-	-
Japan - IMCL	-	-	-	-	-	[**]	[**]	[**]	[**]	[**]	[**]
Total - Lonza	[**]	[**]	-	-	-	-	-	-	-	-	-
Total - IMCL	-	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

Confidential treatment requested by Bristol-Myers Squibb Company, Bristol-Myers Squibb Biologics Company and ImClone Systems Incorporated.

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

Exhibit 4.3A -- C225 Clinical Spending
Non-Registrational Studies
(\$MM)

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Non-Registrational Studies	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
U.S.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Japan	-	-	-	-	-	-	[**]	[**]	[**]	[**]	[**]	[**]	[**]

EXHIBIT B

ImClone Systems Contacts:

Andrea F. Rabney or
Jason E. Farber
ImClone Systems Incorporated
(646) 638-5058

Andrew Merrill or
David Pitts
Abernathy MacGregor
(212) 371-5999

Bristol-Myers Squibb Contacts:

Nancy Goldfarb
Media Relations
212/546-5107

Timothy Cost
Investor Relations
212/546-4103

IMCLONE SYSTEMS AND BRISTOL-MYERS SQUIBB ANNOUNCE REVISED
TERMS OF COMMERCIALIZATION AGREEMENT FOR ERBITUX(TM)

NEW YORK, NY - March 5, 2002 - Bristol-Myers Squibb Company (NYSE:BMJ) and ImClone Systems Incorporated (Nasdaq: IMCL) announced today the revision of certain terms in the companies' commercialization agreement for the co-development and co-promotion of ERBITUX(TM) in the United States, Canada and Japan. The companies have agreed to changes in certain economics of the agreement and have agreed to the expansion of the clinical and strategic role of Bristol-Myers Squibb in the ERBITUX development program.

Under the revised terms:

- o In lieu of the \$300 million milestone payment agreed upon in the

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

original agreement, Bristol-Myers Squibb will pay ImClone Systems \$140 million in cash upon signing of the revised agreement and \$60 million in cash on the one-year anniversary of the signing.

- o Bristol-Myers Squibb will pay ImClone Systems the originally agreed upon \$500 million milestone payment, based on the approval by the U.S. Food and Drug Administration (FDA) of ERBITUX, in two parts: \$250 million will be paid upon approval of the initial indication, and the remaining \$250 million will be paid upon approval of a second indication.
- o ImClone Systems will receive a distribution fee based on a flat rate of 39 percent of product revenues in North America.
- o The term of the agreement will continue to run through 2018.

The companies said that Andrew G. Bodnar, M.D., J.D., senior vice president of Medical and External Affairs, Bristol-Myers Squibb, and a member of ImClone Systems' Board of Directors, will oversee a joint ImClone Systems and Bristol-Myers Squibb team implementing a single clinical and regulatory plan for ERBITUX. Governance of all

12

committees provided for in the original agreement will remain unchanged.

"ImClone Systems' objective is to move ERBITUX through the regulatory process and to patients with cancer expeditiously," said Robert F. Goldhammer, chairman of ImClone Systems. "The leadership and focus of ImClone Systems' senior management and the firm commitment and support of its partner, Bristol-Myers Squibb, strengthens our ability to achieve this goal."

"We are confident that we will now be able to move forward in our partnership with ImClone Systems for the development of ERBITUX," said Peter R. Dolan, chairman and chief executive officer, Bristol-Myers Squibb. "As the world leader in oncology, we are looking forward to playing an expanded clinical and strategic role related to the ERBITUX development program, working in close collaboration with the ImClone Systems team. The revised agreement also reflects the adjusted timeline to market launch based on the current development path for ERBITUX, which has been modified following the February 26th meeting with the FDA."

"ImClone Systems continues to believe that ERBITUX has great potential to treat patients with cancer, and our efforts are focused on gaining FDA approval for the drug," stated Samuel D. Waksal, Ph.D., president and chief executive officer of ImClone Systems. "This agreement reflects the companies' mutual commitment to see ERBITUX jointly developed and successfully moved through the regulatory process."

"I am delighted to have the opportunity to lead a joint Bristol-Myers Squibb and ImClone Systems team that will work diligently to bring ERBITUX through the clinical and regulatory process as quickly and efficiently as possible. Our combined resources - together with our strong commitment to this product - will be fully engaged in this process," said Dr. Bodnar.

ERBITUX is an investigational drug designed to target and block the Epidermal Growth Factor Receptor (EGFR), which is expressed on the surface of

Edgar Filing: IMCLONE SYSTEMS INC/DE - Form SC 13D/A

certain cancer cells.

Bristol-Myers Squibb is a \$19 billion pharmaceutical and related health care products company whose mission is to extend and enhance human life.

ImClone Systems Incorporated is committed to advancing oncology care by developing a portfolio of targeted biologic treatments, designed to address the medical needs of patients with a variety of cancers. The Company's three programs include growth factor blockers, cancer vaccines and angiogenesis inhibitors. ImClone Systems' strategy is to become a fully integrated biopharmaceutical company, taking its development programs from the research stage to the market. ImClone Systems is headquartered in New York with manufacturing facilities in Somerville, New Jersey.

EXCEPT FOR THE HISTORICAL INFORMATION CONTAINED HEREIN, THE MATTERS DISCUSSED IN THIS NEWS RELEASE MAY INCLUDE FORWARD-LOOKING STATEMENTS. ACTUAL RESULTS MAY DIFFER MATERIALLY FROM THOSE PREDICTED IN SUCH FORWARD-LOOKING STATEMENTS DUE TO THE RISKS AND UNCERTAINTIES INHERENT IN THE COMPANIES' BUSINESS, INCLUDING, WITHOUT LIMITATION, RISKS AND UNCERTAINTIES IN OBTAINING AND MAINTAINING REGULATORY APPROVAL, MARKET ACCEPTANCE OF AND CONTINUING DEMAND FOR THE COMPANIES' PRODUCTS AND THE IMPACT OF COMPETITIVE PRODUCTS AND PRICING. THE COMPANIES UNDERTAKE NO OBLIGATION TO REVISE OR UPDATE THIS PRESS RELEASE TO REFLECT EVENTS OR CIRCUMSTANCES AFTER THE DATE HEREOF.