18-01784-E

Madison, Wilton

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Saturday, January 06, 2018 7:34 PM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibit 10.36 to the 12/31/08 10-K, filed by Poniard Pharmaceuticals, Inc. on 3/16/2009. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to $61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

February 1, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr.
Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-01784-E

Dear Mr. Edwards:

This letter is in response to your request, dated January 6, 2018 and received in this office on January 8, 2018, for access to Exhibit 10.36 to the December 31, 2008 10-K, filed by Poniard Pharmaceuticals, Inc. on March 16, 2009.

The search for responsive records has resulted in the retrieval of 15 pages of records that may be responsive to your request. They are being provided to you with this letter in their entirety.

As shown on the enclosed invoice, the processing fee is $30.50 in accordance with our fee schedule. You may use our new *Online Payment* option to pay by debit or credit card. If paying by mail, checks or money orders should be made payable to the SEC and a copy of the invoice should be mailed to our new payment address: Enterprise Services Center, HQ Bldg, Room 181, AMZ-341, 6500 South MacArthur Boulevard, Oklahoma City, OK, 73169. Please refer to the following link for detailed instructions on how to remit payments. http://www.sec.gov/about/offices/ofm.htm

If you have any questions, please contact me at osbornes@sec.gov or (202) 551-8371. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Sonja Osborne

Sonja Osborne
FOIA Lead Research Specialist

Enclosures

***** Indicates confidential material that has been omitted pursuant to a Confidential Treatment Request filed with the Securities and Exchange Commission. A complete copy of this agreement has been separately filed with the Securities and Exchange Commission.**

PRODUCT MASTER PLAN
FOR Picoplatin Injection

This Product Master Plan to the CLINICAL and COMMERCIAL SUPPLY AGREEMENTS is between Poniard Pharmaceuticals Inc. having an office at 300 Elliott Ave. West, Suite 500, Seattle, WA 98119-4114, USA, as such term is defined herein ("**PONIARD**") and Baxter Oncology GmbH, with its principal place of business at Kantstr. 2, 33790 Halle / Westfalen, Germany, as such term is defined herein ("**BAXTER**").

RECITALS

PONIARD and BAXTER have concluded CLINICAL and COMMERCIAL SUPPLY AGREEMENT and a QUALITY AGREEMENT regarding the Production of the Products set forth in this Product Master Plan.

This Product Master Plan is concluded as an integral part of the CLINICAL and COMMERCIAL SUPPLY AGREEMENTS and the CLINICAL and COMMERCIAL QUALITY AGREEMENTS to define details for the production of Presentations of **Picoplatin Injection**.

This document is a living document. Any changes will be made in writing after discussion between the parties and mutual agreement of the changes. Any amendments have to be signed by the representatives of the technical team from both parties. Revisions to the pricing for ***1200L scale Development, Clinical, Validation and Commercial batches shall be subject to the appropriate sections of the COMMERCIAL SUPPLY AGREEMENT.

Version: No. 4

Change Index:

- Update of the chapter 'Recitals'
- New responsibilities for signature at Poniard
- Update of the chapter 'Presentations': ***Implementing additional product codes for semifinished and finished drug product, adding several new countries
- Update of the chapter 'Product manufacturing': Adding of new documents, ***change of shipping temperatures
- Update of the chapter 'Specifications': *** implementing of responsibilities, adding of several specifications, adding of packaging material, implementing a new table for labels
- Update of the chapter 'Quality Control': *** Update on analytical methods, adding a section for WfI, update on documents for stability and studies
- Update of the chapter 'Validation in Production':
- Joining of the updated chapter 'Documentation' and the updated chapter 'Pricing and Production Schedule
- Update of the table 'Contacts and Responsible Persons'

In witness whereof, the parties have caused this Product Master Plan to be signed by their duly authorized representatives.

"BAXTER"		" BAXTER "	
By:	/s/ Sven Remmerbach	By:	/s/ Uwe Wolk
Name:	Sven Remmerbach, Ph.D.	Name:	Uwe Wölk, Ph.D:
Title:	Associate Director Business Development / Contract Manufacturing	Title:	Manager Contract Manufacturing / Process Transfer
Date:	October 10, 2008	Date:	October 9, 2008

"PONIARD"		"PONIARD"	
By:	/s/ Alstair Leigh,	By:	/s/ Kevin Hovda
Name:	Alistair Leigh, Ph.D.	Name:	Keith Hovda
Title:	Sr. Director, Product Development	Title:	Director, Manufacturing
Date:	October 17, 2008	Date:	October 20, 2008

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1 Presentations

***

BAXTER ID#	Product Description
6457 0200	Semi finished product **PICOPLATIN INJECTION 200ML 200H IFL (500L)**
6457 0260	Semi finished product **PICOPLATIN INJECTION 200ML 200H IFL (1200L)**
2457L0200	Finished product with single labels **PICOPLATIN INJECTION 200ML 0.5 MG/ML 6IFL RUSSIA**
2457L0201	Finished product with booklet labels **PICOPLATIN INJECTION 200ML 0.5 MG/ML 6IFL EP**
2457L0202	Finished product with booklet and single labels **PICOPLATIN INJ. 200ML 0.5 MG/ML 6IFL EP WEST**
2457L0203	Finished product with single panel labels **PICOPLATIN INJ. 200ML 0.5MG/ML 6IFL USA**
2457L0204	Finished product with booklet labels **PICOPLATIN INJ. 200ML 0.5MG/ML 6IFL - EP/ROW**
2457L0263	Finished product with single panel labels **PICOPLATIN INJ. 200ML 0.5MG/ML 6IFL - USA-**
2457L0264	Finished product with booklet labels **PICOPLATIN INJ. 200ML 0.5MG/ML 6IFL - EP/ROW-**

BAXTER shall Produce Picoplatin Injection in accordance with cGMP for utilization in clinical trials conducted in the EU, Russia, Ukraine, Bosnia, Belarus, Croatia, Serbia, Montenegro, India, Argentina, Chile, Uruguay, US and Canada.

BAXTER shall Produce Picoplatin Injection in accordance with cGMP for commercial sale in the following countries: Argentina, Armenia, Aruba, Aserbaidschan, Australia, Austria, Bahrain, Bangladesh, Belgium, Belarus, Benin, Bolivia, Bosnia, Brazil, Canada, Chile, China, Czech Rep., Costa Rica, Croatia, Cyprus, Denmark, Dominican Republic, Ecuador, Egypt, Estonia, Finland, France, Georgia, Greece, Germany, Guatemala, Honduras, Hong Kong, Hungary, India, Indonesia, Ireland, Iceland, Italy, Japan, Kamerun, Kazakhstan, Kirgistan, Kroatia, Kuwait, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Moldavia, Montenegro, Myanmar, New Zealand, Nicaragua, Netherlands, Norway, Oman, Pakistan, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Romania, Russia, Saudi Arabia, Serbia, South Korea, Sweden, Switzerland, Singapor, Slowakia, Slovenia, Spain, Sri Lanka, South Africa, Taiwan, Thailand, Trinidad, Turkey, Tunisia, Turkmenistan, Ukraine, Uzbekistan, Venezuela, United Arabian Emirates, UK, US,Uruguay Vietnam, Yemen

No Trademark has currently been registered, therefore the name "Picoplatin Injection" is to be used for the product until such time as a registered mark is available.

The product Picoplatin Injection shall be filled into ***200 mL molded glass vials with dark-grey stopper and flip-off cap with aluminum plastic crimping cap, silver/orange.

2 Product Manufacturing

2.1 Composition of compounding solution

***

Ingredients	Amount per mL
Picoplatin API.	0.5 mg
Sodium Chloride	9 mg
Water for injection	Add to 1 mL

2.2 Manufacturing Instructions / Master Batch Record

***

Document Code	Title
H PPA HA 19623	Picoplatin Injection 200 mL (500L)
H PPA HA 21585	Picoplatin Injection 200 mL (1200L)

2.3 Packaging Master / Aufmachungsvorschrift

***

Document Code	Title
H LCC AV 17519	PICOPLATIN INJECTION 200mL 0.5 mg/mL 6 vials / Injektions-flaschen 2457L0201 EP
H LCC AV 17553	PICOPLATIN INJECTION 200mL 0.5 mg/mL 6 vials / Injektions-flaschen 2457L0202_250907 EP WEST
H LCC AV 17588	PICOPLATIN INJECTION 200mL 0.5 mg/mL 6 Injektions-flaschen/vials 2457L0203_100308 USA
H LCC AV 17599	PICOPLATIN INJECTION 200mL 0.5 mg/mL 6 vials / Injektions-flaschen 2457L0204_280408 Export/Rest of the World (EP/ROW)
H LCC AV 17619	To be defined –USA-
H LCC AV 17620	PICOPLATIN INJECTION 200mL 0.5 mg/mL 6 Injektionsfla-schen/vials 2457L0264_080808 Export/Rest of the World (EP/ROW)

2.4 Storing / Shipping Conditions

***

Material	Storage	Shipment
Picoplatin API	+ 15 to + 25 °C	+ 5 to + 40 °C
Sodium Chloride	+ 2 to + 25 °C	+ 2 to + 25 °C
Picoplatin Injection	+ 15 to + 25 °C	+ 15 to + 30 °C

3 Specifications

3.1 API, supplied by PONIARD

***

Material	PONIARD Document Code	BAXTER Material Number	BAXTER Document Code	Title
Picoplatin API	10-501-387	1997 8044	H QS FS 21461	Purchase and Release Specification Picoplatin Drug Substance - cis-ammine-dichloro (2-methylpridine) platinum (II)

3.2 Excipient(s), supplied by BAXTER

***

Material	BAXTER Material Number	BAXTER Document Code	Pharmacopoeia According to
Sodium Chloride	1997 0169	19970169.F06BC160	EP/USP/JP

3.3 Packaging Material(s), supplied by BAXTER

***

Material	BAXTER Material Number	BAXTER Document Code	Title
Vial	5010 1070	H QK FS 11838	Freigabespezifikation Injektionsflasche farblos 200 H/I
Amber Vial	5010 1072	H QK FS 20760	Release Specification Vial for Injection 200 mL (moulded glass DIN 200H/I amber)
Stopper	5120 0133	H QK FS 11528	Freigabespezifikation Injektions-stopfen S10-F451 D21-7 Daikyo
Seal/Orange Cap	5120 1011	H QK FS 12150	Release Specification Crimping Caps flip-off (Aluminium plastic crimping cap, Size 20 mm for injection vials)
Storage Boxes for Semi-Finished Product	5870 0350	n/a	n/a
Styrofoam box	5870 0000	n/a	(Description: Containment for one vial with a single panel label)
Styrofoam box	5870 0001	n/a	(Description: Containment for one vial with a booklet label)
Cardboard box	5700 0310	00007604.I01BA394	Freigabespezifikation Faltschachteln aus Karton
Corrugated cardboard	5870 0260	n/a	(Description: Filling part for shipping box)
Shipping box	5870 0270	n/a	(Description: Box for six packed vials)

3.4 Clinical labels, supplied by PONIARD.

***

Responsibility for supply of commercial product labels to be determined.

Material	BAXTER Material Number	Title
Booklet label vial/inner box	5545-7012	Supplier: Clintrak Clinical Labeling Services, LLC, US
Booklet label vial/inner box	5545-7013	Supplier: Clintrak Clinical Labeling Services, LLC, US
Booklet label shipping box	5545-7002	Supplier: Clintrak Clinical Labeling Services, LLC, US
Booklet label shipping box	5545-7003	Supplier: Clintrak Clinical Labeling Services, LLC, US
Single panel label shipping box	5545 7101	Supplier: Clintrak Clinical Labeling Services, LLC, US
Single panel label shipping box	5545 7111	Supplier: Clintrak Clinical Labeling Services, LLC, US
Single panel label vial/inner box	5545 7060	Supplier: Clintrak Clinical Labeling Services, LLC, US
Single panel label shipping box	5545 7070	Supplier: Clintrak Clinical Labeling Services, LLC, US
Booklet label vial/inner box	5545 7120	Supplier: Clintrak Clinical Labeling Services, LLC, US
Booklet label shipping box	5545 7130	Supplier: Clintrak Clinical Labeling Services, LLC, US
Booklet label vial/inner box	5545 7160	Supplier: Clintrak Clinical Labeling Services, LLC, US
Booklet label shipping box	5545 7170	Supplier: Clintrak Clinical Labeling Services, LLC, US
Single panel label vial/inner box	5545 7140	Supplier: Clintrak Clinical Labeling Services, LLC, US
Single panel label shipping box	5545 7150	Supplier: Clintrak Clinical Labeling Services, LLC, US

3.5 Drug Product Release Specification

***

PONIARD Document Code	BAXTER Document Code	Title
10-501-394	H QK FS 19649e	Baxter: Picoplatin Injection 200 ml 0,5 mg/ml 6 IFL

4 Quality Control

4.1 In Process Control

***

Test	PONIARD Document Code or Pharmacopoeia	BAXTER Document Code or Pharmacopoeia
Appearance of solution	N/A	N/A
Assay (UV)	N/A	H QK TM 19673e (See Section 4.5)
Bioburden	EP/USP	H QKM TM 19502e (See Section 4.6)
Endotoxin	EP/USP	H QKM TM 19504e (See Section 4.6)
Fill volume	N/A	H03 PPAV SO 12609
Filter integrity test	EP/USP	H PPI IA 13320 and H PPA KA 13322

4.2 Analytical Methods (API)

***

Test	BAXTER Document Code	Title
Identity IR	H QK TM 19648e	Identity of Picoplatin API (NX 473) by IR spectroscopy

4.3 Analytical Methods (Excipients)

***

Tests for	Remark
Sodium Chloride	According to Release Specification: Freigabespezifikation Natriumchlorid (Ph. Eur./USP/JP)

4.4 Analytical Methods (Water for Injection)

***

Tests for	Remark
WFI	According to USP

4.5 Analytical Methods (Drug Product)

***

Test	BAXTER Document Code	Title
HPLC	H QK VV 19535e	**Validation Protocol** HPLC Assay & Degradation Products 1 of NX 473 Drug Product (Picoplatin Solution for Injection)
	H QK VB 19819e	**Validation Report** HPLC Assay & Degradation Products 1 of NX 473 Drug Product (Picoplatin Solution for Injection)
	H QK TM 19536e	**Test Method** Identification, Assay & Degradation Products 1 of Picoplatin Injection 200mL 0.5mg/mL
HPLC	H QK VV 19537e	**Validation Protocol** HPLC Degradation Products 2 of NX 473 Drug Product (Picoplatin Solution for Injection)
	H QK VB 19823e	**Validation Report** HPLC Degradation Products 2 of NX 473 Drug Product (Picoplatin Solution for Injection)
	H QK VV 19538e	**Test Method** Degradation Products 2 of Picoplatin Injection 200mL 0.5mg/mL
UV Assay	H QK TM 19673e	**Test Method** UV In-process control on Assay of Picoplatin (NX 473) bulk solution
Particulate Matter	USP <788>	USP <788>
pH value	USP <791>	USP <791>

4.6 Microbiological Methods (Validation Protocols, Validation Reports and Testing Methods)

***

Test	BAXTER Document Codes
Bioburden	**Validation Protocol** – H QKM VV 19496e
	Validation Report – H QKM VB 19499e
	Testing Method – H QKM TM 19502e
Endotoxin (Kinetic turbidimetric method)	**Validation Protocol** – H QKM VV 19498e
	Validation Report – H QKM VB 19501e
	Testing Method – H QKM TM 19504e
Sterility	**Validation Protocol** – H QKM VV 19497e
	Validation Report – H QKM VB 19500e
	Testing Method - H QKM TM 19503e
Container closure integrity testing	**Validation Protocol** – H QKM VV 19581e
	Validation Report – H QKM VB 19791e
	Testing Method – H QKM TM 19792e

4.7 Stability Storage and Drug Product Development Studies

***

BAXTER Document Code	Title
H QK SV 19674	Stability Protocol for Picoplatin Drug Product (Batch 6L001)
H QK SV 19811	Stability Protocol for Picoplatin Drug Product filled in amber vials (Batch 6L001)
H QK SV 20148	Stability Protocol for Picoplatin Drug Product (Batch 7C002)
H QK SV 20172	Stability Protocol for Picoplatin Drug Product for Batch 7D003
H QK SV 20171	Protocol for Storage of Picoplatin Drug Product samples for study on Extractables & Leachables from primary Packaging Material
H QK SV 20765	Stability Protocol Picoplatin Injection Drug Product Temperature Stability Study
H QK SV 20855	Stability Protocol Picoplatin Injection Drug Product – Protocol to Study the Effect of Temperature and Dissolved Gas on Picoplatin Drug Product
H QK SV 20620	Stability Protocol for Picoplatin Drug Product for Batch 7I004
H QK SV 20621	Stability Protocol for Picoplatin Drug Product filled in amber vials (Batch 7I004)
H QK SV 20764	Stability Protocol Picoplatin Injection Drug Product – Protocol to Study the Effect of Light Exposure during Manufacturing of Picoplatin Drug Product
H QKM TP 20811	Test Protocol Picoplatin Injection Drug Product Compounding Microbial Effect Study Protocol
H QKM UB 21012	Investigation Report Picoplatin Injection Drug Product Compounding Microbial Effect Study
H QK SV 21453	Stability Protocol for Picoplatin Drug Product for batch 8F005

4.8 Retention Samples

Retention samples of the drug or finished product will be handled as described in the Master Batch Record or Sampling Plan and the retention samples of the excipients will be handled as described in the QUALITY AGREEMENT.
If changes are necessary, this will be mentioned in an amendment to this Product Master Plan.

5 Validation in Production

5.1 Cleaning validation

Cleaning validation is required if a multi purpose vessel will be used and if the product should be a new worst-case product. If the product is not a worst-case product, it will be implemented into the existing grouping. Based on the information Poniard has provided so far, a cleaning verification (***performed by swabbing and a Picoplatin specific laboratory test at an external lab for Platinum traces) has been performed for the compounding in the ***500L multi purpose vessel. The assessment of these results led to the conclusion that ***no cleaning validation is needed.

A cleaning validation for the compounding in the ***1200L multi purpose vessel is necessary.

***

BAXTER Document Code	Title
H PPVA VV 21477e	Validation Protocol Cleaning Validation of Process Equipment for Production of Picoplatin Injection 200 mL
To be added when available	Report

5.2 Process validation

***

BAXTER Document Code	Title
To be added when available	Protocol
To be added when available	Report

6 Batch Documentation, Pricing and Production Schedule

6.1 Batch Documentation

- Photocopy of the Released Executed Batch Record(s) to be available to PONIARD upon request within ***2 business days ***once PONIARD has certified BAXTER for batch record review. Prior to this ***certification by PONIARD, BAXTER will provide a photocopy of the Released Executed Batch Record(s) for each produced batch.
- Certificate of Analysis, to be provided by BAXTER to PONIARD for each produced batch.
- Certificate of Compliance, to be provided by BAXTER to PONIARD for each produced batch.

BAXTER shall maintain all of the production and testing records (raw data with respect to analytical measurements including microbiological analysis) for ***6 years. Details are regulated in the QUALITY AGREEMENT.

6.2 Purchase Price

***

500L Clinical Scale: Feasibility / Clinical Batches	
Batch size	**Batch Price (per batch)**
Up to 2,500 vials (theoretical batch size)	135,000 Euro

1200L Scale Batches : Development, Clinical, Validation and Commercial batches		
Batch size	**Number of batches**	**Batch Price (per batch)**
Up to 5,700 vials (theoretical batch size)	At least 2	192,000 Euro

Price Adjustment for Batches is described in the Commercial Supply Agreement

***

Additional Activities related to 1200L Scale Batches		
Activity	**Scope of Proposal #**	**Price (per batch)**
Transfer Activities (Picoplatin-related)	as of July 09, 2007	18,000 Euro
Transfer Activities (not Picoplatin-related)		68,700 Euro
Packaging Activities (per batch)		17,800 Euro
Mixing and Holding Time study	As of May 26, 2008	72,870 Euro

6.3 Value of the API

The value of the API is ***100 Euro per ***gram.

6.4 Production Schedule

PONIARD will provide BAXTER with purchase orders as set forth in the CLINICAL and COMMERCIAL SUPPLY AGREEMENTS.

6.5 Quality Assurance Audits

A charge of ***25,000 Euro (in words: ***twenty-five thousand Euro) for ***two days will be paid to BAXTER by PONIARD for quality assurance audits in excess of the number defined in the COMMERICAL SUPPLY AGREEMENT, except in the case of "For Cause Audits".

6.6 Regulatory Authority Inspection Audits

A charge of ***15,000 Euro (in words: ***fifteen thousand) per day will be paid to BAXTER by PONIARD for Picoplatin Injection related regulatory authority inspections (FDA-PAI). In the event that the inspection is for more than one product, these fees will be pro-rated.

A charge ***175 Euro (in words ***one hundred and seventy-five) per hour will be paid to BAXTER for PONIARD requested regulatory support (per signed regulatory plan).

6.7 Batch Records Review

A charge of ***150 Euro (in words: ***one hundred and fifty) per hour will be paid to BAXTER for PONIARD requested revisions to Master Batch Records in excess of ***two per year.

6.8 Reservation Fees

In case of a change to or cancellation of a Firm Purchase Order, either upon PONIARD's request or due to delayed Component deliveries caused by PONIARD, BAXTER shall use its best efforts to find a replacement for the unused capacity. If Baxter is unable to find a replacement for the unused capacity, PONIARD will be charged ***half of the batch price to compensate BAXTER for any unused direct labor and unused other resources due to the change or cancellation.

6.9 Acceleration Fees

A charge of ***800 Euro (***eight hundred) will be paid to BAXTER for delivery dates of material supplied by Poniard (e.g. API) that are less than the required ***20 days before a reserved Picoplatin manufacturing date.

6.10 Extended Storage of Picoplatin Drug Product

A charge of ***100 Euro (***one hundred) per ***pallet per ***month will be paid to BAXTER for PONIARD requested storage of the Picoplatin Drug Product in the warehouse of BAXTER for more than ***thirty (***30) days after PONIARD's Quality Assurance release of Product.
The duration of the storage time that is free of charge is defined in the COMMERCIAL SUPPLY AGREEMENT.

7 Shipping Responsibilities

All shipping activities will be done under EX WORKS conditions according to the INCOTERMS 2000.
PONIARD will be responsible to assign the shipments with an international forwarding company and to organize the transportation from Baxter to the country and the company specified by PONIARD, which conducts or arranges the final packaging and labeling activities.
BAXTER will support these activities with information to the forwarding company and preparation of the products for transportation.

All shipping activities from Poniard or its designees to Baxter shall be done under DDP conditions according to the INCOTERMS 2000.

8 Contacts and Responsible Persons

BAXTER

Contacts	**Name**	**Phone (Fax), email**
Technical pharmaceutical questions	Uwe Woelk, Ph.D.	~~[telephone number and e-mail address]~~ + 49 5201 711-1809 (1880) uwe_woelk@baxter.com
Technical pharmaceutical questions	Eckhard Fliegner	~~[telephone number and e-mail address]~~ + 49 5201 711-1892 (1880) eckhard_fliegner@baxter.com
Quality Control	Michael Rattay, Ph.D.	~~[telephone number and e-mail address]~~ + 49 5201 711-3463 (3480) michael_rattay@baxter.com
Quality Assurance	Dietmar Hofmann, Ph.D.	~~[telephone number and e-mail address]~~ + 49 5201 711 3489 (3480) dietmar_hofmann@baxter.com
Responsible persons	**Name**	**Phone/Fax**
Responsible for manufacturing	Olaf Reer, Ph.D.	~~[telephone number and e-mail address]~~ + 49 5201 711 2330 (2546) olaf_reer @baxter.com
Responsible for Quality Control (= qualified person as referred to in Art. 48 ff. of EU Directive 2001/83)	Dietmar Hofmann, Ph.D.	~~[telephone number and e-mail address]~~ + 49 5201 711 3489 (3480) dietmar_hofmann@baxter.com
Head of Quality Assurance		

PONIARD

Contacts	**Name**	**Phone/Fax**
Technical pharmaceutical questions/Manufacturing	Keith Hovda	~~[telephone number and e-mail address]~~ + 01-206-859-4103 khovda@poniard.com
Quality Assurance	Dana Wolf	~~[telephone number and e-mail address]~~ + 01206-286-286-2500 dwolf@poniard.com
Quality Control	Bruce Girton	~~[telephone number and e-mail address]~~ + 01206-286-286-2511 bgirton@poniard.com