

**Fill in this information to identify the case:**

Debtor Orexigen Therapeutics, Inc.

United States Bankruptcy Court for the: \_\_\_\_\_ District of Delaware  
(State)

Case number 18-10518

**Official Form 410  
Proof of Claim**

04/16

**Read the instructions before filling out this form. This form is for making a claim for payment in a bankruptcy case. Do not use this form to make a request for payment of an administrative expense. Make such a request according to 11 U.S.C. § 503.**

**Filers must leave out or redact** information that is entitled to privacy on this form or on any attached documents. Attach redacted copies or any documents that support the claim, such as promissory notes, purchase orders, invoices, itemized statements of running accounts, contracts, judgments, mortgages, and security agreements. **Do not send original documents;** they may be destroyed after scanning. If the documents are not available, explain in an attachment.

A person who files a fraudulent claim could be fined up to \$500,000, imprisoned for up to 5 years, or both. 18 U.S.C. §§ 152, 157, and 3571.

**Fill in all the information about the claim as of the date the case was filed. That date is on the notice of bankruptcy (Form 309) that you received.**

**Part 1: Identify the Claim**

<b>1. Who is the current creditor?</b>	<u>ATP, LLC</u> Name of the current creditor (the person or entity to be paid for this claim)	
	Other names the creditor used with the debtor _____	
<b>2. Has this claim been acquired from someone else?</b>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes. From whom? _____	
<b>3. Where should notices and payments to the creditor be sent?</b>  Federal Rule of Bankruptcy Procedure (FRBP) 2002(g)	<b>Where should notices to the creditor be sent?</b>	<b>Where should payments to the creditor be sent? (if different)</b>
	<u>ATP, LLC</u> <u>Hank Gerock, Assistant General Counsel</u> <u>929 North Front Street</u> <u>Wilmington, NC 28401, USA</u>	<u>PPD Medical Communications</u> <u>26361 Network Place</u> <u>Chicago, IL 60673-1263, USA</u>
	Contact phone <u>910-558-2902</u>	Contact phone _____
	Contact email <u>hank.gerock@ppdi.com</u>	Contact email _____
	Uniform claim identifier for electronic payments in chapter 13 (if you use one): _____	
<b>4. Does this claim amend one already filed?</b>	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes. Claim number on court claims registry (if known) _____ Filed on <u>May 09, 2018</u> MM / DD / YYYY	
<b>5. Do you know if anyone else has filed a proof of claim for this claim?</b>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes. Who made the earlier filing? _____	



**Part 2: Give Information About the Claim as of the Date the Case Was Filed**

6. Do you have any number you use to identify the debtor?  No  
 Yes. Last 4 digits of the debtor's account or any number you use to identify the debtor: \_\_\_\_ \_

7. How much is the claim? \$ 152,711.19. Does this amount include interest or other charges?  
 No  
 Yes. Attach statement itemizing interest, fees, expenses, or other charges required by Bankruptcy Rule 3001(c)(2)(A).

8. What is the basis of the claim? Examples: Goods sold, money loaned, lease, services performed, personal injury or wrongful death, or credit card.  
Attach redacted copies of any documents supporting the claim required by Bankruptcy Rule 3001(c).  
Limit disclosing information that is entitled to privacy, such as health care information.  
Services Performed

9. Is all or part of the claim secured?  No  
 Yes. The claim is secured by a lien on property.  
**Nature or property:**  
 Real estate: If the claim is secured by the debtor's principle residence, file a *Mortgage Proof of Claim Attachment* (Official Form 410-A) with this *Proof of Claim*.  
 Motor vehicle  
 Other. Describe: \_\_\_\_\_  
**Basis for perfection:** \_\_\_\_\_  
Attach redacted copies of documents, if any, that show evidence of perfection of a security interest (for example, a mortgage, lien, certificate of title, financing statement, or other document that shows the lien has been filed or recorded.)  
**Value of property:** \$ \_\_\_\_\_  
**Amount of the claim that is secured:** \$ \_\_\_\_\_  
**Amount of the claim that is unsecured:** \$ \_\_\_\_\_ (The sum of the secured and unsecured amount should match the amount in line 7.)  
**Amount necessary to cure any default as of the date of the petition:** \$ \_\_\_\_\_  
**Annual Interest Rate** (when case was filed) \_\_\_\_\_ %  
 Fixed  
 Variable

10. Is this claim based on a lease?  No  
 Yes. Amount necessary to cure any default as of the date of the petition. \$ \_\_\_\_\_

11. Is this claim subject to a right of setoff?  No  
 Yes. Identify the property: \_\_\_\_\_



12. Is all or part of the claim entitled to priority under 11 U.S.C. § 507(a)?

A claim may be partly priority and partly nonpriority. For example, in some categories, the law limits the amount entitled to priority.

No

Yes. Check all that apply:

	Amount entitled to priority
<input type="checkbox"/> Domestic support obligations (including alimony and child support) under 11 U.S.C. § 507(a)(1)(A) or (a)(1)(B).	\$ _____
<input type="checkbox"/> Up to \$2,850* of deposits toward purchase, lease, or rental of property or services for personal, family, or household use. 11 U.S.C. § 507(a)(7).	\$ _____
<input type="checkbox"/> Wages, salaries, or commissions (up to \$12,850*) earned within 180 days before the bankruptcy petition is filed or the debtor's business ends, whichever is earlier. 11 U.S.C. § 507(a)(4).	\$ _____
<input type="checkbox"/> Taxes or penalties owed to governmental units. 11 U.S.C. § 507(a)(8).	\$ _____
<input type="checkbox"/> Contributions to an employee benefit plan. 11 U.S.C. § 507(a)(5).	\$ _____
<input type="checkbox"/> Other. Specify subsection of 11 U.S.C. § 507(a)(____) that applies.	\$ _____

\* Amounts are subject to adjustment on 4/01/19 and every 3 years after that for cases begun on or after the date of adjustment.

13. Is all or part of the claim pursuant to 11 U.S.C. § 503(b)(9)?

No

Yes. Indicate the amount of your claim arising from the value of any goods received by the debtor within 20 days before the date of commencement of the above case, in which the goods have been sold to the Debtor in the ordinary course of such Debtor's business. Attach documentation supporting such claim.

\$ \_\_\_\_\_

**Part 3: Sign Below**

**The person completing this proof of claim must sign and date it. FRBP 9011(b).**

If you file this claim electronically, FRBP 5005(a)(2) authorizes courts to establish local rules specifying what a signature is.

**A person who files a fraudulent claim could be fined up to \$500,000, imprisoned for up to 5 years, or both. 18 U.S.C. §§ 152, 157, and 3571.**

*Check the appropriate box:*

I am the creditor.

I am the creditor's attorney or authorized agent.

I am the trustee, or the debtor, or their authorized agent. Bankruptcy Rule 3004.

I am a guarantor, surety, endorser, or other codebtor. Bankruptcy Rule 3005.

I understand that an authorized signature on this *Proof of Claim* serves as an acknowledgement that when calculating the amount of the claim, the creditor gave the debtor credit for any payments received toward the debt.

I have examined the information in this *Proof of Claim* and have reasonable belief that the information is true and correct.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on date 05/18/2018  
MM / DD / YYYY

/s/Henry Gerock III  
Signature

**Print the name of the person who is completing and signing this claim:**

Name Henry Gerock III  
First name Middle name Last name

Title Assistant General Counsel

Company Pharmaceutical Product Development, LLC  
Identify the corporate servicer as the company if the authorized agent is a servicer.

Address \_\_\_\_\_

Contact phone \_\_\_\_\_ Email \_\_\_\_\_



# KCC ePOC Electronic Claim Filing Summary

For phone assistance: Domestic (888) 830-4646 | International (310) 751-2641

<b>Debtor:</b> 18-10518 - Orexigen Therapeutics, Inc.		
<b>District:</b> District of Delaware		
<b>Creditor:</b> ATP, LLC Hank Gerock, Assistant General Counsel 929 North Front Street  Wilmington, NC, 28401 USA <b>Phone:</b> 910-558-2902 <b>Phone 2:</b>  <b>Fax:</b> 910-558-6951 <b>Email:</b> hank.gerock@ppdi.com	<b>Has Supporting Documentation:</b> Yes, supporting documentation successfully uploaded <b>Related Document Statement:</b>	
	<b>Has Related Claim:</b> No <b>Related Claim Filed By:</b>	
	<b>Filing Party:</b> Authorized agent	
<b>Disbursement/Notice Parties:</b> PPD Medical Communications 26361 Network Place  Chicago, IL, 60673-1263 USA <b>Phone:</b>  <b>Phone 2:</b>  <b>Fax:</b>  <b>E-mail:</b>  <b>DISBURSEMENT ADDRESS</b>		
<b>Other Names Used with Debtor:</b>	<b>Amends Claim:</b> Yes, May 09, 2018 <b>Acquired Claim:</b> No	
<b>Basis of Claim:</b> Services Performed	<b>Last 4 Digits:</b> No	<b>Uniform Claim Identifier:</b>
<b>Total Amount of Claim:</b> 152,711.19	<b>Includes Interest or Charges:</b> No	
<b>Has Priority Claim:</b> No	<b>Priority Under:</b>	
<b>Has Secured Claim:</b> No <b>Amount of 503(b)(9):</b> No <b>Based on Lease:</b> No <b>Subject to Right of Setoff:</b> No	<b>Nature of Secured Amount:</b> <b>Value of Property:</b> <b>Annual Interest Rate:</b> <b>Arrearage Amount:</b> <b>Basis for Perfection:</b> <b>Amount Unsecured:</b>	
<b>Submitted By:</b> Henry Gerock III on 18-May-2018 3:13:45 p.m. Eastern Time <b>Title:</b> Assistant General Counsel <b>Company:</b> Pharmaceutical Product Development, LLC		

**Attachment to Proof of Claim for ATP, LLC**

ATP, LLC (“PPD Medical Communications”) provided certain services for Orexigen Therapeutics, Inc. (“Orexigen”) pursuant to that certain Amendment Number 2 to Work Order Number 1 dated June 12, 2017 (“Amendment 2”), Amendment Number 1 dated May 1, 2017 (“Amendment 1”) and Work Order Number 1 dated May 15, 2016 (together with Amendment 2 and Amendment 1, the “Work Order”). A copy of the Amendment 2 is enclosed with this proof of claim. As requested by Orexigen, PPD Medical Communications engaged its affiliate Evidera, Inc. (“Evidera”) to provide certain services under the Work Order.

PPD Medical Communications submitted the following invoices to Orexigen for service fees earned and pass through costs incurred pursuant to the Work Order (collectively the “Invoices”). Orexigen has failed to pay the Invoices. Copies of the Invoices are attached to this proof of claim.

<b>Invoice Date</b>	<b>Invoice Number</b>	<b>Amount</b>
January 31, 2018	IN00372236 *	\$ 3,880.83
February 9, 2018	66300020118	\$ 57,351.30
March 9, 2018	66300020218	\$ 56,042.19
April 5, 2018	IN00384563 *	\$ 2,218.13 **
April 10, 2018	IN00385002 *	\$ 13,807.43
April 30, 2018	66300020318-US-1	\$ 23,845.27
	<b>Total</b>	<b>\$ 157,145.15</b>

\* Invoices IN00372236, IN00384563 and IN00385002 were issued directly to Orexigen by PPD Medical Communications affiliate PPD Development, L.P. These invoices cover the fees for the services provided by Evidera under the Work Order.

\*\* The total value of invoice IN00384563 is \$7,002.21. PPD Medical Communications only listed \$2,218.13 on the table above because that was the value of the services provided from March 1, 2018 through March 12, 2018.

**Total Proof of Claim Amount**

PPD Medical Communications’ total proof of claim amount is **\$157,145.15.**



PPD Development, LP  
 26361 Network Place  
 Chicago IL  
 60673-1263  
 UNITED STATES OF AMERICA

**INVOICE**

EIN : 74-2325267  
 Duns Number 109359435  
 www.ppdi.com

**Bill To:**

Orexigen Therapeutics, Inc.  
 3344 North Torrey Pines Ct.  
 Suite 200  
 La Jolla  
 CA 92037  
 UNITED STATES OF AMERICA

Global PM: Elizabeth Froom  
 Regional PM: Elizabeth Froom  
 Project Analyst: Sandra.Gay@ppdi.com  
 Customer Account : 2089

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Purchase Order #	Other Customer #	Invoice Number	Invoice Date	Due Date	Terms
US MEDICAL WRITING		IN00385002	10-Apr-2018	10-May-2018	30 Days

US PAMW

**Contract Description: Orexigen**

Invoice Detail Contract: 663002003	USD		
	NET	TAX	GROSS
Direct Cost US PAMW Units Mar 18 NA Estimate	13,807.43	0.00	13,807.43

NOTE: Any meals and entertainment expenses included in the above total are subject to the 50% limitations imposed by Section 274(n) of the Internal Revenue Code

**TOTALS**

<b>13,807.43</b>	<b>0.00</b>	<b>13,807.43</b>
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Where costs are incurred in currencies other than the contract currency, the exchange rates used on this invoice are valid for the stated credit period only. For any payment delays beyond this date, PPD reserves the right to amend the exchange rates and subsequently the invoice value

Invoice Questions should be directed to  
 Analyst: Bonnie.Foster@ppdi.com

**Wiring Instructions :**  
 PPD Development, LP  
 JPMorgan Chase Bank  
 Account Number 500002360  
 R/T Number 021000021  
 SWIFT/BIC CHASUS33

**Bank Details**

**ACH Instructions :**  
 PPD Development, LP  
 JPMorgan Chase Bank  
 Account Number 500002360  
 R/T Number 021000021

Orexigen EVA-20483-01; 66300-03  
Medical Writing Services

**Mysimba Deliverables - March - June 2018**

Deliverables	Rate	Units/Hrs	Total \$
Custom response letters			\$ -
<b>Ad-hoc support (hourly)</b>			\$ 2,216.98
Manager			\$ -
Sr. Medical Writer			\$ 432.00
Medical Writer			\$ -
Sr. Document Review Specialist			\$ -
			\$ 2,648.98

Orexigen EVA-20483-01; 66300-03  
 Medical Writing Services

**Contrave Deliverables - March - June 2018**

Deliverables	Rate	Units/Hrs	Total \$
Custom response letters			\$ -
<b>Ad-hoc support (hourly)</b>			\$ 5,542.45
Manager			\$ -
Sr. Medical Writer			\$ 5,616.00
Medical Writer			\$ -
Sr. Document Review Specialist			\$ -
			\$ <b>11,158.45</b>





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 Customer Account : 2089

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Purchase Order #	Other Customer #	Invoice Number	Invoice Date	Due Date	Terms
US MEDICAL WRITING		IN00377650	28-Feb-2018	30-Mar-2018	30 Days

US PAMW

**Contract Description: Orexigen**

Invoice Detail Contract: 663002003	USD		
	NET	TAX	GROSS
Direct Cost US PAMW Units Jan 18 NA	4,618.49	0.00	4,618.49

NOTE: Any meals and entertainment expenses included in the above total are subject to the 50% limitations imposed by Section 274(n) of the Internal Revenue Code

<b>TOTALS</b>	<b>4,618.49</b>	<b>0.00</b>	<b>4,618.49</b>
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Where costs are incurred in currencies other than the contract currency, the exchange rates used on this invoice are valid for the stated credit period only. For any payment delays beyond this date, PPD reserves the right to amend the exchange rates and subsequently the invoice value

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 Account Number 500002360  
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 SWIFT/BIC CHASUS33

**Bank Details**

**ACH Instructions :**  
 PPD Development, LP  
 JPMorgan Chase Bank  
 Account Number 500002360  
 R/T Number 021000021

**Mysimba Deliverables - January 2018**

Deliverables	Rate	Units/Hrs	Total \$
Custom response letters			\$ -
<b>Ad-hoc support (hourly)</b>			\$ -
Manager			\$ -
Sr. Medical Writer			\$ 216.00
Medical Writer			\$ -
Sr. Document Review Specialist			\$ -
			<b>\$ 216.00</b>

**Contrave Deliverables - January 2018**

Deliverables	Rate	Units/Hrs	Total \$
Custom response letters			\$ -
<b>Ad-hoc support (hourly)</b>			\$ 1,108.49
Manager			\$ -
Sr. Medical Writer			\$ 3,294.00
Medical Writer			\$ -
Sr. Document Review Specialist			\$ -
			\$ 4,402.49

### CRL Support

Product	CRL Title	Month
Contrave	Incidence of Tinnitus	January

### Ad-hoc Support (Queries, adhoc lit searches, and weekly safety lit searches only)

Position	Query Description	Hours	Month
Senior Medical Writer, Medical Writer	<ul style="list-style-type: none"> <li>Weekly safety literature searches (5 searches)</li> <li>Interactions with aripiprazole or lamotrigine?</li> <li>Interactions with Vivitrol</li> <li>lit search - Is there a contraindication with any cardiac conditions especially afib... questioning the interaction with certain neurotransmitters.</li> <li>info on diabetes prevention</li> <li>interactions with Chantix</li> <li>create spreadsheet of all tinnitus events from patient narratives</li> </ul>	15.25	January

**CRL Support**

Product	CRL Title	Month

**Ad-hoc Support (Query or lit search only)**

Position	Query Description	Hours	Month
Senior Medical Writer, Medical Writer	<ul style="list-style-type: none"><li>lit search - hypothalamic obesity</li><li>information available regarding Mysimba and craniopharyngioma in particular.</li></ul>	1	January



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Purchase Order #	Other Customer #	Invoice Number	Invoice Date	Due Date	Terms
US MEDICAL WRITING		IN00372236	31-Jan-2018	02-Mar-2018	30 Days

US PAMW

**Contract Description: Orexigen**

Invoice Detail Contract: 663002003	USD		
	NET	TAX	GROSS
Direct Cost US PAMW Units Dec 17 NA	3,880.83	0.00	3,880.83

NOTE: Any meals and entertainment expenses included in the above total are subject to the 50% limitations imposed by Section 274(n) of the Internal Revenue Code

<b>TOTALS</b>	<b>3,880.83</b>	<b>0.00</b>	<b>3,880.83</b>
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Where costs are incurred in currencies other than the contract currency, the exchange rates used on this invoice are valid for the stated credit period only. For any payment delays beyond this date, PPD reserves the right to amend the exchange rates and subsequently the invoice value

**Bank Details**

Invoice Questions should be directed to  
 Analyst: Bonnie.Foster@ppdi.com

**Wiring Instructions :**  
 PPD Development, LP  
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 Account Number 500002360  
 R/T Number 021000021  
 SWIFT/BIC CHASUS33

**ACH Instructions :**  
 PPD Development, LP  
 JPMorgan Chase Bank  
 Account Number 500002360  
 R/T Number 021000021

**Contrave Deliverables - December 2017**

Deliverables	Rate	Units/Hrs	Total \$
Custom response letters			\$ -
<b>Ad-hoc support (hourly)</b>			\$ 1,108.49
Manager			\$ -
Sr. Medical Writer			\$ 1,728.00
Medical Writer			\$ 1,044.34
Sr. Document Review Specialist			\$ -
			<b>\$ 3,880.83</b>

**CRL Support**

Product	CRL Title	Month
Contrace	Increased Lacrimation and Olfaction-Related Adverse Events	December

**Ad-hoc Support (Queries, adhoc lit searches, and weekly safety lit searches only)**

Position	Query Description	Hours	Month
Senior Medical Writer, Medical Writer	<ul style="list-style-type: none"> <li>Weekly safety literature searches (4 searches)</li> <li>Does the use of Contrace with rizatriptan increase the chance of serotonin syndrome?</li> <li>What MOA of bupropion in Contrace relates to the incidence of headaches seen clinically?</li> <li>Are there any studies on the reduction of visceral fat?</li> <li>Are there any studies on adinopectin levels?</li> <li>Were there any patients on concomitant triptans in phase 3 trials?</li> <li>Do we have any info on Contrace effect on testosterone levels or LH levels?</li> </ul>	13.5	December



## AMENDMENT NUMBER 2 TO WORK ORDER NUMBER 1

This **Amendment Number 2** ("Amendment") is entered into as of June 12, 2017, (the "Effective Date") by and between ATP, LLC d/b/a PPD Medical Communications ("*Provider*" or "*PPD*") and Orexigen Therapeutics, Inc. ("*Orexigen*").

WHEREAS, Orexigen and Provider entered into a certain Amendment Number 1 dated May 1, 2017 and Work Order Number 1 dated May 15, 2016, ("**Work Order No. 1**") pursuant to the terms of the Master Services Agreement dated April 7, 2016, between Orexigen, Orexigen Therapeutics Ireland Limited, and Provider.

WHEREAS, Orexigen and Provider wish to amend the Work Order No. 1, as set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter, the parties hereto agree as follows:

1. Section 4, Fees. Paragraph 4.4 shall be deleted in its entirety and replaced with the following:

"Fees for direct costs under this Work Order No. 1 shall not exceed the estimated budget total as shown below without the prior written approval of Orexigen.

Original Total:	\$799,503
Amendment 1	+ \$4,228
Amendment 2	<u>+ \$750,592</u>
Revised Work Order No. 1 Total:	<u>\$1,554,323</u>

2. Exhibit A, Staffing section. The staffing table shall be amended to add the table below, which extends the staffing from September 1, 2017 through August 31, 2018.

Staff Member	FTE
	<b>September 2017 - August 2018</b>
Nurse	2.72
Manager	0.30

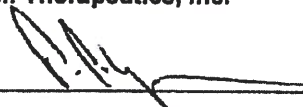
3. Exhibit A, Appendix A - Service Parameters shall be amended to include Appendix A-1 attached hereto and incorporated herein by reference. The Appendix A-1 contains the Service Parameters for ongoing services from September 1, 2017 through August 31, 2018.
4. Exhibit A, Appendix B - Budget Estimate shall be amended to include Appendix B-1 attached hereto and incorporated herein by reference. The Appendix B-1 contains the Budget Estimate for ongoing services from September 1, 2017 through August 31, 2018.
5. Exhibit A, Appendix C - PPD Fee Schedule shall be amended to include Appendix C-1 attached hereto and incorporated herein by reference. The Appendix C-1 contains the


PPD Fee Schedule for ongoing services from September 1, 2017 through August 31, 2018.

6. Exhibit A, Appendix D - IT System Support/Maintenance shall be deleted in its entirety and replaced with the revised Appendix D attached hereto and incorporated herein by reference. Appendix D has been updated to include these key changes:
- o Clarified process of implementing client provided software
  - o Increased time needed to implement new software due to increased desktop and network security protocols
  - o Clarified call flow changes timelines and what is considered in scope
  - o Added call retention language
7. Except as otherwise expressly set forth in this Amendment, all other terms and conditions of the Work Order No. 1 shall remain in full force and effect. In the event of any conflict between the terms of this Amendment and the terms of Work Order No. 1, the terms of this Amendment shall control.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the Effective Date.


Orexigen Therapeutics, Inc.

By:   
Name: Peter Flynn  
Title: SVP, Global Development, Regulatory Affairs & Safety  
Date: 7-18-2017

By:   
Name: Jason Keyes  
Title: SVP & CFO  
Date: 7-18-2017



ATP, LLC  
d/b/a Medical Communications

By:   
Name: Vivian Broach  
Title: VP, Operations  
Date: July 21, 2017



## APPENDIX A-1 - SERVICE PARAMETERS

PPD's budget estimates are based on the assumptions listed below. Any changes to the assumptions stated in these tables may impact service levels, budget and/or staffing levels. PPD will work to proactively notify Orexigen of any scope change that may affect staffing and budget.

**Table 1: Service Parameters**

<b>Medical Information Contact Center</b>	<b>Metrics</b>	
Contract Term	01 September 2017 - 31 August 2018	
Service Level	85/30 (85% of calls answered in 30 seconds or less)	
<b>Services</b>	<b>Volume Per Month</b>	<b>Average Handle Time (in mins)</b>
Inbound Calls	254	10
Adverse Events	112	35
Product Complaints	13	30
Non-Phone/Outbound		
Inquiries	186	15
Adverse Events	112	3
Product Complaints	11	20

<b>Medical Writing</b>	<b>Metrics</b>
Contract Term	01 September 2017 - 31 August 2018
<b>Services</b>	<b>Estimated Volume per Contract Term<sup>1</sup></b>
Develop custom response letter	120

Note 1: The number of units shown above is an estimate, based upon information received from Orexigen and PPD's experience with custom responses. Orexigen will only be billed for actual units expended. This approach may result in a total cost less than or greater than the estimated amount presented.

## **APPENDIX B-1 - BUDGET ESTIMATE**

The following budget estimates are based on the assumptions listed in Appendix A-1 and are based on a timeline of 01 September 2017 through 31 August 2018. All amounts are shown in US dollars (USD).

### **Medical Information Contact Center**

<b>Ongoing Direct Costs</b>	<b>Unit</b>	<b>No. Units</b>	<b>Cost</b>
Program Management			\$115,360
IT Support/Maintenance <sup>1</sup>			\$17,106
Contact Center Operations			
Weekday			\$482,507
<b>Total Direct Cost Estimate</b>			<b>\$614,973</b>

Note 1: Please refer to Appendix D for a detailed description of the services included in the monthly IT support fee

<b>Additional Pass-Through Costs (not included above)</b>	<b>Cost</b>
Language Translation, Copyright Clearance, Wide Area Network Access, Client Access to Telephony System, Travel and Lodging, Meals, Supplies, Phone and Fax Usage, Postage, Off-site Storage and Outsourced Copying	Actual cost, as incurred

### **Medical Writing Support**

<b>Ongoing Direct Costs</b>	<b>Unit</b>	<b>No. Units</b>	<b>Cost</b>
Project Management			\$2,601
Custom response letters			\$133,018
<b>Total Direct Cost Estimate</b>			<b>\$135,619</b>

<b>Additional Pass-Through Costs (not included above)</b>	<b>Cost</b>
Document Procurement, Language Translation, Copyright Clearance, Travel, Supplies, Off-site Storage and Outsourced Copying	Actual cost, as incurred

PPD will invoice the above services on a monthly basis according to the fee schedule shown in Appendix C-1.

## APPENDIX C-1 – PPD FEE SCHEDULE

All amounts are shown in US dollars (USD).

Effective 01 September 2017 – 31 August 2018

Medical Information Contact Center Services	Unit	Rate
<b><i>Ongoing Operational Support &amp; Training, as required</i></b>		
Associate Director		\$181.60
Operations Manager		\$144.30
Nurse – Weekday (Mon – Fri, 9am – 5pm ET)		\$85.42
Nurse – Holiday/Crisis*		\$124.45
Monthly IT Support <sup>1</sup>		\$1,425.52

Note 1. Please refer to Appendix D for a detailed description of the services included in the monthly IT support fee.

Additional Pass-Through Costs (not included above)	Cost
Language Translation, Copyright Clearance, Wide Area Network Access, Client Access to Telephony System, Travel and Lodging, Meals, Supplies, Phone and Fax Usage, Postage, Off-site Storage and Outsourced Copying	Actual cost, As incurred

Medical Writing Support	Unit	Rate
Custom Response Letters		\$1,108.49
<b><i>Hourly Support &amp; Training, as required</i></b>		
Manager		\$216.72
Sr. Medical Writer		\$216.00
Medical Writer		\$189.88
Sr. Document Review Specialist		\$144.12

Additional Pass-Through Costs (not included above)	Cost
Document Procurement, Language Translation, Copyright Clearance, Travel, Supplies, Off-site Storage and Outsourced Copying	Actual cost, As incurred

PPD invoices on a monthly basis according to the fee schedule shown above and Section 4.6 of the Agreement, based on the number of hours spent in one-fourth (1/4) hour increments.

\*The following days are considered as holidays for the purpose of this Agreement. If requested in writing at least 60 working days in advance, PPD's medical information contact center will provide services on these days as mutually agreed at the listed holiday rates. Should the

program operate on weekends, holiday rates will apply to Easter Sunday and to weekend days on which these observed holidays actually occur.

**US:**

New Year's Day (observed)  
Good Friday  
Memorial Day  
Independence Day (observed)  
Labor Day  
Thanksgiving  
Day after Thanksgiving  
Christmas Day (observed)  
Day after Christmas or Christmas Eve Day (observed)

## APPENDIX D – IT SYSTEM SUPPORT/MAINTENANCE

PPD's budget estimate contains a Monthly IT Support Fee, specific to the anticipated needs of this program. PPD's IT Monthly Fee includes routine technical support and management of the following, if applicable:

	Technology Scope	PPD	OREXIGEN
<b>1</b>	<b>PPD Standard End User Hardware</b>		
1.1	Provision of hardware per PPD's hardware standards	X	
1.2	Troubleshooting, repair and replacement of all PPD-owned hardware supporting the program	X	
<b>2</b>	<b>PPD Standard End User Software</b>		
2.1	Assign, configure, install, troubleshoot and maintain all PPD standard software applications	X	
2.2	Deploy and maintain security patches and anti-virus updates according to PPD procedures	X	
<b>3</b>	<b>Access to Orexigen systems (if applicable)</b>		
3.1	Provision of documented requirements for any Orexigen provided hardware and software including but not limited to network, telephony, and desktop configurations, including how each application is accessed		X
3.2	Determine if Orexigen application requires any software configuration changes or installations on PPD hardware identified as being incompatible with PPD's hardware and software standards.	X	
3.3	Evaluate, certify, package, and test software configuration and installation of Orexigen provided system	X	
3.4	Define a communication and support plan that includes a process for engaging Orexigen technical support, primary points of contact from PPD and Orexigen and a periodic review and assessment of system requirements. Establish a schedule for review and update of the plan.	X	X
3.5	Notify PPD a minimum of 45 business days in advance of any Orexigen initiated software implementations and/or updates affecting applications utilized by PPD staff in support of the program. When applicable, Orexigen will provide PPD with access to the software prior to the scheduled upgrade for preliminary testing purposes. Failure to provide notice or access to software in this time frame may result in loss of access to the application until the full process can be completed.		X
3.6	Assess and ensure any validation associated with 21 CFR Part 11 or other global regulatory requirements is conducted for any computerized system provided by Orexigen (software,		X

	Technology Scope	PPD	OREXIGEN
	application, etc.) as well as ongoing maintenance/validation of the system.		
<b>4</b>	<b>PPD Telephony &amp; Call Recording Systems (if applicable)</b>		
4.1	Provide a phone with voicemail	X	
4.2	Maintain and troubleshoot all PPD-issued telephony	X	
4.3	Configure and maintain standard call-routing capabilities	X	
4.4	Programming updates and/or changes to an existing call flow up to 4 times per year and are submitted a minimum of 10 business days prior to go live	X	
4.5	Manage pre-defined holiday call flow changes per the holidays outlined in the agreement.	X	
4.6	Record all calls for QA and training purposes. Call recordings will be retained for 45 days or as specified by country specific regulations.	X	
4.7	Routine maintenance, technical support and troubleshooting assistance to support PPD provisioned telephony services	X	
<b>5</b>	<b>Network Connectivity (if applicable)</b>		
5.1	Support and maintenance for Orexigen's dedicated virtual private network (VPN) connection and the inter-company VPN connections, including administration of the PPD firewall	X	
5.2	Support Orexigen requested connectivity changes and troubleshooting Orexigen's connectivity to PPD such as Orexigen initiated VPN changes, port configuration changes and performance testing. Included in the IT fee are 3 hours per incident.	X	X
5.3	Coordinate Orexigen initiated connectivity changes. Changes must be pre-approved by an authorized PPD security member prior to being scheduled for implementation per PPD's change control procedures. <b>A minimum of 10 business days is required to implement planned connectivity changes.</b>	X	X

#### Authorization for IT Out of Scope Services

Should PPD technical support be required outside of the scope listed above, which is based on the estimate known at the time of the proposal/contract, PPD will provide an estimate for the change(s) in service.

The PPD program manager will initiate a request with IT to obtain a quote for the proposed services. The PPD program manager will then coordinate with the authorized Orexigen representative to ensure the accuracy of the description of services included in the quote, and to obtain the required approvals. IT Out of Scope services are not performed unless mutually agreed upon in writing. Email approvals are acceptable when accompanied by the quote. If applicable, the PPD program manager will initiate a modification to the current Agreement to incorporate the revised scope of services.