## BRYN MAWR BANK CORP

Form 4 June 05, 2009

# FORM 4

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF

OMB

**OMB APPROVAL** 

Number:

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**SECURITIES** 

obligations may continue. See Instruction

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section

30(h) of the Investment Company Act of 1940

1(b).

(Print or Type Responses)

1. Name and Address of Reporting Person \* CONNELL GEORGE W

2. Issuer Name and Ticker or Trading

Symbol

BRYN MAWR BANK CORP

[bmtc]

5. Relationship of Reporting Person(s) to

Issuer

(Check all applicable)

(Last)

(City)

(First)

(Middle)

(Zip)

3. Date of Earliest Transaction

(Month/Day/Year)

06/03/2009

Director Officer (give title below)

X 10% Owner Other (specify

THREE RADNOR CORPORATE CENTER, SUITE 450

(Street)

(State)

4. If Amendment, Date Original

Filed(Month/Day/Year)

6. Individual or Joint/Group Filing(Check

Applicable Line)

\_X\_ Form filed by One Reporting Person Form filed by More than One Reporting

Person

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

RADNOR, PA 19087-4599

		140	1011	Derran	c beer	irides ricqui	rea, Disposea or,	or beneficial	y Owned
1.Title of Security	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if	3. Transactio			cquired (A)	5. Amount of Securities	6. Ownership	7. Nature of Indirect
(Instr. 3)	(Wolldin Buyl Tear)	any	Code	(Instr. 3,		` ′	Beneficially	Form:	Beneficial
(======================================		(Month/Day/Year)	(Instr. 8)	(======================================		-,	Owned Following	Direct (D) or Indirect	Ownership (Instr. 4)
					(4)		Reported	(I)	
					(A)		Transaction(s)	(Instr. 4)	
			Code V	Amount	or (D)	Price	(Instr. 3 and 4)		
common stock	06/03/2009		S	900	D	\$ 19.0721	1,675,075	D	
common stock	06/04/2009		S	4,500	D	\$ 19.022	1,670,575	D	

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

Persons who respond to the collection of SEC 1474 information contained in this form are not (9-02)required to respond unless the form displays a currently valid OMB control number.

Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned (e.g., puts, calls, warrants, options, convertible securities)

1. Title of	f 2.	3. Transaction Date	3A. Deemed	4.	5.	6. Date Exerc	cisable and	7. Title	e and	8. Price of	9. Nu
Derivativ	e Conversion	(Month/Day/Year)	Execution Date, if	Transacti	orNumber	Expiration D	ate	Amou	nt of	Derivative	Deriv
Security	or Exercise		any	Code	of	(Month/Day/	Year)	Under	lying	Security	Secui
(Instr. 3)	Price of		(Month/Day/Year)	(Instr. 8)	Derivative	e		Securi	ties	(Instr. 5)	Bene
	Derivative				Securities			(Instr.	3 and 4)		Owne
	Security				Acquired						Follo
					(A) or						Repo
					Disposed						Trans
					of (D)						(Instr
					(Instr. 3,						
					4, and 5)						
									Amount		
									Amount		
						Date	Expiration		or Number		
						Exercisable	Date		of		
				Code V	(A) (D)				Shares		
				Code v	(A) (D)				Shares		

# **Reporting Owners**

Relationships Reporting Owner Name / Address

> 10% Owner Officer Other Director

CONNELL GEORGE W THREE RADNOR CORPORATE CENTER **SUITE 450** RADNOR, PA 19087-4599



# **Signatures**

/gwconnell/

06/05/2009

\*\*Signature of Reporting Person Date

# **Explanation of Responses:**

- If the form is filed by more than one reporting person, see Instruction 4(b)(v).
- Intentional misstatements or omissions of facts constitute Federal Criminal Violations. See 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, see Instruction 6 for procedure. Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number. ousing, inventory management, storage and distribution of commercial and sample quantities of ANTARA capsules and FACTIVE tablets. We have an exclusive arrangement with Integrated Commercialization Solutions, Inc. (ICS) to perform such supply chain services with respect to commercial product through the second quarter of 2010.

We cannot be certain that ICS will be able to perform uninterrupted supply chain services. If ICS were unable to perform their services for any period, we may incur substantial loss of sales to wholesalers and other purchasers of our products. If we are forced to find an alternative supply chain service provider for ANTARA and FACTIVE, in addition to loss of sales, we may also incur costs in establishing a new arrangement.

Wholesalers, pharmacies and hospitals may not maintain adequate inventory for the distribution for our products.

We sell ANTARA and FACTIVE to wholesale drug distributors who generally sell products to retail pharmacies and other institutional customers. We do not promote ANTARA and FACTIVE to these wholesalers, and they do not determine such products prescription demand.

Reporting Owners 2

However, approximately 93% of our product shipments during the three-month period ended September 30, 2008 was to only three wholesalers. Our ability to commercialize ANTARA and/or FACTIVE will depend, in part, on the extent to which we maintain adequate distribution of ANTARA capsules and FACTIVE tablets via wholesalers, pharmacies and hospitals, as well as other customers. Although a majority of the larger wholesalers and retailers distribute and stock ANTARA and FACTIVE, they may be reluctant to do so in the future if demand is not established. Further, it is possible that wholesalers could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to distribute smaller volume products, or cause higher product distribution costs, lower margins or the need to find alternative methods of distributing products. Such alternative methods may not exist or may not be economically viable. If we do not maintain adequate distribution of ANTARA capsules or FACTIVE tablets, the commercialization of ANTARA and/or FACTIVE and our anticipated revenues and results of operations could be adversely affected.

Under our financing arrangement with Paul Capital, upon the occurrence of certain events, Paul Capital may require us to repurchase the right to receive revenues that we assigned to it or may foreclose on certain assets that secure our obligations to Paul Capital. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital could adversely affect our results of operations and our financial condition.

On August 18, 2006, we and our subsidiary Guardian II Acquisition Corporation, or Guardian II, entered into a Revenue Interests Assignment Agreement with Paul Capital pursuant to which we assigned to Paul Capital the right to receive a portion of our net revenues from FACTIVE tablets and Guardian II assigned to Paul Capital the right to receive a portion of its net revenue from ANTARA capsules. To secure its obligations to Paul Capital, Guardian II also granted Paul Capital a security interest in substantially all of its assets, including the U.S. rights to ANTARA.

Under our arrangement with Paul Capital, upon the occurrence of certain events (the Put Events), including if we experience a change of control, undergo certain bankruptcy events of us or our subsidiary, transfer any or substantially all of our rights in ANTARA or FACTIVE, transfer all or substantially all of our assets, breach certain of the covenants, representations or warranties under the Revenue Interests Assignment Agreement, or sales of ANTARA are suspended due to an injunction or if we elect to suspend sales of ANTARA as a result of a lawsuit filed by certain third parties, Paul Capital may (i) require us to repurchase the rights we assigned to it at the price in cash which equals the greater of (a) 200% of cumulative payments made by Paul Capital under the Revenue Interests Assignment Agreement less the cumulative royalties previously paid to Paul Capital; or (b) the amount which will provide Paul Capital, when taken together with the royalties previously paid, a 22% internal rate of return (the Put/Call Price) in effect on the date such right is exercised or (ii) foreclose on the ANTARA assets that secure our obligations to Paul Capital. Except in the case of certain bankruptcy events, if Paul Capital exercises its right to cause us to repurchase the rights we assigned to it, Paul Capital may not foreclose unless we fail to pay the Put/Call Price as required.

On November 5, 2008 we entered into a first amendment (the Amendment ) to the Revenue Interest Assignment Agreement. The Amendment provides, among other things, that Paul Capital will consent to the grant by Guardian II of a second-ranking security interest in and to the assets of Guardian II to secure Guardian II s guarantee of the proposed new notes that will be issued in the exchange offer launched October 21, 2008 (the Exchange Offer ). The effectiveness of the Amendment is contingent upon, among other closing conditions, the closing of the Exchange Offer. The Amendment provides that any acceleration or failure to pay the new notes to be issued in the Exchange Offer would be considered a Put Event triggering Paul Capital s right to cause us to repurchase the right we assigned to it as described above.

If Paul Capital were to exercise its right to cause us to repurchase the right we assigned to it, there can be no assurance that we would have sufficient funds available to pay the Put/Call Price in effect at that time. Even if we have sufficient funds available, we may have to use funds that we planned to use for other purposes and our results of operations and financial condition could be adversely affected. If Paul Capital were to foreclose on the ANTARA assets that secure our obligations to Paul Capital, our results of operations and financial condition could also be adversely affected. Paul Capital s right to cause us to repurchase the rights we assigned to it is triggered by, among other things, a change in control, transfer of any of our interests in ANTARA or transfer of all or substantially all of our assets, the existence of that right could discourage us or a potential acquirer from entering into a business transaction that would result in the occurrence of any of those events.

The development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase, if third parties upon whom we rely to support the development and commercialization of our products do not fulfill their obligations.

In addition to using third parties to fulfill our manufacturing, distribution and supply chain services, our development and commercialization strategy entails entering into arrangements with corporate collaborators, contract research organizations, licensors, licensees and others to conduct development work, manage our clinical trials and market and sell our products outside of the United States. We do not have the expertise or the resources to conduct such activities on our own and, as a result, we are particularly dependent on third parties in these areas. For instance, we have entered into exclusive arrangements granting rights to Pfizer, S.A. de C.V, Abbott Laboratories, Ltd. and Menarini International Operation Luxembourg S.A. to develop and sell FACTIVE in Mexico, Canada and Europe, respectively. However, we amended our agreement with Abbott Canada on January 31, 2008, whereby Abbott Canada s development and commercial obligations were substantially reduced.

We may not be able to maintain our existing arrangements with respect to the commercialization of our existing products, ANTARA and FACTIVE, or establish and maintain arrangements or partnerships to develop and commercialize Ramoplanin or any additional product candidates or products we may acquire on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to our current products, Ramoplanin, our other product candidates or any additional products we may acquire on terms which we deem favorable, our results of operations would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing and commercializing our products are not within our control. Furthermore, our interests may differ from those of third parties that commercialize our products. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to conduct its activities in a timely and regulatory compliant manner, such breach, termination or failure could:

delay or otherwise adversely impact the development or commercialization of ANTARA capsules, FACTIVE tablets, Ramoplanin, or any additional product candidates or any additional product candidates that we may acquire or develop;

require us to undertake unforeseen additional responsibilities or devote unforeseen additional resources to the development or commercialization of our products; or

result in the termination of the development or commercialization of our products.

We bear substantial responsibilities under our license agreements for ANTARA and FACTIVE and our sublicense agreements to Pfizer, S.A. de C.V., Abbott Laboratories, Ltd. and Menarini International Operation Luxembourg S.A., and there can be no assurance that we will successfully fulfill our responsibilities.

### **ANTARA**

Our exclusive rights to ANTARA are licensed to us by Ethypharm, S.A. (Ethypharm). If we breach the obligations in any of our license agreements relating to ANTARA including the development, license and supply agreement with Ethypharm, the licensor may be entitled to terminate the agreement. Further, in order to maintain our exclusive rights, we must achieve certain minimum annual sales of ANTARA until February 2012 or make payments to Ethypharm to compensate for the difference. Ethypharm also has a right of first refusal on any divestiture of our rights to ANTARA.

We believe that we are currently in compliance with our obligations under the Ethypharm agreement, but there can be no assurance that we will be able to remain in compliance or that we will be able to meet the milestones required for extension of the agreement. As of September 30, 2008, we recorded approximately \$605,000 related to a minimum royalty obligation to Ethypharm for the period February 2006 to January 2007. Moreover, Ethypharm s right of first refusal on a divestiture of our rights to ANTARA may adversely affect our ability to effect a change of

control or sale of our assets.

# *FACTIVE*

We have an exclusive license from LG Life Sciences to develop and market FACTIVE in North America, France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland,

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Norway, Iceland, Switzerland, Andorra, Monaco, San Marino, Vatican City, Poland, Czech Republic, Slovakia, Slovenia, Hungary, Estonia, Latvia, Lithuania, Liechtenstein, Malta, Cyprus, Romania, Bulgaria, Croatia, Serbia and Montenegro, Bosnia and Herzegovina, Albania and the Former Yugoslav Republic of Macedonia. Under this agreement, we are responsible, at our expense and through consultation with LG Life Sciences, for the clinical and commercial development of FACTIVE in the countries covered by the license, including the conduct of clinical trials, the filling of drug approval applications with the FDA and other applicable regulatory authorities and the marketing, distribution and sale of FACTIVE in our territory. The agreement with LG Life Sciences also requires that we achieve a minimum gross sales level of \$30 million from our licensed territories over a 12-month period of time starting in approximately the third quarter of 2007 to the third quarter of 2008 which, if not met, LG Life Sciences could elect to terminate the agreement and have the technology be returned to LG Life Sciences. We believe that we are currently in compliance with our obligations under the agreement with LG Life Sciences, but there can be no assurance that we will be able to remain in compliance and meet all of our obligations due to the limitations on our resources and the challenges inherent in the commercialization of new products as described above in Our product candidates will face significant competition in the marketplace.

LG Life Sciences has the obligation under the agreement to diligently maintain its patents and the patents of third parties to which it has rights that, in each case relating to gemifloxacin, the active ingredient in FACTIVE tablets. We have the right, at our expense, to control any litigation relating to suits brought by a third party alleging that the manufacture, use or sale of gemifloxacin in its licensed field in the territories covered by the license infringes upon our rights. We also have the primary right to pursue actions for infringement of any patent licensed from LG Life Sciences under the license agreement within the territories covered by the license. If we elect not to pursue any infringement action, LG Life Sciences has the right to pursue it. The costs of any infringement actions are first paid out of any damages recovered. If we are the plaintiff, the remainder of the damages are retained by us, subject to our royalty obligations to LG Life Sciences is the plaintiff, the remainder of the damages are divided evenly between us and LG Life Sciences, subject to our royalty obligations to LG Life Sciences. The costs of pursuing any such action could substantially diminish our resources.

In February 2006, we entered into a Sublicensing and Distribution Agreement with Pfizer, S.A. de C.V. (Pfizer Mexico) whereby we sublicensed our rights to commercialize FACTIVE tablets in Mexico to Pfizer Mexico. Under this agreement, we are obligated to exclusively supply all active pharmaceutical ingredient for FACTIVE required by Pfizer Mexico in Mexico. The agreement with Pfizer Mexico may be terminated by either party upon the occurrence of certain termination events, including Pfizer Mexico s right to terminate at any time after August 2007, the first anniversary of launch of FACTIVE tablets in Mexico upon six-months prior written notice.

In August 2006, we entered into a Supply, Development and Marketing Agreement with Abbott Laboratories, Ltd. (Abbott Canada), the Canadian affiliate of Abbott. Under this agreement, we are obligated to exclusively supply all finished packaged FACTIVE product required by Abbott Canada. The agreement also provides that we can terminate the agreement at any time with prior notice to Abbott Canada and Abbott Canada can terminate with prior notice to us after November 30, 2008.

In December 2006, we entered into a License, Supply and Marketing Agreement with Menarini International Operation Luxembourg S.A. (Menarini), whereby we sublicensed our rights to sell FACTIVE tablets in Europe to Menarini. Under the terms of our agreement with Menarini, Menarini is also obligated to exclusively purchase from us, and we must exclusively supply, all API for FACTIVE to be sold in Europe for the earlier to occur of the expiration of the life of certain patents covering the product or expiration of data exclusivity. Our agreement with Menarini may be terminated by either party upon the occurrence of certain termination events, including Menarini s right to terminate if the European regulatory authorities do not recommend approval of FACTIVE at various stages of the approval process with a package insert, or label, that meets certain requirements as to the safety, dosing and indications for which FACTIVE may be prescribed. Menarini may also terminate the agreement if it does not receive approval for reimbursement from European Union member countries that is above a certain minimum price per tablet.

We believe that, together with our manufacturing partners, we will be able to meet such supply and other obligations under these sublicense and supply agreements but can make no assurances that we will be able to remain in compliance with such responsibilities, which would result in our breach of such agreement.

#### Our intellectual property protection and other protections may be inadequate to protect our products.

Our success will depend, in part, on our ability to obtain commercially valuable patent claims and protect our intellectual property. The degree of protection afforded by a patent varies on a country-by-country and a product-by-product basis and depends upon many factors, including the scope of the patent s claims, the availability of regulatory-related patent term extensions, the validity and enforceability of the patent and the availability of legal remedies in a particular country. We currently own or license approximately 56 issued U.S. patents, approximately 40 pending U.S. patent applications, approximately 60 issued foreign patents and approximately 109 pending foreign patent applications. We are not currently involved in any litigation, settlement negotiations, or other legal action regarding patent issues and we are not aware of any patent litigation threatened against us. Our patent position involves complex legal and factual questions, and legal standards relating to the issuance, scope, validity and enforceability of claims in the applicable technology fields are still evolving. Therefore, the degree of future protection for

our proprietary rights is uncertain.

Under our Development, License and Supply Agreement with Ethypharm, S.A., we assumed all of the rights and obligations related to the development, manufacturing, marketing and sale of ANTARA in the United States. This license includes one issued U.S. patent and several pending patent applications. In conjunction with the financing of our acquisition of ANTARA, we entered into a Security Agreement

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with Paul Royalty Fund Holdings II, LP, an affiliate of Paul Capital Partners, or Paul Capital, under which our wholly-owned subsidiary granted Paul Capital a security interest in substantially all of its assets, including all rights to the ANTARA intellectual property, in order to secure its performance under the financing agreements with Paul Capital. In connection with the issuance of the new notes in the proposed Exchange Offer, Guardian II and the collateral agent for the new note holders will enter into a Security Agreement under which Guardian II will grant the collateral agent a second priority security interest in substantially all of the assets of Guardian II to secure Guardian II s guarantee of our obligations with respect to the new notes. The patents and applications include claims that relate to pharmaceutical compositions containing fenofibrate using the drug delivery technologies incorporated in ANTARA, methods of their use and treatment, and methods of preparing the same. The patent issued to Ethypharm which is listed in the FDA Orange Book is set to expire in 2020.

Under our license agreement with LG Life Sciences, we obtained an exclusive license to develop and market gemifloxacin in certain territories. This license covers 18 issued U.S. patents and a broad portfolio of corresponding foreign patents and pending patent applications. These patents include claims that relate to the chemical composition of FACTIVE, methods of manufacturing and its use for the prophylaxis and treatment of bacterial infections. We have received a Notice of Final Determination from the U.S. Patent and Trademark Office on our patent term extension application for U.S. Patent No. 5,776,944 extending its patent term 659 days to April 4, 2017. The principal U.S. patents for FACTIVE are currently set to expire at various dates, ranging from 2015 to 2019. As discussed under, If third parties challenge the validity of the patents or proprietary rights of our marketed products or assert that we have infringed their patents or proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and prevent the commercialization of ANTARA, FACTIVE and/or any other products that we acquire, we recently received notice of a Paragraph IV certification from Orchid Healthcare, a Division of Orchid Chemicals & Pharmaceuticals Ltd. (Orchid), notifying us of their filing of an ANDA for a generic version of FACTIVE. The certification alleges that eight of the nine FDA Orange Book listed patents are invalid and/or will not be infringed by Orchid s manufacture, importation, use, or sale of the product for which the ANDA was submitted. The certification does not, however include a Paragraph IV certification with respect to U.S. Patent No. 5,633,262 which is listed in the Orange Book and expires in June 2015. We are continuing to evaluate whether to commence litigation in response to Orchid s Paragraph IV certification. In the event Orchid elects to amend its ANDA to include a Paragraph IV certification with respect to the ninth patent, U.S. Patent No. 5,633,262, we believe that we will be entitled to an automatic thirty-month stay of FDA approval of the ANDA if either we and/or LG Life Sciences initiate a timely patent infringement lawsuit against Orchid, however, we are not guaranteed the benefit of such a thirty month stay. Patent infringement litigation against Orchid could be a substantial cost and there are no assurances that we would be successful.

We may depend, in part, on the ability of our licensors to successfully obtain, maintain and enforce patent protection for our licensed intellectual property. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

On January 8, 2008 the United States Patent and Trademark Office ( USPTO ) issued us U.S. Patent No. 7,317,001 relating to the treatment of *Clostridium difficile* associated disease ( CDAD ) using Ramoplanin. We received a patent term adjustment of 565 days thus extending the term through December 20, 2024. In addition to the recently issued patent, we have an additional patent which includes claims relating to methods of manufacturing Ramoplanin. We also have several applications pending relating to additional novel uses of Ramoplanin as well as formulations containing Ramoplanin. The patent covering the chemical composition of Ramoplanin has expired. To provide additional protection for Ramoplanin, we rely on proprietary know-how relating to maximizing yields in the manufacture of Ramoplanin, and intend to rely on the five years of data exclusivity we believe we would receive under the Hatch-Waxman Act in the U.S. and the ten years of market exclusivity in Europe available through the European Medicines Agency (EMEA), because Ramoplanin would be a new chemical entity not previously marketed commercially.

We also have the exclusive right to use FACTIVE trademarks, trade names, domain names and logos in conjunction with the use or sale of the product in the territories covered by the license. We acquired exclusive rights to ANTARA trademarks, trade names, domain names and logos. After becoming aware that Antara Biosciences, Inc. filed trademark applications with the USPTO for the ANTARA and ANTARA BIOSCIENCES marks in connection with biotechnology related goods and services we filed a complaint in Federal District Court alleging, among other things, trademark infringement seeking to enjoin ANTARA BIOSCIENCES from using the ANTARA mark. We have reached a settlement with ANTARA BIOSCIENCES whereby they have agreed to abandon their ANTARA trademark applications and cease using the ANTARA marks. Accordingly we have dismissed our complaint before the Federal District Court.

The risks and uncertainties that we will face with respect to our patents and other proprietary rights include the following:

the pending patent applications that we have filed or to which we have exclusive rights may not result in issued patents, may result in issued patents with narrower claims than anticipated or may take longer than expected to result in issued patents;

U.S. Patents may be subject to reexamination or reissue proceedings before the USPTO, and foreign patents may be subject to comparable proceedings in corresponding patent offices;

the claims of any patents which are issued may be limited from those in the patent applications and may not provide meaningful protection;

we may not be able to develop additional proprietary technologies that are patentable;

the patents licensed or issued to us or our partners may not provide a competitive advantage;

other companies, such as Orchid, may challenge patents licensed or issued to us or our partners;

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patents issued to other companies may harm our ability to do business;

the April 30, 2007 U.S. Supreme Court decision in KSR International Co. vs. Teleflex, Inc. may raise the standard for patentability for both patent applications and holders, thus making it more difficult to either obtain patents or withstand challenges to patentability based on a determination of obviousness:

other companies may independently develop similar or alternative technologies or duplicate our technologies; and

the patents may be narrow in scope and accordingly other companies may design around technologies we have licensed or developed.

#### International patent protection is uncertain.

Patent law outside the United States is uncertain and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as U.S. laws. We may participate in opposition proceedings to determine the validity of our or our competitors foreign patents, which could result in substantial costs and diversion of our efforts.

#### Our proprietary position may depend on our ability to protect our proprietary confidential information and trade secrets.

We rely upon certain proprietary confidential information, trademarks, unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We generally protect this information with confidentiality agreements that provide that all confidential information developed or made known to others during the course of the employment, consulting or business relationship shall be kept confidential except in specified circumstances. Agreements with employees provide that all inventions conceived by an individual while employed by us are our exclusive property. We cannot guarantee, however, that these agreements will be honored, that we will have adequate remedies for breach if they are not honored or that our proprietary confidential information and trade secrets will not otherwise become known or be independently discovered by competitors.

# Seasonal fluctuations in demand for FACTIVE, and even possibly ANTARA, may cause our operating results to vary significantly from quarter to quarter.

We expect demand for FACTIVE to be highest between December 1 and March 31 as the incidence of respiratory tract infections, including CAP and AECB, tends to increase during the winter months. In addition, fluctuations in the duration and severity of the annual respiratory tract infection season may cause our product sales to vary from year to year. Due to these seasonal fluctuations in demand, our results in one quarter may not be indicative of the results for any other quarter or for the entire year. Although not related to seasonal weather changes, wholesaler buying patterns may fluctuate for ANTARA during the year and possibly increase toward year end and decrease early in the year. There can be no assurance that the demand for our products or the wholesaler buying pattern will not change.

# Clinical trials are costly, time consuming and unpredictable, and we have limited experience conducting and managing necessary preclinical and clinical trials for product candidates.

To obtain FDA approval to market a new drug product or to expand the approved uses of an existing product, we or our partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we or our partners will have to conduct extensive testing, including potentially preclinical testing and adequate and well-controlled clinical trials. Conducting clinical trials is a lengthy, time-consuming and expensive process. The length of time required to conduct required studies may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which clinical trials are required may cause us to incur additional operating expenses.

The Phase II trial for our product candidate, Ramoplanin, to assess the safety and efficacy of treating *Clostridium difficile*-associated disease, or CDAD, was completed in 2004 but did not meet its primary endpoint. Prior clinical and preclinical trials for Ramoplanin were conducted by Vicuron and its licensees, from whom we acquired rights to Ramoplanin. In December 2005 we agreed with the FDA to a Special Protocol Assessment regarding specific components of a Phase III program that, if completed successfully, would support regulatory approval for the indication. However, due to the nature of Special Protocol Assessments and the fact that our Special Protocol Assessment was agreed to by the FDA in 2005, we can give no assurance that as clinical trials proceed or as part of an NDA review process, if any, the FDA will not determine

that a previously approved Special Protocol Assessment for a particular protocol is no longer valid. Additionally, in October 2007, the FDA issued draft guidance on the use of non-inferiority studies to support approval of antibiotics. Under this draft guidance, the FDA recommends that for some antibiotic indications, sponsor companies carefully consider study designs other than non-inferiority, such as placebo-controlled trials demonstrating the superiority of a drug candidate to placebo. While the indications identified by the FDA in the draft guidance are not indications which we are currently pursuing, the draft guidance does not articulate clear standards or policies for demonstrating the safety and efficacy of antibiotics generally. The lack of clear guidance from the FDA creates uncertainties about the standards for the approval of antibiotics and could delay or ultimately prevent commercialization of new antibiotic product candidates such as Ramoplanin or additional indications for FACTIVE. If the trials or the filings are delayed or not approved by the FDA, our business may be adversely affected. Currently, we have suspended the clinical development program for Ramoplanin pending identification of a partner, licensee, or buyer for the product.

If we choose to pursue additional indications or expand the label for ANTARA or FACTIVE, or are required to conduct additional clinical trials, we may not be able to demonstrate the safety and efficacy of FACTIVE or ANTARA for those indications to the satisfaction of the FDA, or other regulatory authorities. We may also be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies and we may be unable to do so without conducting further clinical studies. Negative, inconclusive or inconsistent clinical trial results could prevent regulatory approval, increase the cost and timing of regulatory approval or require additional studies or a filing for a narrower indication or label expansion.

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In addition, the cost of human clinical trials varies dramatically based on a number of factors, including the order and timing of clinical indications pursued, the extent of development and financial support from alliance partners, the number of patients required for enrollment, the difficulty of obtaining clinical supplies of the product candidate, and the difficulty in obtaining sufficient patient populations and clinicians.

We have limited experience in conducting and managing the preclinical and clinical trials necessary to obtain regulatory marketing approvals. We may not be able to obtain the approvals necessary to conduct clinical studies. Also, the results of our clinical trials may not be consistent with the results obtained in preclinical studies or the results obtained in later phases of clinical trials may not be consistent with those obtained in earlier phases. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal and human testing.

Even if a product gains regulatory approval, the product and the manufacturer of the product will be subject to continuing regulatory review, including the requirement to conduct post-approval clinical studies post-approval adverse event reporting requirements and, potentially, a REMS. We may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered.

#### We could experience delays in clinical development which could delay anticipated product launches.

The speed with which we are able to complete clinical trials for future product candidates, when and if we, or any third party with whom we partner, elects to commence Phase III development of Ramoplanin, and our applications for marketing approval will depend on several factors, including the following:

the rate of patient enrollment, which is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the nature of the protocol;

fluctuations in the disease incidence for patients available to enroll in our trials;

compliance of patients and investigators with the protocol and applicable regulations;

prior regulatory agency review and approval of our applications and procedures;

Institutional Review Board (IRB) review and monitoring;

analysis of data obtained from preclinical and clinical activities which are susceptible to varying interpretations, which interpretations could delay, limit or prevent regulatory approval;

changes in the policies of regulatory authorities for drug approval during the period of product development including the FDA s recent draft guidance released in October 2007 relating to Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval; and

the availability of skilled and experienced staff to conduct and monitor clinical studies, to accurately collect data and to prepare the appropriate regulatory applications.

We depend on key personnel, including members of our direct sales force, in a highly competitive market for such skilled personnel.

We are highly dependent on the principal members of our senior management and key scientific, sales and technical personnel. The loss of any of our personnel could have a material adverse effect on our ability to achieve our goals. We currently maintain employment agreements with the following executive officers: Steven M. Rauscher, President and Chief Executive Officer; Dominick Colangelo, Esq., Executive Vice President, Corporate Development and Operations; Philippe M. Maitre, Executive Vice President and Chief Financial Officer; and Mark A. Glickman, Senior Vice President, Sales and Marketing. The term of each employment agreement continues until it is terminated by the officer or Oscient.

Our future success is dependent upon our ability to attract and retain additional qualified sales and marketing, clinical development, scientific and managerial personnel. Like others in our industry, we may face, and in the past we have faced from time to time, difficulties in attracting and retaining certain employees with the requisite expertise and qualifications. We believe that our historical recruiting periods and employee turnover rates are similar to those of others in our industry; however, we cannot be certain that we will not encounter greater difficulties in the future.

With routine employee turnover, we also face the risk of being unable to enforce our rights under non-compete and non-solicitation provisions as well as confidentiality obligations that protect the Company. We also need to guard against the same obligations that our employees or our potential employees have with their former employers, otherwise we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers and disputes may arise as to rights in related or resulting know-how and inventions. Litigation may be necessary to defend against these claims, which may result in substantial costs, be a distraction to management, require payment of money claims, and result in a loss of valuable intellectual property or personnel.

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## Failure to obtain or maintain regulatory approvals in foreign jurisdictions will prevent us from marketing FACTIVE abroad.

We have entered into commercialization relationships with Pfizer Mexico, Abbott Canada and Menarini whereby we sublicensed our rights to sell FACTIVE tablets in Mexico to Pfizer Mexico, in Canada to Abbott Canada and in Europe to Menarini. Obtaining foreign approvals may require additional trials and expense. Further, in order to market FACTIVE in Europe, we or our distribution partners may need to obtain multiple regulatory approvals. For instance, in the first quarter of 2008, Menarini, submitted a regulatory filing seeking approval of FACTIVE in Europe. Menarini is seeking approval of FACTIVE for the treatment of community-acquired pneumonia and acute bacterial exacerbations of chronic bronchitis. The regulatory review time in Europe is approximately twelve (12) months. Menarini may not be able to obtain regulatory approval for FACTIVE, which could delay or prevent us from receiving revenue from sales of FACTIVE in Europe, and/or may require additional expenditures.

We may not be able to obtain approval or may be delayed in obtaining approval from any or all of the jurisdictions in which we seek approval to market FACTIVE. Further, based on the amendment of our agreement with Abbott Canada of January 31, 2008, Abbott Canada is no longer obligated to pursue the CAP and ABS indications in Canada. If our partners are unsuccessful in their efforts to obtain and/or expand their respective marketing approvals, the revenues that we expect to obtain from the sales of FACTIVE could be significantly limited.

## We rely on operational data obtained from third party vendors which could be inaccurate.

We rely on prescription and wholesaler data obtained from industry-accepted, third-party data sources. These third-party data projections may not accurately reflect actual prescriptions or trade levels of inventory. If this data turns out to be inaccurate or unreliable and our controls are not effective, there could be an adverse effect on our ability to properly manage inventory and our financial performance.

#### RISKS RELATED TO OUR INDUSTRY

#### Health care insurers, the government and other payers may not pay for our products or may impose limits on reimbursement.

Our ability to commercialize ANTARA capsules, FACTIVE tablets, Ramoplanin and our future products will depend, in part, on the extent to which reimbursement for such products will be available from third-party payers, such as Medicare, Medicaid, health maintenance organizations, health insurers and other public and private payers. We cannot assure you that third-party payers will pay for such products or will establish and maintain price levels sufficient for realization of an appropriate return on our investment in product development. If government and private payers do not cover our products or do not reimburse for use of our products at adequate reimbursement levels, our products may fail to achieve market acceptance and our results of operations may be materially adversely affected. Under the Medicare Part D outpatient prescription drug benefit, Medicare beneficiaries (primarily the elderly over 65 and the disabled) may enroll in private drug plans. There are multiple types of Part D plans and numerous plan sponsors, each with its own formulary and product access requirements. The plans have considerable discretion in establishing formularies and tiered co-pay structures and in placing prior authorization and other restrictions on the utilization of specific products. In addition, Part D plan sponsors are permitted and encouraged to negotiate rebates with manufacturers. The profitability of our products may depend on the extent to which they enjoy preferred status on the formularies of a significant portion of the largest Part D prescription drug plans. Our ability to obtain such preferred status on favorable economic terms cannot be assured. Additionally, the Part D program has been the subject of much controversy since its enactment in 2003, and significant amendments, including an amendment to authorize the Federal Government to directly negotiate drug prices with manufacturers, are possible. Such amendments could adversely affect our anticipated revenues and results of operations, possibly materially.

Most state Medicaid programs have established preferred drug lists, or PDLs, and the process, criteria and timeframe for obtaining placement on the PDL varies from state to state. Under the Medicaid drug rebate program, a manufacturer must pay a rebate for Medicaid utilization of a product. The rebate for an innovator product is based on the greater of (i) 15.1% of the product—s average manufacturer price (AMP) or (ii) the difference between the product—s AMP and the best price offered by the manufacturer, plus an inflation adjustment if AMP increases faster than inflation. In addition, many states have established supplemental rebate programs as a condition for including a drug product on a PDL. The profitability of our products may depend on the extent to which they appear on the PDLs of a significant number of state Medicaid programs and the amount of the rebates that must be paid to such states. In addition, there is significant fiscal pressure on the Medicaid program, and amendments to lower the pharmaceutical costs of the program and/or lower manufacturers—rebate liability are possible. Such amendments could adversely affect our anticipated revenues and results of operations, possibly materially.

As a part of the effort to control the costs of prescription drugs, many health maintenance organizations and other third-party payers use formularies, or lists of drugs for which coverage is provided under their benefit plans. Each payer that maintains a drug formulary makes its own determination as to whether a drug will be included in the formulary and whether particular drugs in a therapeutic class will have preferred status over other drugs in the same class. This determination often involves an assessment of the clinical appropriateness of the drug and

sometimes the cost of the drug in comparison to alternative products. We cannot assure you that ANTARA capsules, FACTIVE tablets, Ramoplanin or any of our future products will be added to payers—formularies, whether our products will have preferred status over alternative therapies, nor whether the formulary decisions will be made in a timely manner. We may also decide to enter into discount or formulary fee arrangements with payers, which could result in our receiving lower or discounted prices for our products.

If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, we could be forced to pay substantial damage awards.

The use of any of our product candidates in clinical trials, and the sale of any approved products, might expose us to product liability claims. We currently maintain, and we expect that we will continue to maintain, product liability insurance coverage in the amount of \$10.0 million per occurrence and \$10.0 million in the aggregate. Such insurance coverage might not protect us against all of the claims to which we might become subject. We might not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct financial and managerial resources to such defense and adverse publicity could result, all of which could harm our business.

In addition, a product recall or excessive warranty claims (in any such case, whether arising from manufacturing deficiencies, labeling errors or other safety or regulatory reasons) could have an adverse effect on our product sales or require a change in the indications for which our products may be used.

#### RISKS RELATED TO THE SECURITIES MARKET

#### Our stock price is highly volatile.

The market price of our stock has been and is likely to continue to be highly volatile due to the risks and uncertainties described herein, as well as other factors, including:

the revenues that we may derive from the sale of ANTARA capsules and FACTIVE tablets, as compared to analyst estimates or to our own guidance;

our ability to enter into transactions to acquire, license or co-promote additional products;

the results of any clinical trials that we may conduct and the pace of our progress in those clinical trials;

the results of clinical trials conducted by partners for Ramoplanin or products developed from any of our legacy alliances and the pace of progress in those clinical trials;

whether we will be able to successfully integrate any additional products that we acquire, license or co-promote into our sales and marketing efforts;

the timing of the achievement of development milestones and other payments under our strategic alliance agreements;

termination of, or an adverse development in, our strategic alliances;

conditions and publicity regarding the pharmaceutical industry generally;

our ability to continue to be listed on The NASDAQ Global Market;

price and volume fluctuations in the stock market at large which do not relate to our operating performance;

variations in our rates of product returns, allowances and rebates and discounts;

sales of shares of our common stock in the public market; and

comments by securities analysts, or our failure to meet market expectations, including our projected financial performance. Over the two-year period ending September 30, 2008 the closing price of our stock as reported on The NASDAQ Global Market ranged from a high of \$9.12 to a low of \$0.72. The stock market has from time to time experienced extreme price and volume fluctuations that are unrelated to the operating performance of particular companies. In the past, companies that have experienced volatility have sometimes been the subject of securities class action litigation. If litigation were instituted on this basis, it could result in substantial costs and a diversion of management s attention and resources. These broad market fluctuations may adversely affect the price of our securities, regardless of our operating performance.

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Multiple factors beyond our control may cause fluctuations in our operating results and may cause our stock price to fall.

Our revenues and results of operations may fluctuate significantly, depending on a variety of factors, including the following:

the pace of our commercialization of ANTARA capsules and FACTIVE tablets, and in the case of FACTIVE, seasonal fluctuations in the duration and severity of the annual respiratory tract infection season;

the level of acceptance by physicians and third party payers of ANTARA and FACTIVE;

the progress of any future clinical trials for our products;

the progress of any clinical trials conducted by partners for Ramoplanin or products developed through our legacy alliances;

our success in concluding transactions to acquire additional approved products and product candidates, and the pace of our commercialization of such additional products;

the introduction of new products and services by our competitors;

regulatory actions; and

expenses related to, and the results of, litigation and other proceedings relating to intellectual property rights. We will not be able to control many of these factors. In addition, if our revenues in a particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our business to suffer and may cause our stock price to fall. We believe that period-to-period comparisons of our financial results will not necessarily be meaningful. You should not rely on these comparisons as an indication of our future performance. If our operating results in any future period fall below the expectations of securities analysts and investors, our stock price may fall, possibly by a significant amount.

## RISKS RELATED TO THE EXCHANGE OFFER

The issuance of common shares in the Exchange Offer will result in immediate dilution to the ownership interests of existing stockholders.

We are offering in the proposed Exchange Offer to exchange for each \$1,000 principal amount of 3.50% Convertible Senior Notes due 2011 tendered \$400 principal amount of new notes and shares of our common stock having a value equal to \$100, based on the simple average of the daily volume-weighted average price of a share of our common stock on the NASDAQ Global Market for each of the five trading days prior to and including the second business day before the expiration date of the exchange offer; provided, that in no event shall we issue more than 100 shares of our common stock per each \$1,000 principal amount of existing 2011 notes tendered, which reflects a minimum issue price of \$1.00 per share. The issuance of shares of our common stock in the exchange offer will result in immediate dilution to our existing stockholders.

#### Conversion of the notes will dilute the ownership interests of existing stockholders.

The conversion of some or all of the new notes we are proposing to issue in the Exchange Offer will dilute the ownership interest of our existing stockholders. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the new notes may encourage short selling by market participants because the conversion of

the new notes could depress the price of our common stock and short selling by new note holders engaging in hedging transactions which could further depress the price of our common stock.

As part of the Exchange Offer, the new notes indenture provides restrictions on our ability to incur additional debt which could prevent our ability to raise additional capital.

The new notes indenture provides that we may not incur additional unsecured indebtedness in excess of \$50 million (Permitted Unsecured Indebtedness) from the earlier of (i) the date of the issuance of the new notes to the date that is one year from the date on which our common stock has traded at a price which exceeds the conversion price then in effect for at least 20 trading days during any consecutive 30 trading day period and (ii) the first anniversary of the maturity date of the new notes; provided that, any indebtedness incurred to finance new product acquisition or in connection with any refinancing of Permitted Unsecured Indebtedness, our existing indebtedness including existing 2011 notes not tendered in the Exchange Offer, our obligations to PRF under the Paul Capital Note, revenue interests assignment agreement and our obligations under the 5% Convertible Promissory Notes due 2009 and the new notes shall not be counted toward the aforementioned limit. These restrictions on our ability to incur additional debt could have a negative effect on our ability to raise additional capital in the future.

## We may incur a U.S. federal income tax liability as a result of the Exchange Offer.

As a result of the proposed Exchange Offer, we may realize cancellation of indebtedness ( COD ) income. COD income must generally be included in gross income for U.S. federal income tax purposes. An exception is available if we are insolvent for U.S. federal income tax purposes (i.e., our liabilities exceed the fair market value of our assets). To the extent that we are not insolvent, we expect that the amount of our net operating losses ( NOL ) and other tax attributes will offset the amount of recognized COD income for regular U.S. federal income tax purposes. However, the use of NOLs is limited for alternative minimum tax ( AMT ) purposes and as a consequence we may incur an AMT liability with respect to the COD income recognized on the Exchange Offer.

ITEM 2: UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None

ITEM 3: DEFAULTS UPON SENIOR SECURITIES

None

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#### ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Our annual meeting of shareholders was held on June 12, 2008. At the meeting, our shareholders took the following actions:

(i) To fix the numbers of directors at nine and to elect nine directors.

	For	Withheld
Gregory B. Brown, M.D.	10,280,395	846,134
Robert J. Hennessey	10,074,326	1,052,203
John R. Leone	10,296,334	830,195
William R. Mattson	10,203,792	922,737
Gary Patou, M.D.	10,162,439	964,090
Steven M. Rauscher	10,165,671	960,858
William S. Reardon	10,294,812	831,717
Norbert G. Riedel, Ph.D.	10,127,865	998,664
David K. Stone	10,211,684	914,845

(ii) To approve an amendment to the 2001 Incentive Plan to increase the number of shares of common stock, par value \$0.10 per share, available for issuance under the plan by 1,000,000 shares.

For	Against	Abstain	Non-Voting
3,372,208	885,202	9,241	6,859,878

(iii) To ratify the selection of Ernst & Young LLP as the Company s independent registered public accounting firm for the year ending December 31, 2008.

For	Against	Abstain
10,688,270	393,601	44,658

ITEM 5: OTHER INFORMATION

None

#### ITEM 6: EXHIBITS

#### Description

- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act.
- 32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act.
- 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.

The following Oscient-owned or licensed trademarks are used in this Quarterly Report on Form 10-Q: Oscient, Oscient Pharmaceuticals, ANTARA® and FACTIVE®. All are covered by registrations or pending applications for registration in the U.S. Patent and Trademark Office and other countries. Other trademarks used in this Quarterly Report on Form 10-Q are the property of their respective owners.

## **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized who also serves in the capacity of principal financial officer.

Oscient Pharmaceuticals Corporation

/s/ PHILIPPE M. MAITRE
Philippe M. Maitre
Executive Vice President & Chief Financial Officer
(Principal Financial Officer)

November 10, 2008

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## OSCIENT PHARMACEUTICALS CORPORATION

## **EXHIBIT INDEX**

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