



UPDATE REPORT

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NOVABAY PHARMACEUTICALS (AMEX: NBY)

- **Viral conjunctivitis trial yields favorable trends, but low enrollment precludes statistically significant results.** Investors drop the stock without considering the drug's good prospects. Will Alcon and NovaBay continue their partnership?
 - **Phase II clinical trial of NVC-422 for urinary catheter blockage and encrustation (UCBE) is making good progress.** Data should be available in the fourth quarter, setting the stage for discussions with potential overseas partners.
 - **Galderma will initiate an impetigo Phase IIb trial soon as a prelude to a Phase III study in 2012.** Launch of a topical NVC-422 medicine is slated for 2014.
 - **NeutroPhase[®] will advance NovaBay into wound care.** The irrigation solution is approved for protecting wounds against biofilms, while Aganocides have shown strong therapeutic activity. The Company will announce a U.S. marketing partner for NeutroPhase by 1H 2012.
 - **NovaBay's drug platform generates potent, new antiviral and antifungal agents.** Both may yield new therapies, and the antiviral agent may become a backup to NVC-422.
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- **We reiterate our BUY recommendation and our 12-month target price of \$4.25.**

Share Price (6/7/11)	\$1.37
52-Week Price Low / High	\$1.05-\$2.38
Mkt. Capitalization (issued)	\$32.1 million
Shares Outstand (issued)	23.45 million
12-month Target Price	\$4.25
Avg Daily Volume (3 mos.)	48,260
Website	www.novabaypharma.com
Est'd 2011 Earnings (Loss)	(\$0.33)



NovaBay Pharmaceuticals, Inc. (AMEX: NBY) is a clinical-stage company with a platform technology for developing antimicrobial agents targeting viruses, bacteria, and fungi. Its Aganocides[®] are stable, fast-acting N-chlorinated molecules resembling a compound used by the innate immune system to combat

infections. Three products based on NVC-422 are in clinical testing: an impetigo therapy (partner: Galderma), viral conjunctivitis drug (partner: Alcon) and prophylactic irrigation solution for UCBE (not partnered). NeutroPhase, an antimicrobial wound irrigant, is based on hypochlorous acid.

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PROGRESS ON A DRUG FOR OPHTHALMIC INDICATIONS

The ophthalmology market is especially attractive for a broad-spectrum antimicrobial agent with little/no toxicity to human cells, such as NovaBay's Aganocide NVC-422. Bacterial and viral conjunctivitis are infections common worldwide, with as many as 15 million to 20 million occurring annually in the United States alone. Yet, today's pharmacopeia includes only antibiotics that have no effect on the 40% of patients who suffer from viral infections. NovaBay's NVC-422 is in a position to change the way conjunctivitis is treated, based on its activity against viruses, bacteria, and fungi.

TRIAL CONCLUDES WITH FAVORABLE TRENDS

NovaBay and its partner for the ophthalmology market, Alcon, conducted a Phase II trial of a medicine (AL-46383A) based on NVC-422 to treat viral conjunctivitis. The results were statistically inconclusive because even though more than 450 individuals presented with symptoms of viral conjunctivitis, only 81 were found to have the infection and were therefore eligible for evaluation. The small number of eligible patients prevented the trial from yielding significant results.

Alcon halted the trial before it was able to enroll 220 patients as initially planned. The problem wasn't a lack of interest, but rather a combination of a less than ideal location for the study and a bit of bad luck. The trial was conducted in the United States where viral conjunctivitis has not been a major problem lately, thanks to good hygiene and concerted efforts by healthcare professionals to prevent disease transmission when an infection does occur. As a result, viral conjunctivitis affected a relatively small population during the time the trial was enrolling. And in the few areas, like Chicago, where the disease did breakout, no medical facilities were participating in the study.

Nonetheless, the trial did provide some tantalizing information. Of the 81 patients, 38% were infected by serotypes 8, 19, and 37 that are associated with epidemic keratoconjunctivitis (EKC). This is the most severe form of the disease and one that may cause prolonged visual impairment. The data from this subset of patients found that they responded well. As shown in Table 1, 21 patients with EKC reported blurred vision associated with their infections. And of these, 69.2% reported a sustained clearing of their vision by day 9, versus only 23.8% in the control (vehicle treated) group. The treatment benefit was sustained, as 92.3% of the treated patients had clear vision by day 18, eight days after the therapy ended, versus only 50% of the control group. (Note that viral conjunctivitis is typically a self-limiting infection that normally begins to resolve within two weeks, so a portion of the control group would be expected to show signs of recovery.)

Table 1. Sustained Blurred Vision Clearing Rate by Visit

Visit	Group			
	AL-46383A (n=13)		Vehicle (n=8)	
	N	(%)	N	(%)
Day 3	4	(30.8)	0	---
Day 5	6	(46.2)	1	(12.5)
Day 7	8	(61.5)	1	(12.5)
Day 9	9	(69.2)	2	(25.0)
Day 11	11	(84.6)	3	(37.5)
Day 18	12	(92.3)	4	(50.0)

Source: NovaBay Pharmaceuticals

The drug's benefit was also measured by the microbiological success rate, which was the study's primary endpoint. On day 9, seven of the 17 patients, or 41.2%, who had been diagnosed with EKC achieved microbiological success. (Success was defined as sustained eradication of adenovirus that remained eradicated at all subsequent visits, as determined by genetic analysis.) In contrast, only 3 of the 13 control patients, or 23.8%, reached microbiological success at that time. The favorable comparison persisted through day 18, though the difference between the two patient groups began to diminish, with 76.5% of the treated and 61.5% of the control groups achieving microbiological success.

WILL THE ALCON PARTNERSHIP CONTINUE?

On April 8th, Novartis completed its acquisition of Alcon. The transaction will result in a combination of certain ophthalmic drugs from Novartis Ophthalmics, CIBA Vision, and Alcon to form Novartis's second largest division with more than \$8.7 billion in annual sales. The integration of these businesses is undoubtedly causing some turmoil throughout the Alcon organization, and that may affect the partnership with NovaBay. The recent Phase II clinical trial might have solidified a bond between the companies if the results had been stronger, but given the actual outcome, the trial probably will have little impact.

Alcon has licensed NVC-422 and the Aganocide platform for ophthalmic conditions. It has indicated to NovaBay that it will decide whether to support additional clinical trials of NVC-422 for conjunctivitis will be forthcoming, probably in Q2 or Q3. If Alcon returns the license, then NovaBay intends to pursue development of NVC-422 for viral and bacterial conjunctivitis through the end of Phase II and seek another partner for registration studies.

CONSIDERATIONS BEFORE THE NEXT TRIAL

As NovaBay and Alcon consider their next steps, we think it is worth reviewing some characteristics of adenoviruses and NVC-422 and related compounds:

- **Adenoviruses – A Challenging Foe:** These viruses are segregated into eight species and more than 50 serotypes. Their genetic make-up is changing, and that makes it all the more difficult to create an effective antiviral drug targeting an adenoviral disease. Three serotypes, 8, 19, and 37, have been the most important in causing EKC, though evidence indicates that new serotypes are emerging.^{1,2} The highly contagious nature of these viruses can result in widespread outbreaks, such as those witnessed in Germany when the incidence increased four-fold between 2001 and 2004 and by 250% between 2008 and 2010.^{3,4} Quick intervention can contain the spread of the virus within a population, such as residents/visitors to a medical facility, but that does nothing for those who are infected.
- **Infectious conjunctivitis – A Costly Disease:** Most cases are caused by bacteria (50%) and viruses (40%), but distinguishing between them is not easy. One survey found that 95% of physicians usually prescribe a topical antibiotic, even though 58% reported knowing that the drug had no benefit to at least half of the patients.⁵ Moreover, only 36% thought that they could differentiate between viral and bacterial infections. A separate study examining presumed bacterial conjunctivitis samples taken over an 11.5-year period found that only 60% were culture positive and of those, methicillin-resistant *Staphylococcus aureus* (MRSA) was identified in 11.6%.⁶ Use of inappropriate or ineffective antibiotics constitutes poor healthcare and adds to the overall cost of infectious conjunctivitis. In the United States, the direct and indirect annual cost of bacterial conjunctivitis alone has been estimated at approximately \$590 million, with 83% coming from direct medical costs and the remainder, from a lost wages.⁷

¹ Kaneko, H, et al. Analysis of the complete genome sequence of epidemic keratoconjunctivitis-related human adenovirus type 8, 19, 37 and a novel serotype. J Gen Virol 2009; 90(Pt 6): 1471.

² Walsh, MP, et al. Evidence of molecular evolution driven by recombination events influencing tropism in a novel human adenovirus that causes epidemic keratoconjunctivitis. PLoS One 2009; 4(6): e5635.

³ Shrauder, A, et al. Outbreak report – Epidemic conjunctivitis in Germany, 2004. Euro Surveill 2006; 11(7): 185.

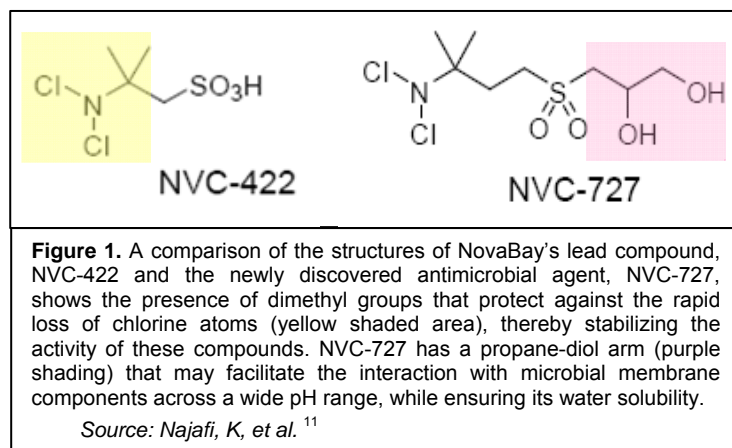
⁴ Adlhoch, C, et al. Increasing case numbers of adenovirus conjunctivitis in Germany, 2010. Euro Surveill 2010; 15(45): 19707.

⁵ Everitt, H, and Little, P. How do GPs diagnose and manage acute infective conjunctivitis? A GP Survey. Fam Prac 2002; 19(6): 658.

⁶ Adebayo, A, et al. Shifting trends in in vitro antibiotic susceptibilities for common bacterial conjunctival isolates in the last decade at the New York Eye and Ear Infirmary. Graefes Arch Clin Exp Ophthalmol 2011; 249(1): 111.

⁷ Smith, AF, and Waycaster, C. Estimate of the direct and indirect annual cost of bacterial conjunctivitis in the United States. BMC Ophthalmol 2009;

- NVC-422 – A Drug Suited to the Challenge:** NVC-422 is a very attractive candidate as a therapy for EKC, based on its antimicrobial and anti-inflammatory properties. This compound is a derivative of a naturally occurring chlorinating agent, N-chlorotaurine, that is used by the immune system to fend off infectious agents. Both compounds act rapidly to oxidize certain portions of proteins in microbial membranes that are essential to proliferation and survival. The chemical reaction occurs without regard to a specific binding site, which allows the chlorinating agents to attack a broad range of microbes, while preventing the microbes from readily escaping their oxidizing effects through, for instance, a simple genetic mutation. Just as important, NVC-422 and N-chlorotaurine suppress inflammation. The natural molecule inhibits the release of the inflammatory mediators nitric oxide, prostaglandin E2, TNF- α and IL-6, but not IL-1 α from stimulated macrophages.^{8,9} It also reduces the histamine levels and neutrophil presence in blood.¹⁰ NVC-422 has a similar effect – it reduces secretion of pro-inflammatory cytokines (interleukin-2, MIP-1 α , and MIP-1 β) in one preclinical model and reduces lymphocyte infiltration and the release of pro-inflammatory cytokines (TNF- α , interleukin-2 and interleukin-6) in another.
- A New Aganocide for Infectious Conjunctivitis:** NovaBay has created another Aganocide that exhibits good activity against viruses that cause EKC.¹¹ Figure 1 shows the structural similarities between the Company's lead compound, NVC-422, and the new molecule, NVC-727. Both have good virucidal activity against adenovirus 5, but the newer compound has better activity against herpes simplex virus-1 and bactericidal activity over a broader pH range, 4 through 7. Moreover, both NVC-422 and NVC-727 have low toxicity, as they cause no/mild eye irritation at therapeutic doses.



The collaboration between NovaBay and Alcon has yielded another family of stable antimicrobial agents that are still under investigation.¹² These molecules retain the N,N-dichloro-dimethyl portion of NVC-422, but have different chain lengths on either side of the sulfonyl group in NVC-727 and contain either a quaternary ammonium or a sulfonate terminus. Structure-activity relationship studies were performed with two bacteria (*E. coli* and *S. aureus*) and the fungus *C. albicans*. The results identified several compounds with

⁸ Marcinkiewicz, J, et al. Taurine chloramine, a product of activated neutrophils, inhibits in vitro the generation of nitric oxide and other macrophage inflammatory mediators. *J Leukoc Biol* 1995; 58(6): 667.

⁹ Barua, M, et al. Taurine chloramine inhibits inducible nitric oxide synthase and TNF-alpha gene expression in activated alveolar macrophages: decreased NF-kappaB activation and IkappaB kinase activity. *J Immunol* 2001; 167(4): 2275.

¹⁰ Wojtecka-Lukasik, E, et al. Taurine-chloramine is a potent antiinflammatory substance. *Inflamm Res* 2006; 55(Suppl 1): S17.

¹¹ Najafi, K, et al. Aganocide® compounds effective against ophthalmic pathogens. Presented at the annual meeting of The Association for Research in Vision and Ophthalmology, May 1-5, 2011.

¹² Low, E, et al. Structure stability/activity relationships of sulfone stabilized N,N-dichloroamines. *Bioorgan Med Chem Lett* 2011; 21: 3682.

good antibacterial activity and variable activity against the fungus. Among these was a compound with a distinct structure (see Figure 4, page 8) that stood out as a strong antifungal agent. In time, it may fulfill one of NovaBay's product development goals.

THE FOCUS OF THE NEXT CLINICAL TRIAL

The next Phase II trial of NVC-422 will probably be conducted in India or Brazil where enrollment should proceed fairly quickly. That's because prevalence of conjunctivitis in those countries is much higher than in the United States where it is about 1.4%.⁷ In India, disease prevalence varies considerably, from 3%-17.5%, depending on the location. Other factors come into play, including socioeconomic status and personal hygiene, as evidenced by a significantly higher prevalence rate among children attending government schools than those in private schools.¹³ Brazil probably offers a sizable patient population too, as viral conjunctivitis accounted for 24.4% of the 574 ophthalmic cases seen by a tertiary hospital in the first week of April 2006.¹⁴ Prevalence there also exhibits a strong seasonal pattern, with the largest number of cases occurring between March and May.¹⁵

The number of individuals who will be screened has not been determined yet. But we think it will be fairly high to ensure that 200 patients with viral conjunctivitis are enrolled. (Enrollment is based on a genetic analysis to confirm the presence of the infectious organism.) A sizable number of patients is important because the disease's self-limiting nature results in the control group having a natural cure rate and because it is difficult to assess precisely what the status of a patient's disease is at the first medical evaluation. The drug regimen may involve up to 8 drug dosages per day and may even include different formulation of NVC-422, one that releases the active ingredient somewhat more slowly than its eyedrop preparation and/or includes a lubricant. The endpoints that were used in the most recent study probably will remain unchanged. But one or two of the subjective endpoints may become objective measurements and patients may be monitored for a few more. For instance, blurred vision may be measured via an eye exam to get objective data, and subepithelial infiltrates might be graded. (Subepithelial infiltrates are white lesions on the cornea, frequently caused by viral infections, and result in blurred vision.)

FINANCIAL CONSIDERATIONS OF A CONJUNCTIVITIS MEDICINE

Whether NovaBay and Alcon continue to jointly develop a medicine for EKC will affect both the Company's near-term capital requirements and the potential return on its investment. On the one hand, a continuation of the partnership would allow NovaBay to devote its resources largely to its current internal projects and perhaps avoid seeking external financing. On the other, the potential reward from assuming responsibility for the next Phase II trial would likely be much greater than the royalty rate included in the Alcon agreement. That's because the next study should provide human proof-of-concept results, thereby reducing the risk associated with further development.

Our financial models are based on an assumption that the partnership is dissolved. Accordingly, we've increased our estimate of the Company's R&D expense in 2012 to include the next Phase II clinical trial and raised the estimated royalty rate to 20% of a partner's sales, which we believe will commence in 2016. Assuming the results of the next trial are favorable, NovaBay should have no difficulty finding a new partner(s) to finance pivotal studies and market the medicine globally. The ophthalmology drug industry includes a fairly small number of companies, and as of the date of this report, not one had a drug in clinical development for viral conjunctivitis, let alone one with the potential to treat both viral and bacterial conjunctivitis.¹⁶

¹³ Gupta, M, et al. Ocular morbidity prevalence among school children in Shimla, Himachal, North India. *Indian J Ophthalmol* 2009; 57(2): 133.

¹⁴ De Souza Carvalho, R, and Jose, NK. Ophthalmology emergency room at the University of Sao Paulo General Hospital: a tertiary hospital providing primary and secondary level care. *Clinics* 2007; 62(3): 301.

¹⁵ Maranhão, AG, et al. Molecular epidemiology of adenovirus conjunctivitis in Rio de Janeiro, Brazil, between 2004 and 2007. *Rev Inst Med Trop Sao Paulo* 2009; 51(4): 227.

¹⁶ Based on searches of the U.S. and EU websites www.clinicaltrials.gov and www.clinicaltrialsregister.eu.

PHASE IIB IMPETIGO TRIAL SET TO START IN THE 3RD QUARTER

NovaBay and Galderma will conduct a second Phase II trial after obtaining solid results from a study that concluded last fall with a 92% cure rate. The next trial will be larger, with 400 – 500 patients, to permit an evaluation of additional dosage strengths and to gain more efficacy data. A key claim that the partners are targeting is eradication of methicillin-resistant *Staphylococcus aureus* (MRSA), because of the rising prevalence of this microbe and because today's drugs for impetigo cannot make that claim. The Phase IIB trial should conclude in the first half of next year, which may permit the pivotal study to commence in the second half.

With Galderma fully committed to the development of the impetigo medicine, NovaBay will shoulder none of the clinical development costs. The Company will continue to receive research support from its partner for approximately three more years, and it is entitled to milestone payments based on the drug's clinical and commercial progress, as well as 10%-30 royalties on Galderma's sales. We view this medicine as an important source of future profits for NovaBay, since impetigo is highly contagious and accounts for about 10% of all pediatric skin infections in the United States. But the market is even larger in tropical countries where the disease's prevalence among children, who comprise the primary patient population, is in the range of 7%-35% in sub-Saharan Africa and approximately 25% in the Pacific Rim.^{17,18} This translates into approximately 13 million prescriptions for antibiotics to treat impetigo annually worldwide and about 1.3 million in the United States.

CATHETER IRRIGATION SOLUTION TRIAL REMAINS ON TARGET

The primary focus of NovaBay's internal R&D program is a irrigation solution containing NVC-422 to maintain patency of chronic indwelling transurethral urinary catheters. A Phase II trial is enrolling male and female spinal-cord injury patients who have a history of urinary tract encrustations. Thus far, 10 of the minimum 20 evaluable patients have been enrolled and no adverse events (i.e., toxicities) have been reported. This is a randomized, double-blind crossover study that involves each patient serving as his/her own control. The treatment regimen involves 7 treatments with either the NVC-422 irrigation solution or saline, with a wash-out period between these regimens.

The goal is to determine whether maintenance of catheter patency results in fewer episodes of urinary catheter blockage and encrustation (UCBE). This will hopefully lead to fewer catheter-associated urinary tract infections, less frequent catheter changes, and an improved quality of life. The results of this study, which should be available in late 2011, will be used to engage a foreign marketing partner to help conduct a larger trial. NovaBay intends to market the product in the United States. At this point, the Company is preparing for a PMA filing that would have the irrigation solution reviewed based on its ability to maintain the function of a medical device, the indwelling catheter. That would limit its clinical trial costs and expedite the application process, since it would avoid the time and expense associated with developing the product as a drug for reducing urinary tract infections.

Our financial model is based on an assumption that the irrigation solution's marketing application is filed in 2013 and that the product is launched in 2014 in the United States and Europe. The number of permanently catheterized individuals in the United States is approximately 335,000, of whom roughly 33% are chronically susceptible to catheter blockage and encrustation. The causative agent, bacteria of the *Proteus* family (largely *P. mirabilis*) account for more than 15% of infections in chronically catheterized patients, second only to *E. coli*.¹⁹ NVC-422 is highly effective in eradicating both types of bacteria. Over time, we believe use of NovaBay's irrigation solution will extend beyond the chronically catheterized

¹⁷ World Health Organization (2005). Epidemiology and management of common skin diseases in children in developing countries. Geneva: World Health Organization Publ #WHO/FCH/CAH/05.12.

¹⁸ Steer, AC, et al. High burden of impetigo and scabies in a tropical country. PLoS Negl Trop Dis 2009; 3(6): e467.

¹⁹ Jacobsen, SM, et al. Complicated catheter-associated urinary tract infections due to *Escheria coli* and *Proteus mirabilis*. Clin Microbiol Rev 2008; 21(1): 26.

population, since more than one million patients develop catheter-associated urinary tract infections that cost about \$2,900 each to treat.

NOVABAY COMPOUNDS FACILITATE WOUND HEALING

An obvious area of interest for a company working with antimicrobial agents is wounds. NovaBay's initial foray into this area is with NeutroPhase[®], which is a moderately acidic irrigation solution of stabilized hypochlorous acid. Tests have demonstrated that a stabilized formulation of this agent is highly efficient in eradicating a broad range of bacteria in less than one minute.²⁰ Comparisons with hydrogen peroxide, a commonly used antiseptic agent, found that NeutroPhase effectively killed common bacteria (*E. coli* and *Staphylococcus aureus*) and had a better safety profile, as evidenced by their therapeutic indices. (See Figure 2.)

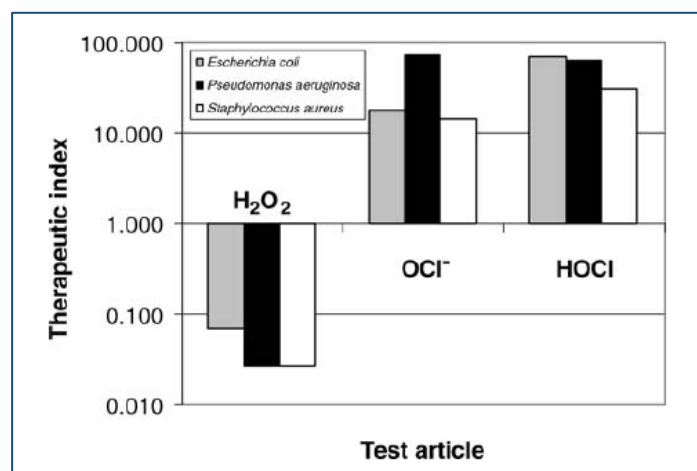


Figure 2. A comparison of the therapeutic indices of NeutroPhase (HOCl, at pH 4.0), hydrogen peroxide (H₂O₂, pH 7.0), and sodium hypochlorite (OCI⁻ pH 10.5) shows that NeutroPhase is safer than the comparators in eradicating three bacteria. (The higher the therapeutic index, the greater is the compound's safety.) The therapeutic index is expressed as a ratio of the concentration of test article needed to kill 50% of the bacteria to the minimum bactericidal concentration.

Source: Wang, L, et al.²⁰

Furthermore, the preclinical safety studies demonstrated that NeutroPhase caused no ocular irritation or systemic toxicity at concentrations up to 0.1% w/v. The data also provided evidence that the solution does not interfere with wound healing at a microscopic level. Indeed, when chronically infected wounds were treated with NeutroPhase (0.01%, pH 4.0) for 15 minutes, wiped gently, and then treated again with NeutroPhase, the bacterial bioburden was eliminated by the 16th day.²¹ This treatment also contributed to significantly faster wound healing when compared with other regimens, including a single application of NeutroPhase and saline.

Clinical results have been consistent with the preclinical data.²² Patients who suffered from chronic, non-healing wounds were treated with NeutroPhase (0.01%) as an irrigation solution along with a hydrophobic mesh dressing (Pioneer Technology's Sorbact[®]). Negative pressure wound treatment, which is commonly used to remove excess fluids, simplified irrigation with NeutroPhase twice daily, while Sorbact trapped bacteria without maceration of the nearby skin.

²⁰ Wang, L, et al. Hypochlorous acid as a potential wound care agent – Part I. Stabilized hypochlorous acid: a component of the inorganic armamentarium of innate immunity. *J Burns Wounds* 2007; 6: 65.

²¹ Robson, MC, et al. Hypochlorous acid as a potential wound care agent – Part II. Stabilized hypochlorous acid: its role in decreasing tissue bacterial bioburden and overcoming the inhibition of infection on wound healing. *J Burns Wounds* 2007; 6: 80.

²² Crew, JR, et al. NeutroPhase[®] with Sorbact[®] dramatically enhances the speed of wound healing. Presented at the 24th Annual Symposium on Advanced Wound Care, April 14, 2011.

NovaBay has also investigated the efficacy of NVC-422 as a therapy to promote wound healing in preclinical models.²³ As shown in Figure 3, the compound is highly effective in keeping wounds clear of microbes, particularly when the wound is wiped gently after application of NVC-422.

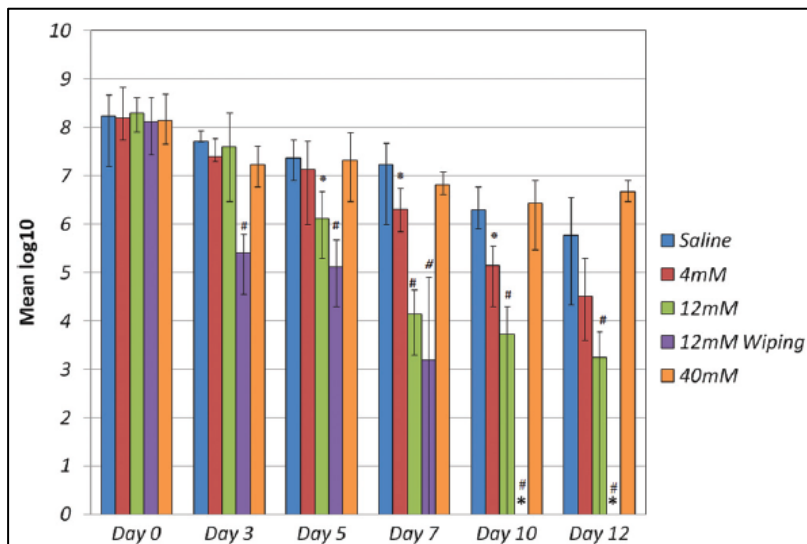


Figure 3. Tests of the antibacterial effectiveness of NVC-422 treatment regimens in a preclinical, chronic wound model yields a typical dose-response curve, except when wound healing was prevented by a high dose of the compound (40mM). The results also show that as with NeutroPhase, gentle wiping of the wound after exposure to NVC-422 increases the effectiveness of the therapy, so much so that a significant reduction in bacteria was seen by day 3 and that by day 10, no bacteria were observable. In contrast, a similar 30-minute application of the same dose (12mM), but without the gentle wiping, did not reduce the bacterial burden significantly until day 5 and never eradicated the microbe.

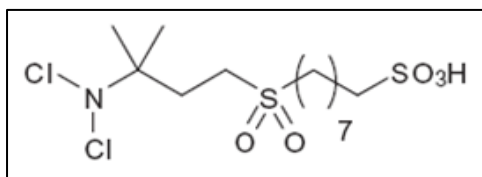
Source: Wang, L, et al.²³

Our financial model is based on an assumption that NeutroPhase is launched in the United States in 2012 and that it gradually gains acceptance in a very competitive marketplace. Nonetheless, the opportunity is huge, with 1.3 million – 3 million patients in the United States with pressure ulcers and an equal number of diabetic individuals at risk of developing an ulcer each year.²⁴ Treating chronic wounds costs an estimated \$5 billion - \$7 billion per annum, and their incidence is rising at a rate of 10% per year.

ONYCHOMYCOSIS DRUG UNDER DEVELOPMENT

NovaBay is examining its library of Aganocides to identify compounds with antifungal properties. And as mentioned earlier (see page 4), the compound with the longest aliphatic chain in a new chemical series (see Figure 4) showed the strongest antifungal activity, while also exhibiting good water solubility and stability in solution.¹² This compound's structure includes the chlorinating site found in NVC-422 and NVC-727, but differs in the 8-carbon chain between the central sulfone group and sulfonic acid terminus. That structure, which may facilitate interaction between the drug and lipid rafts in the fungal membrane, plays an integral, though supportive, role in the molecule's activity. A patent application on this and related compounds was published in October 2010.²⁵

Figure 4. A Newly Discovered Antifungal Aganocide



²³ Wang, L, et al. Chemical characterization and biological properties of NVC-422, a novel, stable N-chlorotaurine analog. *Antimicrob Agents Chemother* 2011; 55(6): 2688.

²⁴ Kuehn, BM. Chronic wound care guidelines issued. *JAMA* 2007; 297(9): 938.

²⁵ Methods of treating infection of the nail. International publication number: WO 2010/124237 A1.

The Company has yet to identify its lead compound for clinical development, but we would not be surprised if this molecule is under serious consideration. The goal is to have a candidate ready for clinical testing later this year, about the time that the catheter irrigation solution trial ends. That would enable the Company to shift its resources smoothly from one project onto the next. Our financial model is based on an assumption that this drug is launched in 2016.

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FINANCIAL PROJECTIONS AND VALUATION

Our financial model incorporating our latest views of the Company is presented in the next Annual and Quarterly Income Statements. Noteworthy changes include a small reduction in R&D support from Galderma starting in the second quarter of 2011 (as specified under their agreement, since Galderma has taken over development of the impetigo drug), incremental costs in 2012 for the next Phase II trial of the viral conjunctivitis medicine, receipt of a milestone payment (estimated amount: \$4 million) from Galderma upon the commencement of a Phase III trial of the impetigo medicine in 2013, and a higher royalty rate (new rate of 20% versus the old rate of roughly 7%) on sales of the conjunctivitis medicine, starting in 2016.

ANNUAL INCOME STATEMENT[#] (FISCAL YEAR ENDS DECEMBER 31ST.)

All data are in thousands, except for per-share figures.

	2009	2010	2011	2012	2013	2014	2015
License & Collaboration Rev	\$ 15,684	\$ 9,754	\$ 6,750	\$ 6,000	\$ 10,000	\$ 17,706	\$ 30,206
Product Sales/Royalties	-	-	-	500	1,123	15,551	23,073
Total Revenues	\$ 15,684	\$ 9,754	\$ 6,750	\$ 6,500	\$ 11,123	\$ 33,257	\$ 53,279
Cost of products sold	-	-	-	-	-	3,438	5,095
Gross Profit	\$ 15,684	\$ 9,754	\$ 6,750	\$ 6,500	\$ 11,123	\$ 29,819	\$ 48,185
Operating expenses							
R&D expense	7,337	8,616	8,600	10,650	9,000	9,000	9,500
Marketing expense	-	-	-	-	2,000	5,000	8,500
SG&A expense	5,607	5,654	6,000	6,250	6,250	6,500	7,750
Total operating costs	12,944	14,270	14,600	16,900	17,250	20,500	25,750
Operating profit/(loss)	\$ 2,740	\$ (4,516)	\$ (7,850)	\$ (10,400)	\$ (6,127)	\$ 9,319	\$ 22,435
Other income/(expense)	(36)	258	-	-	-	-	-
Pretax profit/(loss)	\$ 2,704	\$ (4,258)	\$ (7,850)	\$ (10,400)	\$ (6,127)	\$ 9,319	\$ 22,435
Income taxes	7	(50)	-	-	-	3,541	8,525
Net profit/(loss)	\$ 2,697	\$ (4,308)	\$ (7,850)	\$ (10,400)	\$ (6,127)	\$ 5,778	\$ 13,909
Earnings/(loss) per share	\$ 0.12	\$ (0.18)	\$ (0.33)	\$ (0.40)	\$ (0.23)	\$ 0.18	\$ 0.42
Shares outstanding	23,115	23,326	23,600	26,100	26,500	32,500	33,000

Revenue sources:

- **NeutroPhase:** launch in 2012 and generating royalties on sales of distributors
- **Impetigo medicine:** launch in 2014 by Galderma, generating royalties of 10%-30% for NovaBay
- **UCBE irrigation solution:** launch in 2014, in United States by NovaBay and by a partner(s) overseas paying a 21% royalty to NovaBay
- **Conjunctivitis drug:** launch in 2016 by a partner(s) globally, paying royalties of 20% to NovaBay

Expenses:

- **R&D expenses** change little between 2010 and 2011 overall, though quarterly amounts vary depending on the clinical trial activity. In 2012, these costs begin to increase steadily as the Company conducts clinical trials of its onychomycosis medicine and the conjunctivitis drug. Thereafter, we assume that R&D investments stabilize temporarily as partners assume responsibility for conducting larger and more advanced studies.
- **SG&A costs** rise at a modest pace as NovaBay expands its infrastructure over the next five years as it advances from a clinical-development stage to a commercial operation.
- **Marketing expenses** begin in 2013 in anticipation of FDA approval of the UCBE irrigation solution and eventually stabilize at 18% of revenues.
- **Tax liabilities** are booked for financial reporting purposes at a 38% effective tax rate, even though the Company will minimize its cash liabilities through net operating loss carryforwards that amounted to \$49.9 million (federal and state) as of March 31, 2011.

QUARTERLY INCOME STATEMENTS

	2010				2011				2012			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
License & Collaboration Rev	\$ 2,084	\$ 2,548	\$ 2,086	\$ 3,036	\$ 2,490	\$ 1,810	\$ 1,500	\$ 950	\$ 1,500	\$ 1,500	\$ 1,500	\$ 1,500
Product Sales/Royalties	-	-	-	-	-	-	-	-	100	100	150	150
Total Revenues	\$ 2,084	\$ 2,548	\$ 2,086	\$ 2,652	\$ 2,490	\$ 1,810	\$ 1,500	\$ 950	\$ 1,600	\$ 1,600	\$ 1,650	\$ 1,650
Cost of products sold	-	-	-	-	-	-	-	-	-	-	-	-
Gross Profit	\$ 2,084	\$ 2,548	\$ 2,086	\$ 2,652	\$ 2,490	\$ 1,810	\$ 1,500	\$ 950	\$ 1,600	\$ 1,600	\$ 1,650	\$ 1,650
Operating expenses												
R&D expense	2,233	2,129	2,245	2,009	2,920	2,000	1,700	1,980	2,250	2,500	2,800	3,100
SG&A expense	1,469	1,611	1,487	1,087	1,515	1,500	1,485	1,500	1,500	1,550	1,600	1,600
Total operating costs	3,702	3,740	3,732	3,096	4,435	3,500	3,185	3,480	3,750	4,050	4,400	4,700
Operating profit/(loss)	\$ (1,618)	\$ (1,192)	\$ (1,646)	\$ (444)	\$ (1,945)	\$ (1,690)	\$ (1,685)	\$ (2,530)	\$ (2,150)	\$ (2,450)	\$ (2,750)	\$ (3,050)
Other income/(expense)	(11)	(6)	4	271	(31)	-	-	31	-	-	-	-
Pretax profit/(loss)	\$ (1,629)	\$ (1,198)	\$ (1,642)	\$ (173)	\$ (1,976)	\$ (1,690)	\$ (1,685)	\$ (2,499)	\$ (2,150)	\$ (2,450)	\$ (2,750)	\$ (3,050)
Income taxes	-	-	-	-	12	-	-	-	-	-	-	-
Net profit/(loss)	\$ (1,629)	\$ (1,198)	\$ (1,642)	\$ (173)	\$ (1,988)	\$ (1,690)	\$ (1,685)	\$ (2,499)	\$ (2,150)	\$ (2,450)	\$ (2,750)	\$ (3,050)
Earnings/(loss) per share	\$ (0.07)	\$ (0.05)	\$ (0.07)	\$ (0.00)	\$ (0.08)	\$ (0.07)	\$ (0.07)	\$ (0.10)	\$ (0.08)	\$ (0.09)	\$ (0.11)	\$ (0.12)
Shares outstanding	23,300	23,315	23,335	53,190	23,428	23,470	23,500	24,000	26,000	26,100	26,100	26,200

Fiscal year ends on December 31st. All figures are in thousands, except per-share data. Estimates are shown in *italics*.

BALANCE SHEET# (FISCAL YEAR ENDS DECEMBER 31ST.)

All data are in thousands.

ASSETS	3/31/2011	12/31/2010
Current Assets		
Cash & equivalents	12,619	12,806
Accounts Receivable	-	500
Other	312	448
Total Current Assets	\$ 12,931	\$ 13,754
Property & equipment	\$ 1,598	\$ 1,588
Other	138	174
Total Assets	\$ 14,667	\$ 15,516
LIABILITIES		
Current Liabilities		
Accounts payable	\$ 346	\$ 406
Debt due	42	106
Accrued liabilities	1,033	726
Deferred revenue	2,311	1,485
Total Current Liabilities	\$ 3,732	\$ 2,723
Deferred revenue	\$ 1,889	\$ 2,204
Long-term debt	-	-
Deferred rent	104	99
Total Long-Term Liabilities	\$ 1,993	\$ 2,303
Shareholders Equity		
Common Stock, par value	\$ 235	\$ 234
Additional Paid-In Capital	38,894	38,469
Accumulated Deficit	(30,187)	(28,213)
Total Shareholders Equity	\$ 8,942	\$ 10,490
Total liabilities & equity	\$ 14,667	\$ 15,516

NovaBay closed the March quarter with \$12.6 million of cash on hand and working capital of \$9.2 million. Operations generated \$16,000 of cash.

VALUATION OF NBY SHARES & INVESTMENT CONSIDERATIONS

Our 12-month price target is \$4.25 per NBY share. This valuation reflects the following calculation: We multiplied the 2015 projected share earnings of \$0.42 by a P/E ratio of 25 and got a future price of \$10.50 per share. That was discounted back three years to 2012 with an annual rate of 35% to reflect the uncertainty associated with the development of NovaBay's three major product candidates. This calculation yielded a price of \$4.25.

We believe NBY stock is well suited to growth-oriented investors who are willing to accept the risks associated with new product development programs. However, the risks here seem lower than those of many clinical-stage pharmaceutical companies, given the mechanism of action of NovaBay's compounds and their relatively clean safety profiles. We do not consider the pending Alcon decision to be a major concern, since the extra financing that would likely be required to move that program forward internally would probably be offset by a much higher return on invested capital than the yield on the current Alcon deal. (That agreement, which was NovaBay's first, was signed in 2006 at a preclinical stage of development.) Moreover, the Company has an excellent track record of entering into partnering agreements and we believe this trend will continue, in part because of its unique antimicrobial agents.

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INVESTMENT CONCERNS AND RISKS

For a complete description of risks and uncertainties related to NovaBay Pharmaceuticals business, see NovaBay's 10K reports, which can be accessed from the Company's website, www.novabaypharma.com. Potential risks include:

- **Stock risk and market risk:** There is a limited trading market for the Company's common stock. There can be no assurance that an active and liquid trading market will develop or, if developed, that it will be sustained, which could limit one's ability to buy or sell the Company's common stock at a desired price. Investors should also consider technical risks common to many small-cap or micro-cap stock investments, such as small float, risk of dilution, dependence upon key personnel, and the strength of competitors that may be larger and better capitalized.
- **Competitive risk:** The pharmaceutical market continues to evolve, and research and development are expected to continue. Other companies are already established players in antimicrobial markets and are actively engaged in the development of new drugs that may directly or indirectly compete with those being pursued by NovaBay. These companies may have substantially greater research and development capabilities, as well as significantly greater marketing, financial, and human resources than the Company.
- **Products still in development phases:** NovaBay's products are still at a precommercialization stage. Such products may appear to be promising, but may not reach commercialization for various reasons, including failure to demonstrate safety and efficacy in large clinical trials and/or the inability to be manufactured at a competitive cost. And even if its products are commercialized, there can be no assurance that they will be accepted by physicians, patients, or healthcare payers, which may prevent the Company from becoming profitable.
- **Funding requirements:** It is difficult to predict NovaBay's future capital requirements. The Company may need additional financing to continue funding the development of its products and their production. There is no guarantee that it can secure the desired future capital or, if sufficient capital is secured, that current shareholders will not suffer significant dilution.
- **Regulatory risk:** There is no guarantee that the Company's products will be approved by the U.S. Food and Drug Administration (FDA) or international regulatory bodies for marketing in the U.S. or abroad.
- **Patent risk:** The pharmaceutical industry is one in which patents have not always provided sufficient protection against competition. There can be no assurance that NovaBay's patents will provide sufficient protection to exclude competitors and that patent litigation will not become a financial burden.

DISCLOSURES

ANALYST(S) CERTIFICATION: The analyst(s) responsible for covering the securities in this report certify that the views expressed in this research report accurately reflect their personal views about NovaBay Pharmaceuticals (the “Company”) and its securities. The analyst(s) responsible for covering the securities in this report certify that no part of their compensation was, is, or will be directly or indirectly related to the specific recommendation or view contained in this research report.

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PRICE CHART – 2 Year



Source: BigCharts.com

4/21/2010 – Initiating Coverage: share price: \$2.50; rating: BUY; 12-month price target: \$9.00; **7/22/2010** – Update Report: share price \$2.09; rating: BUY; 12-month price target: \$9.00; **10/18/2010** – Update Report: share price \$1.94; rating: BUY, 12-month price target: \$9.00; **12/6/2010** – Update Report: share price \$1.81; rating: BUY, 12-month price target: \$9.00; **6/8/2011** – Update Report: share price: \$1.37; rating BUY, 12-month price target: \$4.25.

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