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## Funding Opportunities to Support Biotech R&D in Infectious Diseases: from a VC/Merchant Banker's Perspective!

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### Navigating the Sea Change

*But doth suffer a sea-change, into something rich and strange...*

—William Shakespeare, *The Tempest*

# Wall Street's Implosion...What does it mean to us?

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*It's a sea change, not a temporary blip  
.....not a "this too will pass" situation*

- ❑ We've had ≈ 30-40 years of relatively easy access to relatively cheap capital...That Game is OVER! Capital Markets permanently restructured
- ❑ Capital more difficult to find (more expensive)

*Therefore...creativity in financing is an  
absolute requirement!*

# Financing – Circa 2009/2010

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- ❑ IPOs – later stage operating companies with revenues/profits
- ❑ More follow-ons
- ❑ Reverse mergers into public companies, still happening
- ❑ Development stage (rounds now extending to E/F) available but still expensive
- ❑ Equipment/facility financing (even IP)
- ❑ Equity –lines of credit
- ❑ Shelf registration/registered direct
- ❑ Governments/development authorities/research institutes providing capital
- ❑ Corporate venture investments
- ❑ Disease advocacy/charitable organization (active players)

# Stimulus Fund: Biotech Has Also Benefited

Country	Biotech Economic Stimulus
US	\$21.5 B for R&D
Canada	\$200 M for science and technology
China	\$4.81 B in 2009, \$4.4B in 2010 for “11 technology projects” \$129 B in healthcare infrastructure
Norway	\$2.87 B for biotech industry
Taiwan	\$1.83 B to biotech VC fund
UK	\$1.5 B “fund of funds”
Israel	\$96.78 M for high-tech and biotechnology sectors

# “Traditional” Venture Model is Being Squeezed

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- ❑ Cost of nurturing companies to IPO ready has increased
- ❑ No IPOs in 2009 for pre commercial companies
- ❑ Trade sales vs IPO
- ❑ FDA risk and uncertainty has increased
- ❑ Classic “academic spin out” with strong biology and 10-15 years to revenue is no longer economically viable
- ❑ Platform technology companies generally struggling/evolving into “therapeutics” or being acquired if in a “hot area” e.g. antibodies
- ❑ Venture companies are evolving:
  - VIPCO out-sourcing model
  - “Specialty pharma’ with lower risk and faster exit
  - Increasing importance of on-dilutive funding

# Infectious Diseases Investments: a Biased Viewpoint

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## **Anti-bacterial:**

- Significant opportunities for broad spectrum agents with Oral / IV dosing and agents targeting Gram negative bacteria
- Antibiotic resistance a growing concern
- Opportunity for novel mechanisms, e.g. metabolic pathways in bacteria
- Significant novelty is needed to differentiate from generics
- Safety of increasing importance; higher regulatory hurdles

## **Anti-fungals:**

- Significant opportunities for Echinocandins
- Space not as crowded space: novel, safe and effective compounds may have great outlicensing opportunities
- Opportunity for novel mechanisms: HDAC inhibitor, Thymidylate synthase inhibitor, Hsp90 inhibitor

## **Anti-virals:**

- HIV and HCV space very competitive
- Licensing partnerships competing with big pharma internal early-stage programs for HIV and HCV
- Vaccines are the major threat
- Opportunity for novel mechanisms broad spectrum viral targets

# Venture Funded Infectious Disease Companies ('08-'09)

DATE	COMPANY	SIZE (\$mm)	INVESTORS	BUSINESS DESCRIPTION
10/05/2009	Inviragen	15.0	Venture Investors, Charter Venture; Bio*One Capital; Phillip Private Equity	Inviragen (Colorado, USA) develops vaccines to protect against infectious diseases. The company provides vaccines for dengue fever, plague, smallpox, and influenza.
09/12/2009	FAB Pharma	3.36	Bioam Gestion; CDC Innovation; Redmile Group	FAB Pharma (Paris, France) discovers and develops therapeutics for antibiotic resistance and bacterial infections, low-molecular-weight antibacterial molecules for enzymes in Fatty Acid Biosynthesis I (FAB I).
07/07/2009	Taiwan Liposome Co.	-	Burrill Venture Capital; Boston Life Sci. Venture YFY biotech Mgt Co.	Taiwan Liposome Company (Taiwan and California), engages in the research, development, and commercialization of proprietary drug delivery systems for improving the treatment of cancer, ophthalmic conditions, and infectious diseases.
06/18/2009	Lumavita AG	22.21	Atlas Venture; HealthCap; BioMedinvestor AG; Bellevue Asset Mgt; Endeavour Vision SA	Lumavita AG (Basel, Switzerland) engages in the development and commercialization of novel anti-infectives for women's health. Its products include FemiFect, an antibiotic to treat infections known to cause vaginitis, such as bacteria, fungi, and protozoa
06/05/2009	Alios BioPharma	32.0	EuclidSR Partners; SR One; Novartis Venture; Novo A/S; Roche Venture	Alios BioPharma, Inc. (California, USA) engages in the discovery and development of medicines to treat viral infections and cancer. It involves in the development of protein and small-molecule therapeutics. The company's products include Glycoferon
03/04/2009	Regulus Therapeutics	20.0	Isis Pharmaceuticals; Alnylam Pharma.	Regulus Therapeutics, LLC, (California, USA) engages in the discovery, development, and commercialization of microRNA therapeutics. Its microRNA program targets miR-122 for the treatment of hepatitis C virus infection.
01/28/2009	Immune Targeting Systems Ltd.	8.46	Novartis Venture Funds; HealthCap; Truffle Capital; Co. Guides Venture	Immune Targeting Systems, Ltd. (London, UK) develops vaccines for mutating viruses. It offers vaccines for the prevention and treatment of life-threatening viral infections, including pandemic and seasonal influenza, HIV/AIDS, and hepatitis-C.

# Venture Funded Infectious Disease Companies ('08-'09)

DATE	COMPANY	SIZE (\$mm)	INVESTORS	BUSINESS DESCRIPTION
10/23/2008	Defyrus Inc.	2.46	Tancho Inno. Capital	Defyrus Inc. (Toronto, CN) develops anti-viral drugs and vaccines as medical countermeasures to bioterrorist threats and emerging infectious diseases.
09/22/2008	Amplix Pharmaceuticals	0.78	Tech Coast Angels; Life Science Angels	Amplix Pharmaceuticals, Inc. (California, USA) develops oral and injectable anti-infective drugs, including protease inhibitors and antibiotics.
08/15/2008	Mirina Corporation	-	Arch Venture Partners; OVP Venture Partners; WRF Capital; Alexandria Equities;	Mirina Corporation (Washington, USA) engages in developing therapeutics to affect cellular processes involving microRNAs. Its technology allows the treatment for diseases, including cancers, infectious diseases, and various metabolic disorders.
08/06/2008	Tetraphase Pharmaceuticals	25.0	CMEA Capital; Flagship Ventures; Skyline Ventures; Mediphase Venture;	Tetraphase Pharmaceuticals, Inc. engages in discovering and developing new tetracycline antibiotics to treat drug resistant bacterial infections. The company was founded in 2006 and is based in Watertown, Massachusetts.
06/04/2008	Immune Design, Inc.	18.0	Alta Partners; Versant Ventures; The Column Group LLC	Immune Design, Inc. (Seattle, USA) a vaccine company, identifies adjuvants and technologies targeting and controlling dendritic cells to create prophylactic and therapeutic vaccines for infectious diseases.
05/01/2008	Great Lakes Pharmaceuticals	2.4	JumpStart; Tech. Commercialization Case Tech. Ventures; North Coast Angel	Great Lakes Pharmaceuticals, Inc. (Ohio, USA) engages in the clinical development and commercialization of anti-infective compounds and technologies. It focuses on the clinical development of antibiotic and antifungal compounds.
02/04/2008	Traversa Therapeutics	2.0	SD Tech Coast Angels; Morningside Group; Mesa Verde Partners	Traversa Therapeutics, Inc. (California, USA) engages in the discovery, design, development, and commercialization of short interfering RNA (siRNA) delivery technologies which are used in pharmaceutical companies and RNA interference screening application

# Early-Stage VC Investments in Anti-bacterials ('07-'09)

Announced/initial Filing Date	Company	Round	Total Transaction Value (\$mm)	VC	Description
3/18/2008	InflaRx GmbH	Start up & Seed	N/A	bm-t beteiligungsmanagement thuringen gmbh, Affentranger Associates	Developing highly specific prototype monoclonal <b>antibodies</b> targeting activation products of the complement system for
05/06/2007	BioRelix Inc.	Series A	25.75	New Leaf Venture Partners, Aisling Capital, CHL Medical Partners, Novartis Venture Fund, Elm	Focusing on <b>riboswitches</b> as the novel target for developing anti-bacterials
03/26/2007	Affinium Pharmaceuticals, Inc.	Series A	18	Forward Ventures; Oxford Bioscience Partners; Genesys Capital Partners Inc.; SV Life Sciences	Developing an oral, <b>fatty acid biosynthesis</b> inhibitor for antibiotic resistant staphylococcal infections
02/26/2007	Trius Therapeutics, Inc.	Series A	20	InterWest Partners; Prism VentureWorks; Versant Ventures; Sofinnova Ventures, Inc.	Developing a second generation <b>oxazolidinone</b> antibacterial prodrug
03/24/2008	Trius Therapeutics, Inc.	Series B	30	InterWest Partners; Kleiner, Perkins, Caufield & Byers; Prism VentureWorks; Versant Ventures; Tech Coast Angels; Sofinnova Ventures, Inc.; FinTech Global Capital	Developing a second generation <b>oxazolidinone</b> antibacterial prodrug
01/08/2007	Novoxel SA	Series B	65.02	3i Group plc; Abingworth Management Limited; Atlas Venture LLP; Goldman Sachs Group, Merchant Banking Division; Sofinnova Partners; TechFund Capital; Edmond de Rothschild Investment Partners, S.A.S.; Daiwa SMBC Capital Co.,Ltd.; 123 Venture; Novo A/S; NeoMed; ACE Management; Financiere De l'Echiquier	Currently developing a novel <b>beta-lactamase</b> inhibitor for Gram negative infections; a novel oral <b>streptogramin</b> antibiotic active against Gram-positive bacteria; <b>Penicillin Binding Protein (PBP)</b> inhibitor is a novel class antibacterial for an anti-Pseudomonas agent
07/07/2009	Viamet	Series B	18	Novartis Option Fund (Lead), Lilly Venture (Lead), Intersouth Partners, Hateras Venture Partnersm Lurie Investment Fund and Astellas Venture Management	Developing novel inhibitors of key <b>metalloenzymes</b> via a proprietary metal-binding approach, the Metallophile Technology

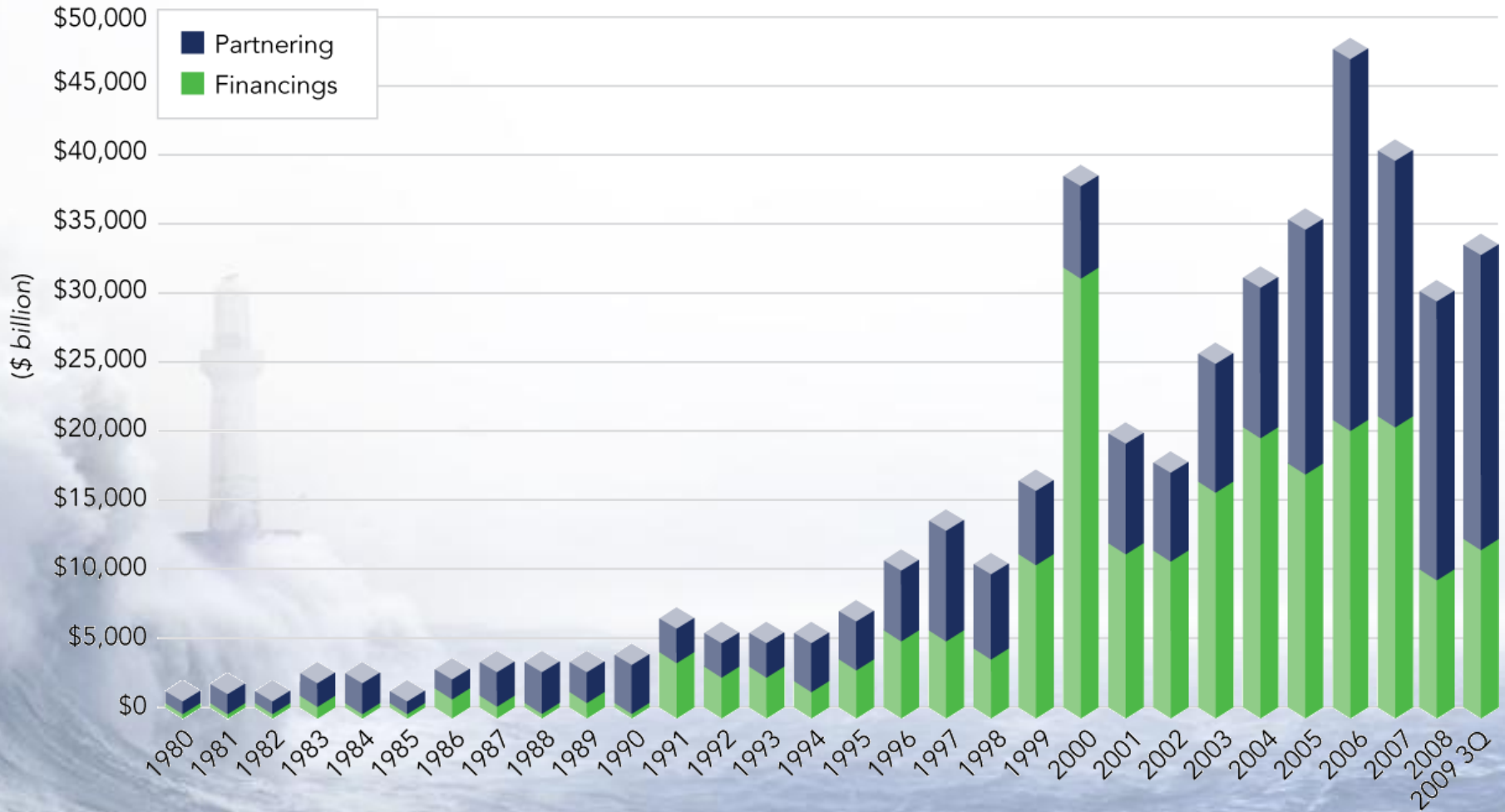
Source: Capital IQ, MedTrack

- New investment still primarily focuses on small molecule drugs

# Mid-to-Late Stage Clinical Infectious Disease Companies Have Yielded Lucrative Total Deal Values For Investors via M&A

Deal Date	Buyer	Target	Target Location	Target Priv/Pub	Latest Phase	Mol Type	TDV \$M	Cash Stock	Earnout Y/N	Deal Summary
Q1 2009	Vertex	ViroChem Pharma	Canada	Private	Phase II	Vaccine	\$405	Both	N	The deal gives Vertex potential for a strong worldwide presence in the HCV market via two promising oral non-nucleoside HCV NS5B polymerase inhibitors--Phase I VCH222 and Phase II VCH759. Vertex plans to combine each candidate with its first-in-class Phase III protease inhibitor telaprevir to create more potent, faster-acting hepatitis C drugs called STAT-Cs (specifically targeted antiviral therapies for hepatitis C). ViroChem reportedly had many suitors before Vertex not only won the bid, but also scored some points in its race against competitor Schering-Plough to bring the first HCV protease inhibitor to market.
Q2 2008	Novartis	Protez	US	Private	Phase II	Small Molecule	\$400	Cash	N	Novartis gets North American and European rights to PZ601, an injectable antibiotic (part of a class of carbapenems) in Phase II which has the potential to treat bacterial infections, including MRSA, in hospital patients. Protez gained rights to its now-lead compound through its mid-2005 alliance with Daiippon Sumitomo. Also in Protez's pipeline are various formulations of PZ601 such as oral prodrug, aerosol, and combinations and beta lactamase inhibitors for bacteria-resistant infections (all in discovery). These complement Novartis's Cubicin for skin and soft-tissue infections (gained through its acquisition of Chiron in 2005), and Mycograb antifungal, Aurograb antibacterial, and Tifactogin for severe community-acquired pneumonia (from its buy out of NeuTec Pharma in 2006).
Q1 2007	AstraZeneca	Arrow Therapeutics	UK	Private	Phase II	Small Molecule	\$150	Cash Satock	N	The acquisition strengthens AZ's new leading therapeutic area of focus--infection and antibacterials. Arrow's lead compound is RSV604, partnered with Novartis and in Phase II clinical trials for respiratory syncytial virus (RSV), a severe infection that mainly afflicts babies, the elderly, and people with compromised immune systems. The company also has A831 and A689 in Phase I and preclinical studies, respectively, to treat hepatitis C, and a candidate in the discovery phase for herpes. Through Arrow, AZ strengthens an antiviral product line that already includes Apatef / Cefotan, for various bacterial infections, and Merrem / Meronem , primarily for hospital-acquired infections.
Q4 2006	Pfizer	PowderMed	UK	Private	Phase I	DNA vaccine	\$230	Cash	Y	PowderMed's Particle Mediated Epidermal Delivery (PMED) technology uses pressurized helium gas to deliver DNA-based vaccines through the outer layer of skin. The technology could overcome the manufacturing hurdles that conventional egg-based vaccine-makers face, as they can be produced in a very high volume in a matter of weeks, while conventional ones take six-to-nine months to produce.
Q4 2006	Forest	Cerexa	US	Private	Phase II	Small Molecule	\$594	Cash	Y	The transaction gives Forest exclusive worldwide rights to the Phase II broad-spectrum cephalosporin antibiotic ceftaroline acetate. Cerexa's other candidate, ME1036, is a broad-spectrum parenteral carbapenem in preclinical studies for aerobic and anaerobic gram-positive and gram-negative bacteria, including drug-resistant pathogens. Forest also gets an option to an undisclosed early-stage antibiotic.

# Capital Raised 1980-3Q 2009



## US Biotech Financings (\$M) 2004-2009 Trend – Partnering has Picked up the Slack

	2004	2005	2006	2007	2008	1H 2009
<b>Public</b>						
IPO	\$1,701	\$819	\$920	\$2,041	\$6	\$0
Follow-ons	\$3,388	\$4,194	\$5,766	\$6,311	\$1,726	\$2,043
PIPEs	\$2,417	\$2,376	\$2,027	\$1,818	\$1,078	\$733
Debt	\$8,418	\$5,565	\$13,978	\$6,569	\$2,824	\$4,156
<b>Private</b>						
VC	\$3,733	\$3,518	\$4,236	\$4,445	\$4,175	\$2,335
Other	\$269	\$1,114	\$425	\$611	\$294	\$56
<b>Subtotal</b>	<b>\$19,927</b>	<b>\$17,586</b>	<b>\$27,352</b>	<b>\$21,975</b>	<b>\$10,103</b>	<b>\$9,321</b>
<b>Partnering</b>	<b>\$10,933</b>	<b>\$17,268</b>	<b>\$19,796</b>	<b>\$23,365</b>	<b>\$20,023</b>	<b>\$12,779</b>
<b>Total</b>	<b>\$30,860</b>	<b>\$34,854</b>	<b>\$47,148</b>	<b>\$45,340</b>	<b>\$30,126</b>	<b>\$22,100</b>

# Infectious Diseases: Phase II Deals

Deal Date	Buyer	Target	Target Location	Target Priv/Pub	Latest Phase	Mol Type	TDV \$M	Cash Stock	Earnout Y/N	Deal Summary
Q1 2009	Vertex	ViroChem Pharma	Canada	Private	Phase II	Vaccine	\$405	Both	N	The deal gives Vertex potential for a strong worldwide presence in the HCV market via two promising oral non-nucleoside HCV NS5B polymerase inhibitors--Phase I VCH222 and Phase II VCH759. Vertex plans to combine each candidate with its first-in-class Phase III protease inhibitor telaprevir to create more potent, faster-acting hepatitis C drugs called STAT-Cs (specifically targeted antiviral therapies for hepatitis C). ViroChem reportedly had many suitors before Vertex not only won the bid, but also scored some points in its race against competitor Schering-Plough to bring the first HCV protease inhibitor to market.
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# Infectious Diseases: Phase I Deals

Deal Date	Licenser	Licensee	Phase	Total Value	Drug Type	Deal Summary
Q1 2008	Crucell NV	Sanofi-Aventis	Phase I	\$111	Antibody	Sanofi pasteur and Crucell N.V signed a collaborative agreement to develop and commercialize Crucell's rabies monoclonal antibodies (mAbs) to be used in association with a rabies vaccine as a post-exposure prophylactic therapy.
Q1 2008	Novoxel SA	Forest Laboratories	Phase I	\$218	Other	Forest Laboratories has licensed exclusive North American rights to develop, manufacture, and commercialize Novoxel SA's intravenous beta lactamase inhibitor NXL104 in combination with its own ceftaroline. NXL104 is an inhibitor of beta lactamase enzymes, which break down antibiotics such as penicillin and cephalosporin, and so has potential in combating drug resistance. Ceftaroline is a broad-spectrum injectable cephalosporin for treating gram-positive pathogens such as methicillin-resistant staphylococcus aureus and multi-drug resistant streptococcus pneumoniae, as well as gram-negative bacteria.
Q1 2009	ZymoGenetics	BMS	Phase I	\$1107	Peptide	ZymoGenetics has licensed Bristol-Myers Squibb exclusive worldwide rights to its type 3 interferon program including a pegylated recombinant form of interferon lambda (IL29) in Phase Ib for hepatitis C virus.. BMS says PEG-interferon lambda--which prompts antiviral activity through a receptor located only on a few cell types within tissues prone to viral infection--will complement its pipeline of small-molecule antivirals in early-stage studies for HIV/AIDS and hepatitis B and C.
Q4 2008	AlphaVax Inc.	Novartis	Phase I	\$20	Vaccine	AlphaVax licensed Novartis exclusive global rights to its Phase I vaccine for cytomegalovirus (CMV).

# Infectious Diseases: Preclinical Partnerships

Deal Date	Licenser	Licensee	Phase	Total Value	Drug Type	Deal Summary
Q1 2008	XTL Biopharmaceuticals	Presidio Pharmaceuticals Inc.	Preclinical	\$108	Small molecule	XTL Biopharmaceuticals licensed Presidio Pharmaceuticals exclusive development and commercialization rights to preclinical hepatitis C compounds targeting NS5A. the company seeks to develop small-molecule drugs that inhibit the function of NS5A, which is a protein responsible for HCV replication. The resulting compounds could prove to be better than protease and polymerase inhibitors for HCV due to their ability to fight drug resistance.
Q1 2008	Tacere Therapeutics	Pfizer	Preclinical	\$145	RNAi or antisense	Tacere Therapeutics will enlist the help of Pfizer to develop and commercialize its preclinical TT033 for hepatitis C. Pfizer will fund the collaboration and gets an exclusive worldwide license to any resulting therapeutics. Tacere will finish preclinical studies and perform early human testing, expected to begin in 2009, and Pfizer will take over later clinical development. TT033 is surrounded by an adeno-associated virus vector coating and comprised of three separate RNAi elements. Following intravenous administration, it has shown to effectively target and penetrate the site of HCV replication without toxicity. Tacere originally licensed the compound from Benitec .
Q2 2009	Concert Pharmaceuticals	GSK	Preclinical	\$983	Small molecule	Concert Pharmaceuticals has granted GlaxoSmithKline options to exclusively license global rights to three of its deuterium-containing drug candidates.;CTP518, the most advanced candidate in this deal, is about to enter Phase I for HIV. A modified version of the protease inhibitor atazanavir that substitutes select hydrogen atoms with deuterium, CTP518 could have an advantage over the branded product ( BMS 's Reyataz ) because it may not need to be combined with ritonavir, which is typically co-administered with atazanavir to increase serum levels of the drug. The alliance includes two other optional candidates from Concert's pipeline--a preclinical agent for chronic renal disease and an unnamed research-stage program
Q3 2009	Nabi Biopharmaceuticals	GSK	Preclinical	\$46	Vaccine	Nabi Biopharmaceuticals has sold its pentavalent vaccine PentaStaph for Staphylococcus aureus bacterial infections to GlaxoSmithKline Biologicals SA . PentaStaph was developed under a license from the NIH. The vaccine has five antigen components, three of which induce antibodies against S. aureus polysaccharides--types 5 and 8 capsular polysaccharides, which are being evaluated in Phase III, and type 336 cell-wall polysaccharide, in Phase I. The two other antigens, in preclinical studies, produce antibodies targeting the virulent toxins Panton-Valentine Leukocidin and alpha toxin.

# Infectious Diseases: Research Collaborations

Deal Date	Licensor	Licensee	Phase	Total Value	Drug Type	Deal Summary
Q1 2009	Forma Therapeutics	Cubist Pharmaceuticals	Research	\$68	Small molecule	In a three-year deal, Forma Therapeutics will use its proprietary chemistry platform to discover new antibacterial compounds for Cubist Pharmaceuticals. Cubist will be responsible for development and commercialization. Forma's integrated transformative biology and chemistry-based approach to structure-guided drug discovery enables the screening of discrete targets in cells, as well as quantitative genome and proteome-wide profiling and target identification. The compounds involved in the collaboration could be used to fight methicillin-resistant Staphylococcus aureus and gram-negative infections.
Q1 2009	Biotica Technology	GSK	Research	\$130	Small molecule	In a three-year deal, Biotica will identify drug candidates using its bioengineering platform, which intervenes during polyketide synthesis to generate improved versions of these naturally occurring molecules. In the case of erythromycin, the technology's main advantage over traditional medicinal chemistry techniques is that it can engineer analogs of this broad-spectrum macrolide that cause little or no antibiotic resistance.
Q2 2008	Ranbaxy Laboratories	Merck & Co.	Research	\$200	Undisclosed	Merck and India's drug giant Ranbaxy Laboratories have agreed to collaborate on the development of new anti-infective therapeutics. Terms of the five-year (renewable) deal call for Ranbaxy to perform drug discovery and development through Phase IIa clinical trials, after which point Merck will take over development, and be responsible for regulatory submissions and commercialization.
Q2 2008	Mpex Pharmaceuticals	GSK	Research	\$258	Peptide	GlaxoSmithKline has agreed to team up with biotech Mpex Pharmaceuticals to use the latter's expertise in antibiotic drug resistance with efflux pump inhibitors (EPIs). Mpex is responsible for identifying EPIs and developing them in combination with GSK's existing antibiotics or drug candidates through proof-of-concept. The compounds will be against three different targets with the goal of providing up to seven treatment options.
Q2 2008	Medivir AB	J&J	Research	\$427	Small molecule	Medivir AB will team up with Johnson & Johnson's Tibotec to discover and develop orally active HCV polymerase NS5B inhibitors. The companies will screen new and current nucleoside analogue libraries belonging to Medivir that already demonstrate anti-HCV tendencies in vitro. They will then jointly conduct preclinical studies to determine which drug candidates to further develop.
Q3 2008	Orchid Research Laboratories	Merck & Co.	Research	\$100	Small molecule	Orchid Chemicals & Pharmaceuticals and Merck will develop new compounds for bacterial and fungal infections. Merck will work with Orchid Research Laboratories on multiple targets and compounds, which Orchid will discover and take through Phase IIa. Merck will complete late-stage trials and be responsible for regulatory activities and commercialization, while Orchid retains any patents pertaining to its discoveries.

# Infectious Diseases Funding: Take Home Messages

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- ❑ Infectious diseases remain a “hot” therapeutic area for pharma and investors
- ❑ Angel investors, corporate ventures and “traditional” VC are active
- ❑ Non-dilutive funding available to fund early stage R&D
- ❑ Partnering continues to be an attractive funding source and partnerships on early stage opportunities are getting done
- ❑ M&A a viable and attractive exit for venture investors
- ❑ Novel mechanism, differentiated product profile key to success for anti-bacterials, anti-fungals and anti-virals

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“It is not the strongest of  
the species that survives,  
nor the most intelligent,  
but the one most  
responsive to change”

*Charles Darwin*

