Zacks Equity Research

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Inhibitex, Inc. (INHX-NASDAQ)

INHX: Poised For A Big Second Half…

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	09/21/2009
Current Price (05/13/10)	$1.94
Target Price	**$3.00**

OUTLOOK

We believe that Inhibitex is poised for a big second half of the year. The ongoing phase II program on FV-100 is expected to complete here in the third quarter, with data expected in the fourth quarter 2010. FV-100 has the potential to be a game-changer for the treatment of herpes zoster, or shingles. Inhibitex is also progressing with a phase Ia program on nucleoside polymerase inhibitor, INX-189, with data expected later this quarter. INX-189 looks to have unrivaled potency in the genotype 1 replicon assay. INX-189 looks to be the most potent nucleotide polymerase inhibitor in clinical development. Both compounds present management with the opportunity to strike lucrative partnerships in 2011.

SUMMARY DATA

52-Week High	**$2.95**
52-Week Low	**$0.44**
One-Year Return (%)	**312.77**
Beta	**0.99**
Average Daily Volume (sh)	**174,635**
Shares Outstanding (mil)	**62**
Market Capitalization ($mil)	**$120**
Short Interest Ratio (days)	**3.98**
Institutional Ownership (%)	**63**
Insider Ownership (%)	**25**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**24.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2010 Estimate	**N/A**
P/E using 2011 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**59 of 141**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	0.3 A	0.3 A	0.3 A	0.3 A	1.2 A
2010	1.0 A	0.3 A	0.3 E	0.3 E	1.9 E
2011					3.5 E
2012					5.0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	-$0.10 A	-$0.10 A	-$0.10 A	-$0.08 A	-$0.38 A
2010	-$0.08 A	-$0.09 A	-$0.09 E	-$0.10 E	-$0.36 E
2011					-$0.34 E
2012					-$0.27 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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WHAT'S NEW

Second Quarter Financial Review…

On August 10, 2010, Inhibitex reported financial results for the second quarter ended June 30, 2010. Total revenues in the quarter were $0.3 million and were comprised of $0.250 million in collaborative R&D payments from Pfizer on licensing the company's MSCRAMM technology, as well as a $0.0375 million licensing and milestone payments. Revenues were right in-line with our expectations. Net loss for the first quarter totaled $5.6 million, or $0.09 per share. This was right on with our financial forecast. The company exited the second quarter ended June 30, 2010 with $29.3 million in cash and investments. We believe the current cash balance is sufficient to fund operations into 2011.

Phase II FV-100 Trial Progressing on Plan…

It's been smooth sailing so far for the company's phase II program on FV-100. Since initiated in May 2009, the independent data safety monitoring board (DSMB) responsible for reviewing safety data from the trial has met three times to review 30-day follow-up safety data from the first, second and third quartiles. After each time, most recently as of July 22, 2010, the DSMB recommended the trial continue on plan.

We expect that enrollment at ~350 patients should complete in the third quarter 2010, with top-line data to become available in the fourth quarter 2010. Back in April 2010, an independent statistician conducted a prospectively described interim analysis of the primary efficacy endpoint on the first half of the patients enrolled in the trial and recommended that the trial continue to completion as designed.

As a reminder, the phase II program, initiated in May 2009, is a well-controlled, double-blind, clinical trial evaluating FV-100 against an active control of Glaxo's Valtrex (valacyclovir). Roughly 350 patients, aged 50 years and older, will be randomized to one of three treatment arms: 200 mg FV-100 administered once daily; 400 mg FV-100 administered once daily; and 1,000 mg valacyclovir administered three times per day. The primary endpoint of the trial is a reduction in herpes zoster associated pain and severity as measured by the Zoster Brief Pain Inventory (ZBPI) scale after 30 days of treatment. The trial is 80% powered to detect an approximate 25% difference between the FV-100 and Valtrex cohorts. In addition to the primary endpoint, Inhibitex will also report: 1) reduction in ZBPI after 90 days, 2) incidence of post herpetic neuralgia (PHN), 3) mean time to lesion healing, and 4) use of concomitant pain medications. We are optimistic on the outcome of this trial and believe it presents management with a significant partnering opportunity in 2011.

The next step for management following completion of the phase II trial would be to schedule an End-of-Phase II meeting with the U.S. FDA in 2011. We expect that Inhibitex will look to push FV-100 into a pivotal phase III program shortly thereafter. Our best guess is that the phase III program will include two concurrent programs, with a total enrollment of around 1000 patients, and take an estimated two years to complete. Therefore, if all goes well, we could be looking at a new drug application (NDA) on FV-100 around 2014, with U.S. FDA action in 2015. We note that management has mentioned being in discussion with potential partners on FV-100, and we fully expect a deal in 2011. However, at this point it remains to be seen whether or not a deal is signed prior to the initiation of a phase III program. We note the longer management waits to partner FV-100, potentially the better economics management can negotiate for shareholders.

Phase I Program on INX-189 Initiated…

During the first quarter 2010, management filed an investigational new drug application (IND) on INX-189, the company's high potency nucleoside NS5b polymerase inhibitor. The U.S. FDA responded favorably to the application and human clinical trials are now underway. The phase Ia trial is a double-blind, placebo-controlled, single ascending dose study to evaluate the safety and pharmacokinetics of INX-189 in healthy volunteers all in the U.S. (single site). The trial will employ up to six escalating doses of INX-189, ranging from 3 mg up to 200 mg. Each dose cohort will include eight subjects, six of which will receive INX-189 and two that will receive placebo, for a total of 48 subjects. There will also be a food-effect study in one of the dose cohorts. We expect that this program will complete in the third quarter 2010.

Pending a successful completion of the above phase Ia program, we anticipate that management will seek to initiate a phase Ib multiple ascending dose, three day monotherapy study in genotype 1 naive HCV infected patients shortly after the top-line data has been released from the phase Ia program. On the second quarter conference call management noted that this program will probably study 4 or 5 doses, with 10 patients in each cohort, for a total of 50 to 60 subjects. This trial should begin early fourth quarter of 2010, with top line data from one or more cohorts potentially available before the end of the year. Full data from the phase Ib should become available in the first quarter of 2011.

Inhibitex has also initiated 28 day animal toxicology studies of INX-189 and plans to conduct longer term toxicology studies beginning shortly. Assuming successful completion of these chronic toxicology studies and favorable data from both the phase Ia and Ib trial, management should be in position to advance INX-189 in a phase II, 12+ week clinical trial in combination with standard of care and other complementary direct antiviral compounds in 2011. We expect that management will partner the candidate for the phase II program in 2011 assuming safety and proof-of-concept have been effectively demonstrated.

INX-189 is a nucleoside polymerase inhibitor under development for the treatment of chronic hepatitis C caused by the hepatitis C virus (HCV). More specifically, the drug is a phosphoramidate nucleoside analogue, also referred to as pronucleotides or protides, which targets the RNA-dependent RNA polymerase ("NS5b") of HCV. We believe this protide approach possesses several pharmacological advantages over earlier, first generation approaches that use the parent nucleoside (non-phosphorylated) alone. These include a significant increase in antiviral activity, higher concentrations of the anti-virally active triphosphate in liver, and potentially less toxicity due to reduced systemic exposure.

Preclinical data suggests that INX-189 has unrivaled potency in genotype 1 replicon assay. We believe that INX-189 is the most potent nucleotide polymerase inhibitor in clinical development. And, importantly, the pharmacodynamic data from the preclinical program suggests that INX-189 can be evaluated as a once-a-day therapy in future clinical studies. The preclinical profile of INX-189 suggests: rapid onset of anti-viral activity, a long half-life that could allow for once daily dosing, low toxicity, and a potential synergistic mechanism with ribavirin. This is certainly something to be excited about. We note that Inhibitex is also working on several other backup nucleotide analogues into animal studies and management is actively engaged in evaluating additional HCV polymerase nucleotide inhibitors as well.

Pfizer Starts Phase I on SA3Ag…

In early January 2010, Pfizer reported to Inhibitex that it had initiated patient recruitment for 408-patient, randomized, double-blind phase I clinical trial to evaluate the safety, tolerability, and immunogenicity of three ascending dose levels of a 3-antigen *Staphylococcus aureus* vaccine (SA3Ag) in healthy adults. The SA3Ag vaccine contains an antigen originating from Inhibitex' MSCRAMM protein platform. Management licensed its MSCRAMM protein platform to Wyeth (acquired by Pfizer in 2009) on an exclusive worldwide basis for the development of active vaccines against staphylococcus in 2001. Pfizer is responsible for all clinical development, manufacturing and marketing of the vaccine. Inhibitex earned a $0.7 million milestone payment upon the initiation of the phase I program, and is eligible to receive milestones, as well as royalties on future net sales. This $0.7 million milestone was recognized fully in the first quarter 2010.

Cash Position Solid…

Inhibitex exited the second quarter 2010 with $29.3 million in cash and investments. This should be enough to fund operations, including completing the ongoing phase II FV-100 program and completing a phase Ia and phase Ib program on INX-189 in 2011. We estimate that the company will still have roughly $18 million in cash on hand at the end of the year. Therefore, Inhibitex may be in need of cash at some point in 2011. However, with the potential to partner both FV-100 and INX-189, as well as receive additional milestone from Pfizer on SA3Ag, we believe there is significant opportunity to raise non-dilutive cash in 2011. If management does choose to raise cash through a secondary offering, we do not expect anything before the release of data on FV-100, and we do not expect it to be greater than a 20% dilution.

RECOMMENDATION

FV-100 a Game Changer…

Inhibitex lead development candidate, FV-100, has the potential to be a game changer for the treatment of herpes zoster, or shingles. The current standard of care, Glaxo's Valtrex (valacyclovir), with an estimated 55% market share, is dosed at 1000mg three times a day. Valtrex has improved lesion healing and pain indication reduction over older drugs Famvir (famciclovir) and Zovirax (acyclovir), but the treatment option can still be improved upon significantly. Inhibitex is developing FV-100, a potential once daily dosing agent, currently in a phase II trial. The trial is designed to show FV-100 is superior to Valtrex on pain and severity reduction after 30 days, the primary endpoint, as well as show superiority on key secondary endpoints including: pain after 90 days, incidence of post herpetic neuralgia (PHN), mean time to lesion healing, and use of concomitant pain medications.

If successful, we believe that Inhibitex' drug has $500+ million peak sales worldwide. However, even with efficacy only on par with Valtrex, we still believe that FV-100 has commercial potential given the reduction in dosing (improved compliance – especially in the elderly population) from three times daily to once daily.

FV-100 Peak Sales (in Millions)		
Scenario:	Base	...phase II efficacy on par with Valtrex, primary driving force is QD dosing vs. TID for Valtrex
FV-100 Price:	$225	per Rx
FV-100 Market Share:	40%	...takes sizable share from Valtrex, but generics still hold onto 40% of the market
Market Opportunity (U.S.):	$203	...peak U.S. sales
Market Opportunity (Ex-U.S.):	$142	...about 70% of U.S. sales
Total Peak Sales	$345	...under "Base" case scenario
Scenario:	Bull	...phase II efficacy superior to Valtrex, primary driving force is both efficacy and dosing
FV-100 Price:	$275	per Rx
FV-100 Market Share:	65%	...takes sizable share from both Valtrex and all generics
Market Opportunity (U.S.):	$403	...peak U.S. sales
Market Opportunity (Ex-U.S.):	$302	...about 75% of U.S. sales
Total Peak Sales	$705	...under "Bull" case scenario

INX-189 Could Be Huge…

Inhibitex' HCV phosphoramidate nucleoside analogue (protide) candidate, INX-189, could be a potential blockbuster given its rapid onset, favorable once daily dosing, high potency activity, and improved tolerability profile. Preclinical *in vitro* data has been very impressive. Plus, INX-189 could have potential synergistic benefits with ribavirin, making the drug an excellent add-on therapy to standard of care. With phase I concept data that confirms the exciting preclinical work and management's optimism on the drug, INX-189 could fetch $100 million or more in a development partnership. We remind investors that in March 2009, Vertex Pharmaceuticals paid nearly $400 million to acquire privately-held ViroChem and its HCV non-nucleoside N25b polymerase inhibitor, VCH-222. Inhibitex' nucleosides N25b polymerase inhibitor looks to offer similar potency with potentially less resistance and improved dosing. Phase Ib concept data is expected early 2011. Two other phosphoramidate candidates, Pharmasset's PSI-7851 and Idenix' IDX-184, are over a year ahead of INX-189 in development, although we note neither candidate looks as potent as INX-189.

PROJECTED FINANCIALS

Inhibitex, Inc.
Income Statement

	2008 A	2009 A	Q1 A	Q2 A	Q3 E	Q4 E	2010 E	2011 E	2012 E	2013 E
FV-100 (U.S.)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
FV-100 (Ex-U.S.)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
FV-100 Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
INX-189	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Collaborative R&D	$1.5	$1.0	$0.3	$0.3	$0.3	$0.3	$1.0	$2.5	$2.5	$2.5
Licenses Fees & Milestones	$1.7	$0.2	$0.7	$0.0	$0.0	$0.0	$0.9	$1.0	$2.5	$5.0
Total Other Revenues	**$3.2**	**$1.2**	**$1.0**	**$0.3**	**$0.3**	**$0.3**	**$1.9**	**$3.5**	**$5.0**	**$7.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$3.2**	**$1.2**	**$1.0**	**$0.3**	**$0.3**	**$0.3**	**$1.9**	**$3.5**	**$5.0**	**$7.5**
YOY Growth	-	*-63.5%*	-	-	-	-	*61.9%*	*88.0%*	*42.9%*	*50.0%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	*100.0%*	-	-	-	-	-	-	-	-	-
SG&A	$5.1	$3.6	$1.0	$1.0	$1.1	$1.2	$4.3	$4.5	$4.7	$5.0
% SG&A	-	-	-	-	-	-	*230.1%*	*128.6%*	*94.0%*	*66.7%*
R&D	$12.7	$15.4	$4.8	$4.9	$5.0	$5.2	$19.9	$21.0	$18.0	$18.0
% R&D	-	-	-	-	-	-	*1069.2%*	*600.0%*	*360.0%*	*240.0%*
Operating Income	($14.5)	($17.8)	($4.8)	($5.6)	($5.8)	($6.1)	($22.3)	($22.0)	($17.7)	($15.5)
Interest & Other Net	$1.3	$0.2	$0.0	$0.0	$0.0	$0.0	$0.1	$0.2	$0.2	$0.2
Pre-Tax Income	($13.2)	($17.6)	($4.8)	($5.6)	($5.8)	($6.1)	($22.2)	($21.8)	($17.5)	($15.3)
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($13.2)	($17.6)	($4.8)	($5.6)	($5.8)	($6.1)	($22.2)	($21.8)	($17.5)	($15.3)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.31)**	**($0.38)**	**($0.08)**	**($0.09)**	**($0.09)**	**($0.10)**	**($0.36)**	**($0.34)**	**($0.27)**	**($0.23)**
YOY Growth	-	-	-	-	-	-	*-4.9%*	*-5.1%*	*-22.2%*	*-15.1%*
Shares Outstanding	43.1	46.7	61.6	61.8	62.0	62.2	61.9	64.0	66.0	68.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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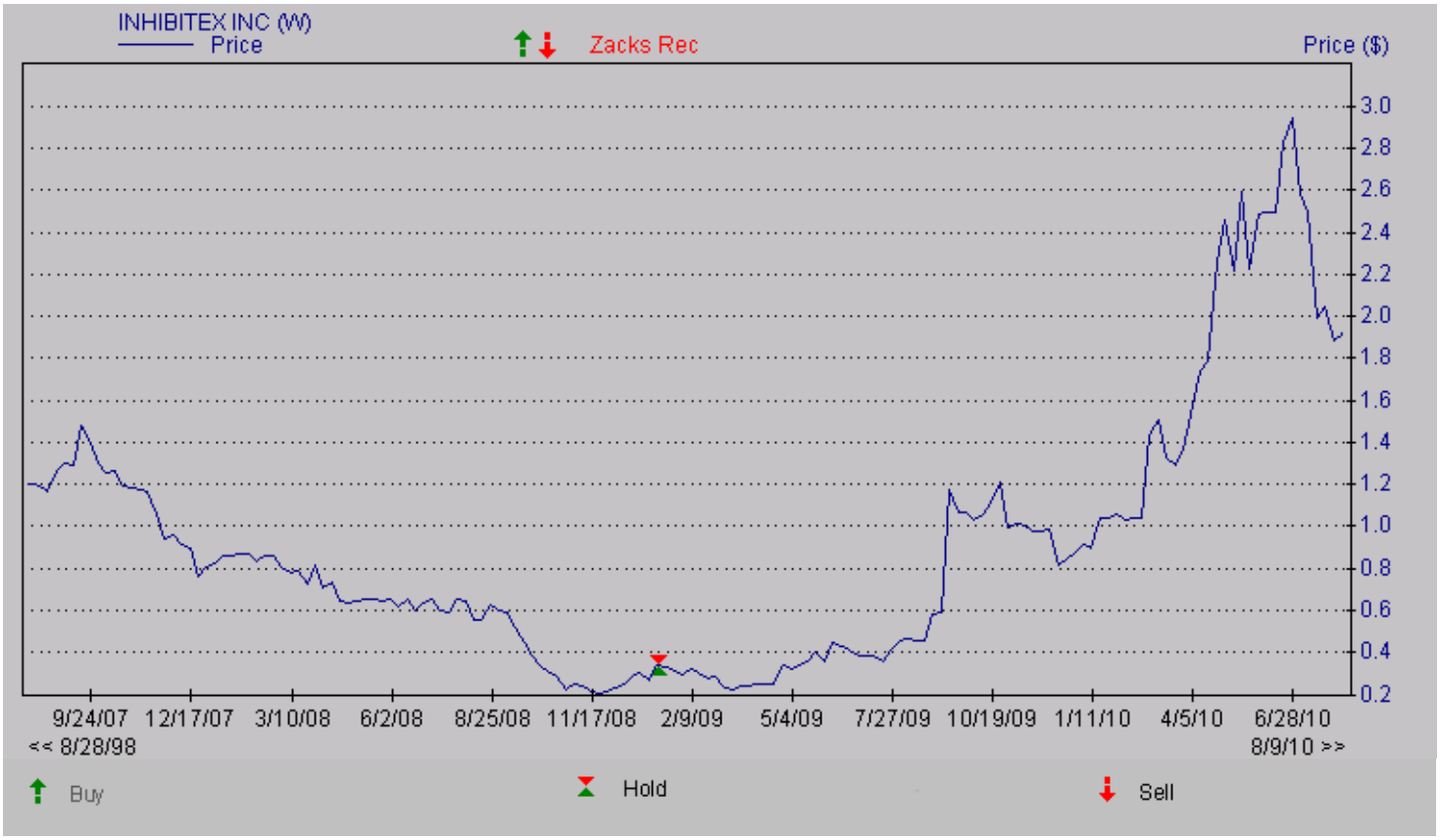

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