Zacks Equity Research

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Inhibitex, Inc. (INHX-NASDAQ)

INHX: FV-100 Phase 2 Data Show Utility In Shingles, Expect Partnership In 2011…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	11/09/2010
Current Price (12/14/10)	$2.25
Target Price	**$4.00**

OUTLOOK

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he selloff following the release of the phase II data is a big over-reaction in our view. We remind investors that this was a phase II program, not phase III. What really matters is completing the program and pushing forward into phase III. Far too often we see investors get caught up with statistical significance in a phase II program when what really matters is generating concept and safety data that can be brought in front of the FDA and potential development partners. We believe that FV-100 works based on the BOI data and the clear lower incidence in PHN. Once management has its end of phase II meeting with the FDA and outlines a plan for the phase III program we believe the market will begin to look more favorably on these results.

SUMMARY DATA

52-Week High	**$3.00**
52-Week Low	**$0.75**
One-Year Return (%)	**240.00**
Beta	**1.19**
Average Daily Volume (sh)	**419,548**
Shares Outstanding (mil)	**62**
Market Capitalization ($mil)	**$180**
Short Interest Ratio (days)	**7.07**
Institutional Ownership (%)	**50**
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	**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 A	0.8 E	2.4 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	-$0.08 A	-$0.09 E	-$0.34 E
2011					-$0.35 E
2012					-$0.27 E

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

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WHAT'S NEW

Phase 2 FV-100 Data Show Potential

On December 13, 2010, Inhibitex announced results from the company's phase II trial studying FV-100 as a treatment for herpes zoster, commonly known as shingles. As a reminder, the company initiated the program in May 2009. The trial was 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, were 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 study was a reduction in herpes zoster associated pain and severity as measured by the Zoster burden of illness (BOI) scale after 30 days of treatment. The trial was 80% powered to detect an approximate 20-25% difference between the FV-100 and Valtrex cohorts. Secondary endpoints included the BOI after 90 days, incidence of post herpetic neuralgia (PHN), mean time to lesion crusting and healing, and use of concomitant pain medications. The results:

	FV-100 200mg QD (n=107)	FV-100 400mg QD (n=113)	Valacyclovir 1000mg TID (n=109)
Zoster BOI Day 30	114.49	110.31	117.96
Zoster BOI Day 90	221.53	196.94	229.59
Incidence of PHN	17.8%	12.4%	20.2%

For FV-100 200mg QD: The data show a 3% reduction on the BOI-30 primary endpoint and a 4% reduction on the BOI-90 endpoint vs. valacyclovir 1000mg TID. Patients on FV-100 200mg also had a 12% reduce incidence of PHN (17.8% vs. 20.2%) vs. valacyclovir.

For FV-100 400mg QD: The data show a 7% reduction on the BOI-30 primary endpoint and a 14% reduction on the BOI-90 endpoint vs. valacyclovir 1000mg TID. Patients on FV-100 400mg also had a 39% reduce incidence of PHN (12.4% vs. 20.2%) vs. valacyclovir.

The trial missed the primary endpoint of a 20-25% difference between the FV-100 cohorts vs. Valtrex on the BOI-30 scale. In fact, results weren't even close. But we believe the trial was far from a failure. On the contrary, we are highly encouraged by the following:

- ✓ There was continued separation from the FV-100 cohorts and valacyclovir between BOI-30 and BOI-90:
  - o FV-100 200mg QD went from 3% improvement at BOI-30 to 4% improvement at BOI-90
  - o FV-100 400mg QD went from 7% improvement at BOI-30 to 14% improvement at BOI-90

  This shows the drug is working over time. Additionally, management noted that the average "worst pain" at day 90 was lower for the FV-100 cohorts vs. valacyclovir. The BOI composite endpoint is a measure of both severity and duration. We believe severity clearly trended in FV-100's favor.

- ✓ There is clear dose response. The FV-100 400mg arm showed reduced BOI-30 and BOI-90 scores vs. the FV-100 200mg arm. This present the opportunity to test even higher doses in the future. Does response is one of the key things we look for during a phase II proof-of-concept program.

- ✓ The reduced incidence of PHN is the most clinically meaningful endpoint. PHN is the paramount concern for physicians and patients treating a zoster infection. Onset of PHN brings use of additional pain medications, including opioids, added cost potential complications. We believe a 39% reduced risk of PHN for patients taking FV-100 400mg is enough alone to drive prescription use if approved.

- ✓ Roughly 20% more patients on valacyclovir used opioids (52% vs. 42%) than on FV-100. We think this is important to note because the BOI-30 and BOI-90 data accounts for pain severity and duration regardless of the use of concomitant pain medications. For FV-100 400mg the BOI-90 showed a 14% reduction vs. valacyclovir despite the fact that 20% more on valacyclovir were also on opioids.
  - o This is something to keep an eye on for the phase III program. Management cannot control opioid use during the trial. If more control patients are using opioids then the pain scores in the control will be tainted (lowered) as a result. Pain may not be the best way to asses FV-100's utility. We think investors should be focusing on the lower incidence of PHN and the increase opioid use as clear signs that FV-100 is superior to valacyclovir.

- ✓ FV-100 offers secondary benefits vs. valacyclovir:
    - o FV-100 is once daily (QD) dosing vs. valacyclovir three-times daily (TID) dosing. Also, the FV-100 400mg pill is a lot smaller and easier to swallow than the valacyclovir 1000mg pill.
    - o Enrollment characteristic showed that 10% of the patients randomized to the study had baseline creatinine serum levels less than 50. The Valtrex label requires that these patients with potential renal insufficiency receive a lower dose for safety reasons. FV-100 is primarily cleared by the liver, and thus management does not believe the FDA will require this creatinine level test prior to dosing. This could save the physician time and the patient money in the long run.

Safety and tolerability of FV-100 looks generally similar to valacyclovir during the phase II program. The chart below shows the adverse events (AEs) and serious adverse events (SAEs) as well as discontinuations.

	FV-100 200mg QD (n=117)	**FV-100 400mg QD (n=117)**	**Valacyclovir 1000mg TID (n=116)**
Excluded as Zoster Negative	n=10	n=4	n=7
Any Adverse Events	46%	55%	42%
Treatment-Related AEs	21%	26%	20%
Serious Adverse Events	0%	4%	3%
Treatment-Related SAEs	0%	0%	2%

Adverse events in any cohort that exceeded 10% were headache and nausea. Serious adverse events were low and generally not related to drug treatment. Given the similar safety and tolerability profile of FV-100 vs. valacyclovir, we do not believe there is any limitation that would prohibit use if approved. Management has additional safety data of FV-100 800mg QD as well. Given the clear dose response seen in the phase II data above, testing a higher dose for the phase IIb or phase III program may be appropriate.

…Next Steps…

Management continues to analyze the data from the phase II program. We expect to see the full data at a medical conference during the spring of 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 around the middle of 2011. This meeting will be key in determining what trial design for the phase III program. Things to look for:

- ➢ Can “Incidence of PHN” be the primary endpoint? We would view this as a significant positive considering the 39% reduction in PHN seen for the FV-100 400mg cohort. A phase III program designed to show reduction in PHN could easily be powered and meet statistical significance based on the phase II results. Also, incidence of PHN is far less subjective and influenced by use of concomitant pain medications and opioid use.

- ➢ Will management test a higher dose of FV-100 or a longer duration? Results from the BOI endpoint were more favorable at day 90 than at day 30.

- ➢ What additional benefits can management design into the phase III program to improve the label? This includes improved compliance for dosing and a lack of screening for renal insufficiency. Also, what type of pharmaco-economic benefit can management show given the lack of this creatinine screen step (an added cost to the patient and insurance provider) and less opioid use? We remind investors that valacyclovir is generic, and will cost far less than branded FV-100. However, with less opioid use, no creatinine screening, and a shorter duration of illness, the cost issue may disappear or even swing to FV-100’s favor.

…Seeking A Partner…

Inhibitex plans to seek a partner for the phase III program. We do not expect a partnership to be signed until after the phase II data has been presented at a medical conference during the spring of 2011. However, following the full data presentation we believe pharmaceutical companies will be very interested in FV-100. This is a potential $500 million opportunity in shingles. Management has commented in the past that they are in talks with potential interested parties, but we caution investors that these talks were probably only in the preliminary stages of interest prior to the data coming out. Now that the data is out we expect talks to heat up.

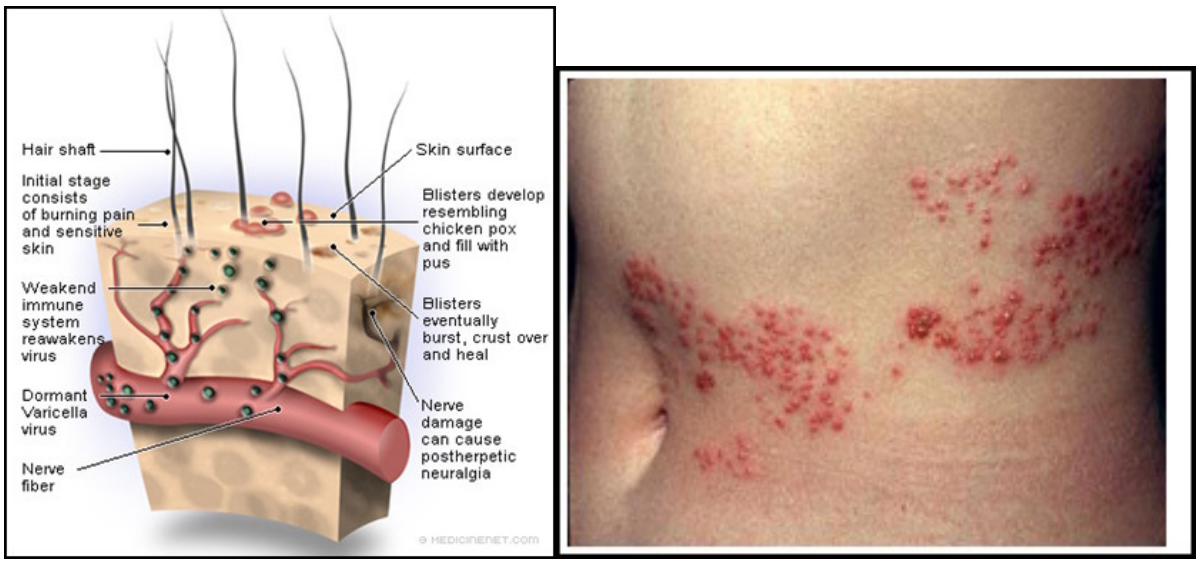
We expect that Inhibitex and its partner will look to push FV-100 into a pivotal phase III program shortly after a deal is done. Our best guess is that the phase III program will include two concurrent programs, with a total enrollment of around 1000 patients, and take an estimated two years to complete. Inhibitex plans a global program, so a meeting with the EMEA will need to take place in 2011 as well. 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.

OVERVIEW

FV-100 Background Info

The leading product candidate at Inhibitex is FV-100, an orally available bicyclic nucleoside analogue prodrug being developed for the treatment of shingles (herpes zoster), which is caused by varicella zoster virus (VZV).

- Varicella Zoster, a DNA virus and member of the herpes family, is the virus that causes chickenpox during childhood. After the chickenpox infection subsides, VZV remains latent in the dorsal root and cranial nerve ganglia. Individuals who have had chickenpox are at risk for reactivation of the VZV virus, known as shingles. Although shingles can occur in any individual with a prior VZV infection, its incidence varies with age and immune status, which are the key risk factors. In 2008, there were an estimated 1.2 million new cases of shingles in the U.S. In Europe and Japan, the estimated number of shingles cases is 1.0 and 0.4 million, respectively. Shingles is largely a disease of the aged, with over 50% of all cases occurring in individuals over the age of 60, and approximately 80% of the cases occurring in individuals over the age of 40. Incidence is often un-reported because the CDC does not require notification for a herpes zoster flare-up. Inhibitex estimates that approximately 20-30% of all persons in the U.S. will suffer from shingles during their lifetime. The pain associated with an episode of shingles is a result of damage to the nerve fibers caused by the replication of VZV and the subsequent inflammation associated with the infection. Pain symptoms are commonly described as a burning sensation, with bouts of stabbing and shooting pain.



Published preclinical data demonstrates that FV-100 is significantly more potent against VZV than older generation nucleoside analogue drugs commonly used to treat herpes such as acyclovir, valacyclovir, famciclovir. Patients often take multiple medications during flare-up, leaving the door open to a potential more potent single agent. Preclinical studies further demonstrate that FV-100 has a more rapid onset of antiviral activity and can fully inhibit the replication of VZV more rapidly than currently used drugs at significantly lower concentration levels. Inhibitex estimates that FV-100 is 10,000 the potency of acyclovir *in vitro*, with onset of action in as little as two hours post-dosing. Valtrex (valacyclovir), the current market leader sold by GlaxoSmithKline, posted worldwide sales of $2.2 billion in 2008, up 16% from 2007 levels. U.S. sales of Valtrex totaled $1.6 billion, up 20%. However, the majority of Valtrex use is for non-shingles indications such as herpes simplex 1 and 2.

Still, there were an estimated 2.5 million prescriptions written for herpes zoster in 2008, and Valtrex has an estimated 55% market share even in the face of cheaper generic competition from acyclovir and famciclovir thanks to improved bioavailability and less frequent dosing. Inhibitex is currently conducting human clinical trials with FV-100 testing its hypothesis that the drug can reduce the incidence, severity, and duration of shingles-related symptoms, including lesions, acute pain, and post herpetic neuralgia (PHN) relative to Valtrex.

- PHN is a persistent neuropathic pain condition caused by nerve damage after a shingles, or herpes zoster, viral infection and afflicts approximately one in five patients diagnosed with shingles (~200k individuals) in the U.S. The incidence of PHN increases in elderly patients, with 75% of those over 70 years old who have shingles, developing PHN. The pain associated with PHN reportedly can be so severe that patients are unable to resume normal activities for months. There are a number of treatment options for PHN including antidepressants, anticonvulsants (such as gabapentin or pregabalin) and topical agents such as lidocaine patches or capsaicin lotion. Opioid analgesics may also be appropriate in the most severe situations.

…Commercialization Plans…

FV-100 has several differentiating characteristics that could catapult it into the market leading position for herpes zoster shortly after approval. Among these include a favorable tolerability and safety profile, strong pharmacokinetic rapid absorption with potent anti-viral activity profile, convenient once-daily dosing – a very strong potential driver of scripts in the elderly – and the potential that FV-100 can be freely used in patients with insufficient renal function, unlike Valtrex.

Branded Valtrex sells for roughly $275 per script (undiscounted). Generic valacyclovir, acyclovir and famciclovir sell for about half that price at around $150 – 200 per script (Valtrex lost patent protection in November 2009). We suspect that FV-100 will be priced competitively with branded Valtrex. However, even with a price comparable to Valtrex, we believe there is significant pharmaco-economics that could benefit FV-100 even in the face of cheaper generic alternatives. Once daily dosing is a major advantage over 3x/daily valacyclovir and 5x/daily acyclovir, and could reduce the number of necessary re-treats due to non-compliance. Also, as seen during the phase II program, use of opioids was about 20% less with FV-100 and patients on FV-100 should not require a creatinine screening prior to dosing. Adding up the additional costs of the renal screening and the opioids, and the compliance issues, and pricing disadvantage for FV-100 vs. generic valacyclovir may all but disappear.

Based on the phase II data, we characterize the market as such:

	valacyclovir	**famciclovir**	**acyclovir**	**FV-100**
Dose:	1000mg 3x/day	500mg 3x/day	800mg 5x/day	400mg 1x/day
Lesion Healing:	++	+	+	++
Reduction in Pain:	++	+	+	+++
Reduction of PHN:	++	+	+	+++
Opioid Use:	~50%	>50%	>50%	~40%
Adjust for Renal Insufficiency:	Required	Required	Required	Not-required
Price:	$175/Rx	$125/Rx	$125/Rx	$250/Rx

We clearly see a market opportunity with FV-100 given the above characteristics. Valtrex (valacyclovir), the current market leader sold by GlaxoSmithKline, posted worldwide sales of $2.2 billion in 2008, up 16% from 2007 levels. U.S. sales of Valtrex totaled $1.6 billion, up 20%. However, the majority of Valtrex use is for non-shingles indications such as herpes simplex 1 and 2. Still, there were an estimated 2.5 million prescriptions written for herpes zoster in 2008, and Valtrex has an estimated 55% market share even in the face of cheaper generic competition from acyclovir and famciclovir thanks to improved bioavailability and less frequent dosing. We believe that FV-100 is well-positioned with the profile above to capture 30-40% of the market from generic valacyclovir. This puts potential peaks sales in the U.S. at $400 million. Outside the U.S., the drug may be able to capture another $200 million, making worldwide peak sales in the $600 million range. Impediments to gaining market share are cost vs. the three generics and the potential re-formulation of Valtrex by a drug delivery company that could improve the dosing from three-time daily to twice-daily or even once-daily. As of yet, we are unaware of any generic / drug delivery company working on an extended release Valtrex product.

RECOMMENDATION

Selloff An Over-reaction

The selloff following the release of the phase II data is a big over-reaction in our view. Yes, the phase II program failed to show statistical significance on the primary endpoint, which was looking for a 20-25% improvement in pain scores at day 30 using the BOI-AUC. But we remind investors that this was a phase II program, not phase III. The 20-25% improvement is not the end-all be-all hurdle for approval. In fact, it was more an exploratory section by management in an effort to quantify proof-of-concept. If management had established the program to be a non-inferiority program, then these same results would have sent the shares up 20% instead of down 20%. What really matters is completing the program and pushing forward into phase III. Far too often we see investors get caught up with statistical significance in a phase II program when what really matters is generating concept and safety data that can be brought in front of the FDA and potential development partners. We believe that FV-100 works based on the BOI data and the clear lower incidence in PHN. Once management has its end of phase II meeting with the FDA and outlines a plan for the phase III program we believe the market will begin to look more favorably on these results.

Inhibitex Remains Well Positioned

Inhibitex exited the third quarter 2010 with $24.2 million in cash and investments. This should be enough to fund operations, including presenting the full data from the phase II FV-100 program and completing a phase Ib monotherapy and ribavirin combination program on INX-189 in early 2011. We estimate that the company will still have roughly $18 million in cash on hand at the end of the year.

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. We think there will be significant interest from partners on both molecules. We think that 2011 has the potential to be a big year for Inhibitex with signing major development collaborations its two pipeline candidates. Accordingly, we recommend investors ‘Buy’ at today’s price. Our target is $4 per share.

PROJECTED FINANCIALS

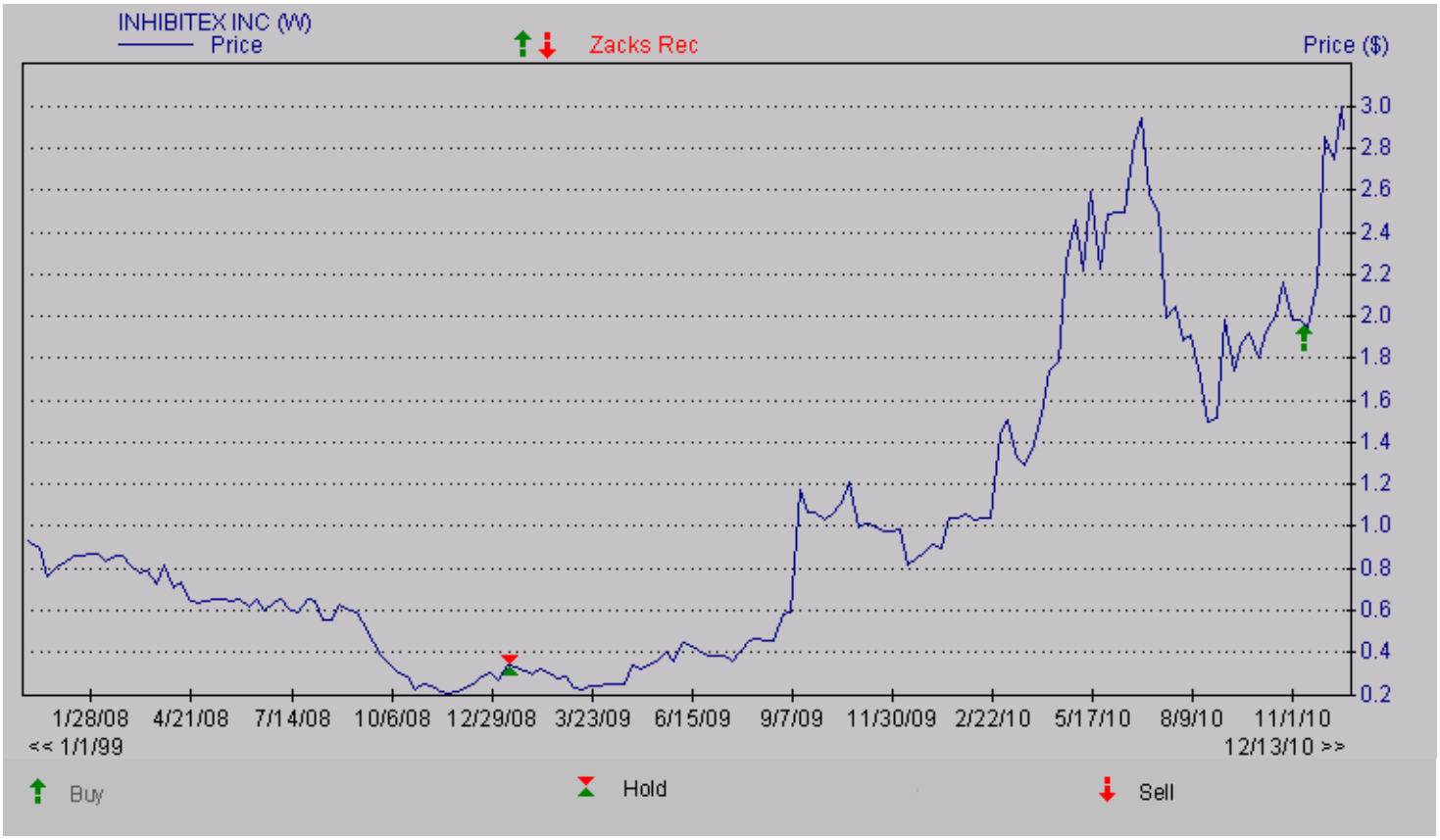
Inhibitex, Inc.
Income Statement

	2008 A	2009 A	Q1 A	Q2 A	Q3 A	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
License Fees & Milestones, Grants	$1.7	$0.2	$0.7	$0.0	$0.0	$0.5	$1.4	$1.0	$2.5	$5.0
Total Other Revenues	**$3.2**	**$1.2**	**$1.0**	**$0.3**	**$0.3**	**$0.8**	**$2.4**	**$3.5**	**$5.0**	**$7.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$3.2**	**$1.2**	**$1.0**	**$0.3**	**$0.3**	**$0.8**	**$2.4**	**$3.5**	**$5.0**	**$7.5**
YOY Growth	-	*-63.5%*	-	-	-	-	*104.4%*	*48.9%*	*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	$0.9	$1.0	$3.9	$4.5	$4.7	$5.0
% SG&A	-	-	-	-	-	-	*164.2%*	*128.6%*	*94.0%*	*66.7%*
R&D	$12.7	$15.4	$4.8	$4.9	$4.7	$5.5	$19.9	$21.5	$18.0	$18.0
% R&D	-	-	-	-	-	-	*846.8%*	*614.3%*	*360.0%*	*240.0%*
Operating Income	($14.5)	($17.8)	($4.8)	($5.6)	($5.3)	($5.7)	($21.4)	($22.5)	($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)	($5.3)	($5.7)	($21.3)	($22.3)	($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)	($5.3)	($5.7)	($21.3)	($22.3)	($17.5)	($15.3)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.31)**	**($0.38)**	**($0.08)**	**($0.09)**	**($0.08)**	**($0.09)**	**($0.34)**	**($0.35)**	**($0.27)**	**($0.23)**
YOY Growth	-	-	-	-	-	-	*-8.8%*	*1.4%*	*-23.9%*	*-15.1%*
Shares Outstanding	43.1	46.7	61.6	61.8	62.2	62.4	62.0	64.0	66.0	68.0

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

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HISTORICAL ZACKS RECOMMENDATIONS



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