

Acapodene Meets Primary Endpoint In Phase III ADT Trial
2008-02-25 14:07 (New York)

Outperform (1)

Biotechnology GTx
February 25, 2008

Acapodene Meets Primary Endpoint In Phase III ADT Trial

Eric Schmidt, Ph.D. Craig Gordon, M.D.
(646) 562-1345 (646) 562-1378
eric.schmidt@cowen.com craig.gordon@cowen.com

Conclusion: GTx announced its Phase III trial on	GTXI (02/25)
\$18.02	
Acapodene in prostate cancer patients on androgen	Mkt Cap
\$632.5MM	
deprivation therapy (ADT) met its primary endpoint of	Dil shares out 35.1MM
reducing vertebral fractures. The company holds an	Avg daily vol
220.0K	
SPA for Acapodene in this indication and plans to	52-wk range
\$10.8-23.6	
file an NDA this summer. If approved, Acapodene will	Dividend Nil
likely share a \$500M+ market with bisphosphonates and	Dividend yield Nil
denosumab. With ADT providing downside support, we	BV/sh
\$2.25	
view the risk/reward of owning GTXI shares into	Net cash/sh
\$3.13	
interim Phase III PIN data (March or April) as	Debt/cap
0.0%	
favorable.	ROE (LTM) NA
	5-yr fwd EPS NA
Phase III ADT Trial Succeeds By A Whisker. The chief	growth concern heading into
Acapodene's ADT study was that it lacked statistical power.	
Indeed, while Acapodene reduced vertebral fracture rates by a convincing	
magnitude (50% in the SPA-specified modified	
intent-to-treat primary endpoint), the study's	S&P 500
1354.7	
p-value was only modestly lower than p=0.05.	
Acapodene met several secondary endpoints including a decrease in cholesterol,	
LDL, and triglycerides and an improvement in gynecomastia (breast enlargement and	
pain) which may help differentiate the drug in a competitive market.	

Adverse Events Look Reasonable. GTx has indicated Acapodene was associated with no negative trend in death, SAEs, or prostate cancer progression. Although Acapodene was associated with a higher incidence of venous thromboembolic events (17 vs. 7 on placebo), other SERMs have been approved for the treatment of osteoporosis despite higher VTE risk. Nonetheless, given the FDA's heightened interest in drug safety, we expect Acapodene's risk/benefit will be discussed at an FDA panel.

PIN Data Next. The Phase III PIN trial passed another DSMB safety review in January. As the upcoming interim efficacy analysis includes no futility assessment (trial will be halted for favorable efficacy or will continue), we see little downside and potentially large upside into this event.

Revenue \$MM							
FY	2007	2008E		2009E		2010E	2011E
Dec	Actual	Prior	Current	Prior	Current	Current	Current
Q1	1.7	--	4.3	--	--	--	--
Q2	1.9	--	4.3	--	--	--	--
Q3	1.7	--	4.3	--	--	--	--
Q4	1.9	--	4.3	--	--	--	--
Year	7.2	--	17.0	--	29.0	111.0	203.0
EV/S	--	--	18.0x	--	10.5x	2.7x	1.5x

EPS \$							
FY	2007	2008E		2009E		2010E	2011E
Dec	Actual	Prior	Current	Prior	Current	Current	Current
Q1	(0.23)	--	(0.24)	--	--	--	--
Q2	(0.26)	--	(0.25)	--	--	--	--
Q3	(0.29)	--	(0.29)	--	--	--	--
Q4	(0.36)	--	(0.37)	--	--	--	--
Year	(1.16)	--	(1.15)	--	(1.70)	(0.45)	1.00
P/E	--	--	--	--	--	--	18.0x

Please see addendum of this report for important disclosures.

www.cowen.com

Investment Thesis

GTx develops and commercializes drugs for unmet medical conditions in the field of men's health. GTx's pipeline is built around compounds that selectively modulate estrogen and testosterone pathways. The company's lead compound, Acapodene, recently completed a pivotal trial for the treatment of the side effects, including osteoporosis, associated with androgen deprivation therapy in prostate cancer patients. Positive top-line data indicated Acapodene reduced the incidence of new vertebral fractures by 50%. Acapodene is also in a Phase III trial for the prevention of prostate cancer in patients with high grade precancerous lesions (PIN), a condition that currently has no therapeutic options. GTx plans on commercializing Acapodene independently in the U.S. for both indications and has signed a collaboration with Ipsen to market Acapodene in Europe. GTx and partner Merck are also leading the way in the discovery and development of a new class of agents called selective androgen receptor modulators

(SARMs) that have potential to induce the positive effects of testosterone or anabolic steroids (increased muscle and bone mass) without their unwanted effects on the skin, prostate, or pituitary gland. Lead SARM candidate, Ostarine, has produced compelling proof-of-principle data in elderly patients and has entered Phase IIb trials for cancer-related cachexia. GTx and Merck plan to announce the development plan for their combined SARM programs this summer. Preclinical candidates include GTx-758, a novel oral luteinizing hormone inhibitor for advanced prostate cancer that will enter Phase I trials by YE:08,

and GTx-878, an estrogen receptor beta agonist for BPH that will begin Phase I trials in H1:09.

Upcoming Milestones

Milestone

Timing

Interim efficacy analysis from Phase III Acapodene high grade PIN March/April trial Likely start Phase III Acapodene trials for reducing gynecomastia

H1:08

related pain and hot flashes

Finalize SARM development plans for sarcopenia, cancer cachexia, Mid

2008

and other indications with partner Merck

File NDA for Acapodene in men treated with androgen deprivation Mid

2008

therapy (ADT) for prostate cancer

Phase IIB data from Ostarine trial in cancer cachexia Mid

2008

File IND for GTx-838, a second SARM candidate

2008

Possibly file Acapodene NDA for treatment of PIN

H2:08

Begin Phase I GTx-758 (novel oral luteinizing hormone inhibitor)

YE:08

trial for advanced prostate cancer

Begin Phase I GTx-878 (estrogen receptor beta agonist) trial for H1:09 BPH

Source: Cowen and Company

GTx Quarterly P&L Model (\$MM)

(A graphical object has been removed from this text version of the original document.)

Source: Cowen and Company

GTx Annual P&L Model (\$MM)

(A graphical object has been removed from this text version of the original document.)

Source: Cowen and Company

Addendum

STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
GTXI	GTx

ANALYST CERTIFICATION Each author of this research report hereby certifies that (i) the views expressed in the research report accurately reflect his or her personal views about any and all of the subject

securities or issuers, and (ii) no part of his or her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed in this report.

IMPORTANT DISCLOSURES

Cowen and Company, LLC and or its affiliates make a market in the stock of GTXI securities.

Cowen and Company, LLC compensates research analysts for activities and services intended to benefit the firm's investor clients.

Individual

compensation determinations for research analysts, including the author(s) of this report, are based on a variety of factors, including the overall profitability of the firm and the total revenue derived from all sources, including revenues from investment banking. Cowen and Company, LLC does not compensate research analysts based on specific investment banking transactions.

DISCLAIMER

This research is for our clients only. Our research is disseminated primarily electronically and, in some cases, in printed form. Research distributed

electronically is available simultaneously to all Cowen and Company, LLC clients. All published research, including required disclosures, can be obtained on the Firm's client website, www.cowenresearch.com.

Further information on any of the above securities may be obtained from our offices. This report is published solely for information purposes, and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state where such an offer or solicitation would be illegal. Other than disclosures relating to Cowen and Company, LLC, the information herein is based on sources we believe to be reliable but is not guaranteed by us and does not purport to be a complete statement or summary of the available data. Any opinions expressed herein are statements of our judgment on this date and are subject to change without notice.

Notice to UK Investors: This publication is issued in the United Kingdom by or through Cowen International Limited. In the United Kingdom, Cowen and Company is a Trading Name of Cowen International Limited.

This communication has been issued in the U.K. only to persons of a kind described in Article 19 and 49 of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2001 ("relevant persons"). It must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is only available to relevant persons and will be engaged in only with relevant persons.

Copyright, User Agreement and other general information related to this report

(C) 2008 Cowen and Company, LLC. Member NYSE, FINRA and SIPC. All rights reserved. This research report is prepared for the exclusive use of Cowen clients and may not be reproduced, displayed, modified, distributed, transmitted or disclosed, in whole or in part, or in any form or manner, to others outside your organization without the express prior written consent of Cowen. Cowen research reports are distributed simultaneously to all clients eligible to receive such research prior to any public dissemination by Cowen of the research report or information or opinion contained therein.

Any unauthorized use or disclosure is prohibited. Receipt and/or review of this research constitutes your agreement not to reproduce, display, modify, distribute, transmit, or disclose to others outside your organization the contents, opinions, conclusion, or information contained in this report (including any investment recommendations, estimates or price targets).

All Cowen trademarks displayed in this report are owned by Cowen and may not be used without its prior written consent.

Cowen and Company, LLC. New York (646) 562-1000 Boston (617) 946-3700
San Francisco (415) 646-7200 Chicago (312) 516-4690 Cleveland (440) 331-3531
London (affiliate) 44-207-071-7500 Geneva (affiliate) 41-22-707-6900

COWEN AND COMPANY RATING DEFINITIONS (a) Rating Definition

Outperform (1)	Stock expected to outperform the S&P 500
Neutral (2)	Stock expected to perform in line with the S&P 500
Underperform (3)	Stock expected to underperform the S&P 500

(a) Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period.

COWEN AND COMPANY RATING ALLOCATION (a)

Rating	Pct of companies under services	Pct for which Investment Banking coverage with this rating have been provided within the past 12 months
Buy (b)	48.4%	8.6%
Hold (c)	49.3%	3.0%
Sell (d)	2.3%	0.0%

(a) As of 12/31/2007. (b) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions (see above). (c) Corresponds to "Neutral" as defined in Cowen and Company, LLC's ratings definitions (see above). (d) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions (see above).

Note: "Buy," "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with NASD and NYSE regulations.