

CV THERAPEUTICS INC
Form SC TO-C
March 16, 2009

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Schedule TO

**Tender Offer Statement under Section 14(d)(1) or 13(e)(1)
of the Securities Exchange Act of 1934**

CV Therapeutics, Inc.

(Name of Subject Company (Issuer))

Apex Merger Sub, Inc. (Offeror)

Gilead Sciences, Inc. (Parent of Offeror)

(Names of Filing Persons)

COMMON STOCK, PAR VALUE \$0.001 PER SHARE

(Title of Class of Securities)

126667104

(CUSIP Number of Class of Securities)

Gregg H. Alton, Esq.

Senior Vice President and General Counsel

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**(Name, address, and telephone number of person authorized to receive notices
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CALCULATION OF FILING FEE

Transaction Valuation
Not Applicable

Amount of Filing Fee
Not Applicable

☐ Check the box if any part of the fee is offset as provided by Rule 0-11(a)(2) and identify the filing with which the offsetting fee was previously paid. Identify the previous filing by registration statement number or the form or schedule and the date of its filing.

☒ Check the box if the filing relates to preliminary communications made before the commencement of a tender offer.
Check the appropriate boxes below to designate any transactions to which the statement relates:

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☒ third-party tender offer subject to Rule 14d-1.

☐ issuer tender offer subject to Rule 13e-4.

☐ going-private transaction subject to Rule 13e-3.

☐ amendment to Schedule 13D under Rule 13d-2.

Check the following box if the filing is a final amendment reporting the results of the tender offer: ☐

Gilead to Acquire CV Therapeutics
Announced March 12, 2009

Slide 2

Safe Harbor Disclaimer

This
presentation
contains

forward-looking
information

(within the meaning of the Private Securities Litigation Reform Act of 1995) that involves substantial risk and uncertainty. Actual results may differ materially based on a variety of factors, particularly those relating to the development and marketing of pharmaceutical products as described in the Risk Factors section of Gilead's SEC reports, including the report on Form 10-K for the year

ended December 31, 2008.

Slide 3
Safe
Harbor
Disclaimer
(cont d)
This
is
neither
an
offer
to
purchase
nor
a
solicitation

of
an
offer
to
sell
CV
Therapeutics
shares.
The
tender
offer
will
only
be
made
through
an
offer
to
purchase,
letter
of
transmittal
and
related
tender
offer
materials.
At
the
time
the
expected
tender
offer
is
commenced,
Gilead
will
file
these
tender
offer
materials
with
the
Securities
and
Exchange
Commission

and
CV
Therapeutics
will
file
a
solicitation/
recommendation
statement
with
respect
to
the
offer.
The
tender
offer
materials
and
the
solicitation/
recommendation
statement
will
contain
important
information.
Stockholders
are
urged
to
read
this
information
carefully
before
making
any
decisions
about
the
tender
offer.
The
tender
offer
materials,
certain
other
offer

materials,
and
the solicitation/
recommendation
statement
will
be
sent
free
of
charge to all
stockholders
of
CV
Therapeutics.

Slide 4

Gilead's Platform Spans Four Therapeutic Areas

Atripla

Atripla

Truvada

Truvada

Viread

Viread

Emtriva

Emtriva

Elvitegravir

Elvitegravir

(Ph III)

GS 9350

GS 9350
Integrase
Integrase
FDR
FDR
(Ph I)
PAH
PAH
Letairis
Letairis
Flolan
Flolan
Cicletanine
Cicletanine
(Ph II)
(Ph II)
Resistant
Resistant
Hypertension
Hypertension
Darusentan
Darusentan
(Ph III)
(Ph III)
HBV
HBV
Hepsera
Hepsera
Viread
Viread
HCV
HCV
GS 9450
GS 9450
GS 9190
GS 9190
NASH
NASH
GS 9450
GS 9450
HIV/AIDS
HIV/AIDS
Cardiovascular
Cardiovascular
Liver Disease
Liver Disease
Respiratory
Respiratory
Influenza
Influenza

Tamiflu
Tamiflu
CF
CF
Aztreonam
Aztreonam
Lysine
Lysine
(Applications Pending)
(Applications Pending)
GS 9310 / 11
GS 9310 / 11
GS 9411
GS 9411
Bronchiectasis
Bronchiectasis
Aztreonam
Aztreonam
Lysine
Lysine
(Ph II)
(Ph II)
IPF
IPF
Ambrisentan
Ambrisentan
(Ph III)
(Ph III)

Slide 5

2008 Financial Highlights

Full year total revenues of \$5.34 billion,
up 26 percent over 2007

Full year product sales of \$5.08 billion,
up 36 percent over 2007

Cash flow from operations of \$2.2 billion

Non-GAAP operating margin of 51% from
product sales

(1)

\$3.24 billion in cash, cash equivalents and
marketable securities as of December 31, 2008

(1) Excludes the impact of stock-based compensation expense.

Slide 6

Organizational Strengths

Gilead's reputation as an innovative company
resonates across our key audiences

Productive drug discovery and development track
record

Seven product approvals over the last seven years

Efficient organizational structure

Maintain strong connections with the communities
we serve

Slide 7

Vision for CV Therapeutics

Ranexa

for chronic angina with new, stronger

US label

Specialty sales force detailing cardiologists

Lexiscan

opportunity in EU

Proven development and regulatory organization

Improved

opportunity

for

Letairis

and

darusentan

Pipeline of cardiovascular products

Improved future earnings profile and growth rate

Bolsters Gilead's presence in the
cardiovascular space by providing:

Slide 8

Transaction Overview

Cash tender offer at \$20.00 per share

Transaction value of \$1.4 B

Tender offer expected to close within Q2 09

Subject to minimum tender requirement and
Hart-Scott-Rodino
(antitrust) clearance

Slide 9

Contribution from 2 additional marketed products

Ranexa (US sales and EU royalty)

Lexiscan (North American royalty, unpartnered in the EU and Japan)

Increased spend for sales and marketing

Increased clinical spend

Increased discovery spend

Maintain site

Rationalization of overlapping positions and functions

Contribution from 2 additional marketed products

Ranexa (US sales and EU royalty)

Lexiscan (North American royalty, unpartnered in the EU and Japan)

Increased spend for sales and marketing

Increased clinical spend

Increased discovery spend

Maintain site

Rationalization of overlapping positions and functions

REVENUES

REVENUES

EXPENSES

EXPENSES

Sales &

Marketing

Clinical

Development

Discovery

Research

G&A

Sales &

Marketing

Clinical

Development

Discovery

Research

G&A

Impact on Gilead's P&L

*

* Expected to be dilutive in 2009, neutral to accretive in 2010, and accretive in 2011 and beyond.

Slide 10
CV Therapeutics
Products and Pipeline Would
Significantly Augment Gilead's Cardiovascular Efforts
Product
MOA
Clinical Indication(s)
Stage
Partnerships
Ranexa
®
(ranolazine
ER)
Late sodium
channel inhibitor

Chronic Angina
Marketed
(US and EU)
Licensed from Roche,
Menarini
has E.U. rights
(CV Therapeutics has
co-promote in UK &
Germany)
Lexiscan
®
(regadenoson)
A
2
a-adenosine
receptor agonist
Myocardial Perfusion
Imaging
Marketed
Astellas
has
North American rights
Unpartnered
Ex-NA
Adentri
®
(CVT-124)
A
1
-adenosine
receptor
antagonist
Acute Heart Failure
Phase III
Biogen
Idex has
worldwide rights
Tecadenoson
A
1
-adenosine
receptor agonist
Atrial
Fibrillation
Phase II
Unpartnered
CVT-6883
A
2b
-adenosine

receptor
antagonist
Pulmonary Diseases
(asthma, COPD, IPF)
Phase I
Unpartnered
CVT-3619
Partial A
1
-
adenosine
receptor agonist
Diabetes
Phase I
Unpartnered

Slide 11

Ranexa:

Granted New U.S. Indication in November 2008

Ranexa is indicated for the
treatment of chronic angina.

Ranexa may be used with beta-blockers,
nitrates, calcium channel blockers, anti-
platelet therapy, lipid-lowering therapy, ACE
inhibitors and angiotensin receptor blockers.

Slide 12

Chronic Angina: US Patient Waterfall

75

10,197

0

1,000

2,000

3,000

4,000

5,000

6,000

7,000

8,000

9,000

10,000

11,000
1,071
Refractory Angina
3,4,5
Diabetes/Angina
Ranexa Pts
6
1,784
(25%)
1,499
(21%)
7,138
Treated Angina
2
Angina Prevalence
1
3,854
Other
268
HF, 225
7%
Chronic HF/Angina
70%
15%
Patients (000s)
1AHA
Statistical
Update.
Heart
Disease
and
Stroke
Statistics

2009
update.
2 F.C.
Wiest,
et.
al.
Suboptimal
Pharmacotherapeutic
Management
of
Chronic
Stable
Angina
in
the
Primary

Care
setting.

Am J Med.

2004;117:234-241.

3 Gilead Market Research.

4Diabetes

rate

in

angina

patients

in

the

CARISA

trial

23%

and

in

the

Marisa

trial

was

24.1%.

5Cardiovascular Resource Group Report (Heart Failure 2008-2017).

6Trx data analysis (Wolters

Kluwer).

Refractory angina patients include

patients with symptoms despite

maximum tolerated doses of Beta

Blockers, Calcium Channel

Blockers, and Long Acting Nitrates

Significant portions of treated and

refractory angina patients have co-

morbidities (Diabetes, Heart

Failure).

Slide 13

Provides Opportunity to Relaunch

Ranexa

Sales and marketing roadmap for relaunch

Size salesforce

appropriately (currently 170 reps)

Target specialty and intervention cardiologists who treat refractory
angina patients

Leverage proven medical education model

Favorable revisions to the label based on proven safety
in outcomes study in 6,500 high-risk coronary patients
(MERLIN)

Removed contraindications for diltiazem
and verapamil

Can be used with major classes of cardio-protective drugs

HbA1c reduction now referenced

Claims for safe reductions in ventricular tachycardia, supraventricular
tachycardia, new onset atrial
fibrillation, bradycardia

Slide 14

Limitations of older therapies

Beta Blockers: bradycardia
(especially in the elderly),
fatigue, drowsiness and depression

Calcium Channel Blockers: may cause bradycardia,
dizziness and peripheral edema

Long Acting Nitrates: occurrence of tolerance, headaches,
dizziness and contraindicated with ED drugs
COURAGE trial supports medical management
prior to stenting
10% growth in the angina population since 2006

Currently

9.8M

patients

in

US,

with

500K

new

patients

annually

Angina Largely Underserved by

Previous Classes of Drugs

1

AHA 2009 Heart & Stroke Stats (500k is pts older than 45)

1

Slide 15

64% YOY Growth in US Ranexa

Sales

Growth through 11/6/08 was with old label

Increasingly favorable managed care status

(\$ in millions)

\$15.3

\$18.4

\$20.9

\$22.0

\$25.4

\$30.3

\$31.5

\$12.0

Q1'07

Q2'07

Q3'07

Q4'07

Q1'08

Q2'08

Q3'08

Q4'08

Slide 16
Ranexa
Opportunity in Europe
Menarini
has EU rights to Ranexa

Strong cardiology commercial presence in EU

Launched in UK and Germany (March 2009)

Other EU countries to follow
In
most
European
countries,

20,0000

-

40,000

individuals per million suffer from angina

1

European Heart Journal, 2006

Ranexa

is indicated as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta-blockers and/or calcium antagonists).

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Successful Lexiscan U.S. Launch

Lexiscan

®

(regadenoson) launched by Astellas in the U.S.

in June 2008 (\$46 M

sales in 2008)

Already taking substantial portion of pharma stress market

Expanding Myocardial Perfusion Imaging (MPI) market

1

"Stress Protocols and Tracers" section of the ASNC Imaging Guidelines for Nuclear Cardiology Procedures)

1996

1998

2000

2002

2004

2006

MPI Scans

(in millions)

Pharma Stress

(in millions)

7.7

3.4

7.1

3.1

6.0

2.5

5.0

1.8

4.0

1.2

3.4

0.9

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Regadenoson

EU Filing in 2009,

Potential Launch in 2010

Ex-US rights unpartnered; MAA submission
planned in 2009

Based on US NDA including 10 clinical trials in
1,651 patients

Eligibility for centralized filing confirmed

EMA pre-submission meeting completed

Will work to define commercialization strategy

1

NEJM 360:213, 2009

2

Multiple detector computed tomography

Slide 19
Adentri
for Acute Heart Failure

A
1
adenosine antagonist which
maintains renal function while
facilitating diuresis
in patients with
heart failure
Licensed to Biogen
Idec in 1997

Potential for milestone and royalty
payments

Ongoing Phase III study
(TRIDENT-1; began 8/08)

Assess the efficacy and safety of IV
Adentri

®
dosed up to 5 days on
body weight in ADHF patients with
impaired renal function

1
JACC Vol

50, No. 7, 2007

Phase II Results

Change from Baseline
in Urine Volume

-400

-200

0

400

600

800

Day 1

Day 6

Day 10

3 mg

15 mg

75 mg

225 mg

Placebo

200

Slide 20

Tecadenoson
for Rapid Atrial
Fibrillation

A

1

adenosine receptor agonist which produces
rapid rate control without drop in blood pressure
Phase III results in PSVT patients

Rapidly convert PSVT in up to 90% of patients to normal heart rhythm

No significant adverse symptoms or hemodynamic side effects

Development in PSVT halted due to small market opportunity

Completed second Phase II in rapid atrial
fibrillation (AF) patients in Q308

Intravenous tecadenoson
co-administered with ultra low doses of
beta-blockers

Demonstrated synergy in providing adequate rate control during atrial
fibrillation without decreasing blood pressure

Determining future development strategy in AF

Slide 21

CVT-3619 for Diabetes

A small molecule partial A

1

adenosine

receptor agonist

Orally bioavailable, once-a-day dosing

Inhibitor of adipose tissue lipolysis:

lowers circulating FFA1

Improves insulin sensitivity

Decreases plasma triglycerides by inhibiting the
breakdown of triglycerides from the liver

May raise HDL

Completed first Phase 1 study

Safe and well-tolerated up to 1800 mg

No significant effect on HR, BP and PR interval

Appears to elicit reduction in circulating FFA

Plan to start multiple ascending dose study in
2009

FFA

Activate A

1

agonist

Triglycerides

Insulin Sensitivity

HDL

Proposed Physiologic

Cascade:

1

Based on preclinical data

Slide 22

CVT-6883 for Pulmonary Disease

(Asthma, COPD, IPF)

Proprietary small molecule that is anti-fibrotic, anti-inflammatory and anti-angiogenic

First in class selective antagonist of A

2B

adenosine

receptor

mediated

actions

(does

not

attenuate

A

1

,

A

2A

, or A

3

-receptor mediated actions)

Completed three Phase 1 studies

Good oral absorption

Safe and well tolerated at concentrations that exceed 100x
receptor binding affinity

PK coverage consistent with once/day dosing

Number of patients exposed >100

Slide 23

Gilead's Platform Spans Four Therapeutic Areas

Atripla

Atripla

Truvada

Truvada

Viread

Viread

Emtriva

Emtriva

Elvitegravir

Elvitegravir

(Ph III)

(Ph III)

GS 9350
GS 9350
Integrase
Integrase
FDR
FDR
(Ph I)
(Ph I)
PAH
PAH
Letairis
Letairis
Flolan
Flolan
Cicletanine
Cicletanine
(Ph II)
(Ph II)
Resistant
Resistant
Hypertension
Hypertension
Darusentan
Darusentan
(Ph III)
(Ph III)
HBV
HBV
Hepsera
Hepsera
Viread
Viread
HCV
HCV
GS 9450
GS 9450
GS 9190
GS 9190
NASH
NASH
GS 9450
GS 9450
HIV/AIDS
HIV/AIDS
Cardiovascular
Cardiovascular
Influenza
Influenza
Tamiflu
Tamiflu

CF
CF
Aztreonam
Aztreonam
Lysine
Lysine
(Applications Pending)
(Applications Pending)
GS 9310 / 11
GS 9310 / 11
GS 9411
GS 9411
Bronchiectasis
Bronchiectasis
Aztreonam
Aztreonam
Lysine
Lysine
(Ph II)
(Ph II)
IPF
IPF
Ambrisentan
Ambrisentan
(Ph III)
(Ph III)
Respiratory
Respiratory
Liver Disease
Liver Disease

Slide 24

CV Therapeutics Product Portfolio

Significantly Augments This Platform

Gilead

Gilead

Tamiflu

Tamiflu

-

-

Influenza

Influenza

Aztreonam

Aztreonam

Lysine -

Lysine -

CF
CF
GS 9310 / 11 -
GS 9310 / 11 -
CF
CF
GS 9411 -
GS 9411 -
CF
CF
Aztreonam
Aztreonam

Lysine -

Lysine -
Bronchiectasis
Bronchiectasis
Ambrisentan
Ambrisentan
-
-
IPF
IPF
CV Therapeutics
CV Therapeutics
CVT-6883 -
CVT-6883 -
Pulmonary Diseases
Pulmonary Diseases
Respiratory
Respiratory
Gilead
Gilead
Letairis
Letairis
-
-
PAH
PAH
Flolan
Flolan
-
-
PAH
PAH
Cicletanine
Cicletanine
-
-
PAH

PAH

Darusentan

Darusentan

-

-

Resistant Hypertension

Resistant Hypertension

CV Therapeutics

CV Therapeutics

Ranexa

Ranexa

-

-

Angina

Angina

Lexiscan

Lexiscan

-

-

MPI

MPI

Adentri

Adentri

-

-

Acute Heart Failure

Acute Heart Failure

Tecadenoson

Tecadenoson

-

-

Atrial

Atrial

Fibrillation

Fibrillation

CVT-3619 -

CVT-3619 -

Diabetes

Diabetes

Cardiovascular / Metabolic

Cardiovascular / Metabolic

Slide 25

Gilead and CV Therapeutics:

Strength in Partnership

S&M relaunch resource

Commercial Operations

infrastructure

Medical Affairs experience

European operating

affiliates

Gilead

Revised Ranexa label

US Cardiology sales team

Cardiovascular clinical

know-how

Managed Care network

CV Therapeutics
CV Therapeutics

Slide 26

Vision for CV Therapeutics

Ranexa for chronic angina with new, stronger

US label

Specialty sales force detailing cardiologists

Lexiscan opportunity in EU

Proven development and regulatory organization

Improved opportunity for Letairis and darusentan

Pipeline of cardiovascular products

Improved future earnings profile and growth rate

Bolsters Gilead's presence in the
cardiovascular space by providing: