

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**

Edgar Filing: CV THERAPEUTICS INC - Form SC TO-C

**Gilead Sciences, Inc.**

**333 Lakeside Drive**

**Foster City, California 94404**

**Tel: (650) 574-3000**

**(Name, address, and telephone number of person authorized to receive notices  
and communications on behalf of filing persons)**

*with copies to:*

**David A. Lipkin, Esq.**

**Michelle Sonu Park, Esq.**

**Brandee L. Shtevi, Esq.**

**Cooley Godward Kronish LLP**

**Five Palo Alto Square**

**3000 El Camino Real**

**Palo Alto, CA 94306-2155**

**Tel: (650) 843-5000**

**Fax: (650) 849-7400**

**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:

Edgar Filing: CV THERAPEUTICS INC - Form SC TO-C

☒ 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).

Slide 17

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

Slide 18

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: