



Citrus Research and  
Development Foundation, Inc.

**QUARTERLY REPORT  
TO THE  
COMMERCIAL PRODUCT DEVELOPMENT  
COMMITTEE  
OF THE  
CITRUS RESEARCH AND DEVELOPMENT  
FOUNDATION**

March 2013

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## Overview

This Quarterly Report covers the period January through March, 2013. For each of the eight CPDC projects, it focuses on activity highlights of the past quarter, issues and gaps that have surfaced, and performance against milestones. That report also includes project-level budgetary information as well as a consolidation at Committee level.

The established purpose of the reporting system is to provide the Committee with integrated information needed to inform planning, project prioritization and resource allocation decisions going forward.

For ease of tracking progress on the roadmap charts, changes from the January Quarterly Report are highlighted in yellow. **The box with an “J” indicates the projected date from the January report, while the “M” box represents the projected date from this report. The arrow represents the direction of the change.**

At the March CPDC meeting, we will also be talking about strategic priorities and discuss the Committee’s approach to next year’s programs. The goal is to achieve alignment so that more detailed planning and budgeting information can be provided at the April CPDC meeting.

## Feedback

I welcome your feedback on the content, level of detail, and organization of the report. If there are items that you would like added to or deleted from the report, please let me know. Also let me know if there are items where you disagree, or have additional information or perspective. The goal is to make this a useful working document for Committee members.

I look forward to our discussions at the March 26 committee meeting

Thanks and regards,

Jim Dukowitz  
Commercial Product Manager

# **PROJECT REPORTS**

# 1. Psyllid Control (Neonicotinoid Label Modification)

## Quarterly Activity Update

### Imidacloprid

- Following the October 2012 FDACS conditional approval of the 24(c) Special Local Need (SLN) label change for Admire®.Pro, in mid-January FDACS received the letter of acceptance from EPA, so the label, as negotiated, stands.
- Additional coordination with the registrant and regulatory process to assure the appropriate information is collected to support the continued availability of the product as well as any modifications that may be needed for existing labeling are ongoing. Data collection continues on efficacy, and potential non-target risk avoidance mechanisms are being collected and will be used to support further regulatory discussions later this year.

### Thiamethoxam

- The registrant for thiamethoxam has indicated the SLN submission date to FDACS will be pushed back to the late fall time frame to accommodate concerns raised with respect to potential pollinator protection that current ongoing data collection will address during the spring bloom period. The active ingredient is included in the Agency's ongoing process of dealing with the Center for Food Safety and NRDC petitions related to the registration of this product. The same environmental groups joined by beekeepers filed a law suit in March seeking the cancellation of the registration of both thiamethoxam and clothianidin.
- Negotiations are ongoing with the registrant on a process to accelerate the data collection and analysis that would allow grower needs to be addressed. The information to allow assessment of non-target risks, particularly to pollinators, is being collected and hopefully will be available for review and presentation to the regulatory agencies later this summer.

### Clothianidin

- The January report noted that this active ingredient's petition to allow use on bearing citrus has been delayed at the EPA with a renegotiated PRIA due date for a decision in mid-June. As the primary target of the two actions discussed relative to thiamethoxam above, this decision date may slip to later in the summer. Discussions with the Agency and the registrant do not raise concerns over the eventual successful completion of this effort, unless the pending litigation results in a court ruling that directs a decision process or end point other than currently applied during the normal FIFRA registration process.
- Active coordination with the registrant is underway to prepare the necessary package of information to label soil applications under 24 (c) SLN labeling for juvenile trees (transplant until five years) up to nine feet tall with an increased total yearly maximum to accommodate additional applications to these age and size class trees. It is anticipated that this activity increase over the summer pending the influence and impact of the above referenced litigation.

- If the June 2013 PRIA decision date remains on track, it will be followed by an SLN submitted to DACS for increased applications levels for Florida citrus. With completion still targeted for the July-August time frame, this timetable should allow growers to get in one application of clothianidin in the fall.

## **Issues and Gaps**

### **Need for Pollinator Impact Data**

- The common issue for all registrants remains the perceived risk-reward associated with registrants moving forward with label expansions given the extremely small dataset that exists regarding pollinator impacts, and the increased call for additional information by EPA/ FDACS.
- In February, Dan Botts met with EPA to continue discussions of EPA information requirements. Based on those discussions, Dan will be discussing with CPDC the need for additional information on the critical importance to growers of neonic usage, and the label expansion program for 3-5 year old trees. This will help EPA better assess the “risk reward” equation.

## **Performance to Milestones**

- **Imidacloprid:** Label expansion has proceeded according to milestones established in the September 2012 and January 2013 reports.
- **Thiamethoxam:** The SLN submission date to FDACS is projected to slip further to the late fall 2013 time frame. The September Quarterly Report projected the 24(c) label modification would be submitted to FDACS in October 2012, with conditional approval in December. The January 2013 Quarterly Report projected a minimum five month slippage to March 2013 for submission. The latest projections from registrant is that submission to FDACS will be in the November 2013 time frame.
- **Clothianidin:** The June 2013 PRIA decision date for clothianidin registration, remains on track with projections in the January 2013 Quarterly Report. This represents a six month slippage from the September Report projection of EPA registration. FDACS registration would immediately follow.

# CRDF 2012-13 Project Roadmap: Neonicotinoid Label Modification

What	Who	Start	End	Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov
FDACS/EPA Mtgs	Team	2011	2013	
Registrant Mtgs	Team	2011	2013	
Submit 24(c) package for Imidacloprid	Bayer	Sep'12	Sep'12	
Imidacloprid approval	FDACS	Oct'12	Oct'12	
Submit 24 (c) package for Thiamethoxam	Syngenta	Nov'13	Nov'13	
Thamethoxam approval	FDACS	Dec'13	Dec'13	
Clothianidin Section 3 approval	EPA	Jun'13	Jun'13	
Clothianidin 24© approval	FDACS	Jul'13	Jul'13	
Additional data collection	Team	Apr'13	2013	
Additional label changes	Team	2013	2014	

S = September projection J = January Projection M = March Projection

## 2. Psyllid Control (RNAi)

### Quarterly Activity Update

#### *Agreement Reached on Research Agreement Templates*

- This project continues CRDF-funded research performed the prior year to evaluate candidates as part of the RNAi InnoCentive™ Challenge. This research takes the 14 winners, and will identify the best sequence/sequence combinations to target with dsRNA within the psyllid genome, and the most economical and efficacious delivery strategy.
- In January Harold Browning reviewed a proposed commercial research agreement template created by CRDF staff for the RNAi and Antimicrobials research projects (InnoCentive™ follow-on) with University of Florida (UF) Department of Research. The template addressed commercial issues such as Good Laboratory Practices (GLP), ownership of data and confidentiality of information. Rather than create a new agreement, the University of Florida recommended CRDF use a combination of the existing UF Research Services Agreement and a standard research agreement already in use by CRDF with the University for research projects.
- In February, CRDF staff evaluated both the RNAi and Antimicrobials research projects to determine how to best place the two research projects within the RSA and standard RA templates. It was determined that the first year of the RNAi project, which was approved for funding by the CRDF board, would fit appropriately under the research agreement, while the Antibacterials project will be divided into a Research Services Agreement and a Research Agreement. These will be described in the discussion of the Antibacterials project (Project 3).
- In early April the RNAi research agreement with attached scope of work and budget will be forwarded to UF Division of Sponsored Research for review and projected approval in the mid-April timeframe.

#### *Invention Disclosures Filed*

- USDA ARS in Fort Pierce has taken the lead and has filed RNAi-related Invention Disclosures through USDA channels for the InnoCentive™ materials, and are awaiting committee review for potential patenting.
- CRDF is monitoring this closely and is in regular communications with USDA ARS researchers to help ensure this is completed in a timely fashion.

#### *Progress on CRADA Modification*

- The current USDA CRADA (Dr. Wayne Hunter at Fort Pierce) with Monsanto is being modified to allow Monsanto to synthesize large quantities of two of the dsRNA gene targets associated the InnoCentive™ follow-on research project for greenhouse and field testing. The modified agreement was approved by USDA and is currently at Monsanto awaiting their signature. Once finalized, the modified CRADA can advance the science and (hopefully) increase the possibility of a long term Monsanto partnership..

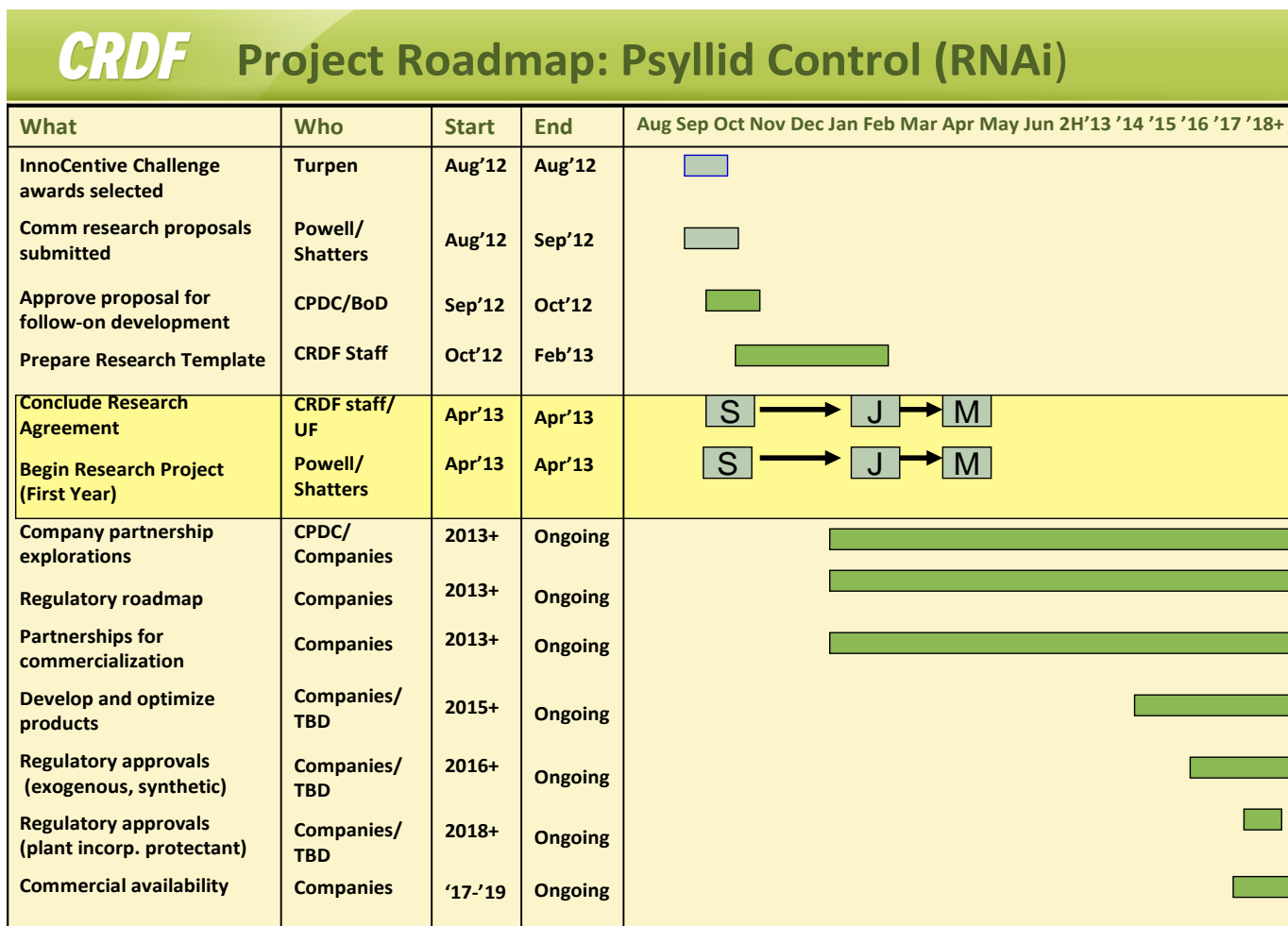


## Issues and Gaps

- USDA must complete evaluation of the invention disclosures and develop a patenting approach.
- Monsanto needs to sign the modified CRADA with USDA
- USDA and CRDF need to leverage the CRADA relationship to help develop a long term commercial relationship with Monsanto.

## Performance to Milestones

- There has been a two month slippage in the projected conclusion of the commercial research agreement with UF and start of research project from the January Quarterly Report. The September Quarterly Report listed October as the start date for follow-on research project, and the January report projected a slippage to the February time frame. The current quarterly report projects a mid-April finalization of research agreement between CRDF and UF



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### **3. Antibacterials**

#### **Quarterly Activity Update**

##### **Research Services Agreement and Research Agreement**

- Based on discussions with the University of Florida Office of Research, CRDF will be using a combination of standard Research Services Agreement and Research Agreement templates for relevant portions of the Antibacterials follow-on study project/ This is a three year proposed project, the first year of which has been approved by the CPDC and CRDF board last fall. This project will evaluate the 11 candidates identified from the InnoCentive™ Challenge to advance understanding of their efficacy for control of the HLB bacterium, individually and in combinations, and to determine optimum chemical formulations and application methods that may be registered for field control of HLB.
- The proposed approach is to “carve out” activities in the first year of the project related to evaluation of combinations of the 11 compounds using the graft-based chemotherapy method, and place these under the Research Services Agreement research proposal and placed in the Research Services Agreement. In addition, the Research Services Agreement will include up to 20 trials involving compounds (or combinations) recommended by 3<sup>rd</sup> party companies and other institutions. The Research Services Agreement will accomplish several goals: it will move the InnoCentive™ compound assessment forward by evaluating them in combinations; it will provide an opportunity for further assessment of new compounds from 3<sup>rd</sup> parties; and it will help establish connections that may promote commercial partnerships.
- The standard Research Agreement will conduct all the research elements in the original research proposal, less the work “carved out” for the RSA.

##### **Invention Disclosures**

- Chuck Powell at UF has completed Invention Disclosure forms for the 11 InnoCentive™ compounds, and they are under evaluation by the UF Office of Technology Licensing.
- CRDF is monitoring this closely and is in regular communication with UF researchers to ensure this is completed in a timely fashion.

##### **Company Partnerships**

- CRDF staff has established Confidentiality Agreements and has provided information to two companies interested in further evaluation of the 11 InnoCentive™ compounds. One of the companies is also interested in providing compounds for testing under the Research Services agreement.
- The intent is to develop a partnership to complete development, regulatory and “take to market” activities.

## Issues and Gaps

### Accelerate Path to Market

- Perhaps the greatest challenge in managing the Antibacterials program is to balance the need to leave **“no stone unturned”** in terms of identifying and evaluating potential candidates, while **focusing resources** on the most promising compounds and define a critical path to market as quickly and efficiently as possible. There are several elements of this approach:
- This will require finding **additional candidate commercial partners** to commercialize promising compounds. Experimental design should have the benefit of a commercial partner perspective and experimental data relevant to regulatory approvals needs to be collected in a GLP compliant process. For that reason CRDF is actively seeking to involve commercial partners in the commercial research. By funding only the first year of the proposed three year commercial research program, the intent is to identify and work with prospective commercial partners who may be in a position to take on all or parts of future commercialization activity.
- It will require identification of compounds that are expected to pose a **somewhat lower regulatory challenge**, e.g. plant essential oils. These need priority attention to move through the process.
- There may be a number of additional antibacterial and antibiotic compounds that may already have regulatory approval for other applications, or could be added to an existing registered active ingredient and delivery system.
- It will require deeper understanding of the relative regulatory barriers for the various compounds. This will include a **pre-registration visit with EPA** to discuss plans and understand their viewpoint and data requirements.

### Performance to Milestones

- The major change in milestones is the two month slippage in the projected start of the research projects from February (as projected in the January Quarterly Report) to April. The delays were caused by the need to develop research scope of work and budgets for a Research Services Agreement and standard Research Agreement. These will be presented for approval at the March CPDC and CRDF Board meetings. With approval, the Research Services Agreement and Research Agreement will be forwarded to UF for approval, which is expected in the mid-April time frame.

What	Who	Start	End	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	2H'13	2014	2015	2016	2017	
InnoCentive challenge awards selected	Turpen	Aug	Aug	█																
Comm research proposals submitted	Powell	Aug	Sep	█	█															
Approve proposal for follow on research	CPDC/BoD	Sep	Oct		█	█														
Prepare/approve comm research template	CRDF staff/ BoD	Oct	Feb		█	█	█	█	█	█										
Conclude comm research agreement	CRDF Staff/UF	Apr'13	Apr'13			S	→			J	→									
Begin follow-on comm research (first year)	Powell/ Team	Sep	Ongoing			S	→			J	→									
Company partnership explorations	CPDCstaff/ companies	2013	Ongoing																	
Regulatory roadmap	Comp/TBD	2013	Ongoing																	
Partnerships for prod devt/commercialization	CPDC/ Comp	2015	Ongoing																	
Develop and optimize products	Companies	2015+	Ongoing																	
Regulatory approvals (antibacterials)	Companies / TBD	2015+	Ongoing																	
Regulatory approvals (antibiotics)	Companies / TBD	2017+	Ongoing																	
Commercial availability	Companies	2017+	Ongoing																	

**S = September projection   J = January projection   M = March projection**

## 4. Genetic Disease Resistance to Citrus Canker

### Quarterly Activity Update

#### Recruit New MCTF Manager

- Efforts over the past quarter have focused on recruiting an individual with both research and industry experience to manage the MCTF, which operates under CREC in Lake Alfred and is funded by CRDF
- Working closely with CREC Director Jackie Burns, we have screened 16 applicants, selected six for interviews, and, based on those interviews, have identified two for a second round of interviews. The two candidates will come to Lake Alfred in early April for those interviews.

#### Steering Committee

- We are also working closely with Dr. Burns to establish a Steering Committee for the MCTF. This is being established to provide strategic oversight to the program, and would include representatives from CREC, CRDF, and outside experts in transgenic trait introduction and evaluation.

#### Outreach to Leandro Pena

- Tom Turpen is in communication with Leandro Pena, who developed the MCTF protocol at IVIA in Spain that has been transferred to Lake Alfred. Our goal is to keep him engaged as a scientific advisor to the project to help ensure a smooth transition and re-launch under the new manager.

### Issues and Gaps

#### Secure a Qualified Manager and Establish the Steering Team

- It will be important to secure a qualified MCTF manager and establish the Steering Team in a timely fashion to provide needed oversight and move the program forward.

#### Pre-Launch Planning

- Once in place, the MCTF manager will work with the Steering Committee to determine the technical support requirements for the MCTF lab and clean growing area to rapidly move objectives to completion. This includes an operational plan and model; establishing techniques and protocols, and IP management issues.
- Dr. Pena can be provide valuable support in ensuring the facilities, tools, protocols and work plan are in place

#### Re-Launch

- Once the support requirements are identified, the MCTF manager and Steering Team will work together to re-launch the MCTF with a commercial product development focus only and not a research service facility.
- The focus will be on incorporating high potential candidate genes for canker resistance into commercially important citrus scion and rootstock cultivars, allowing

head-to-head comparisons in a high throughput environment, and evaluating performance based on commercial as well as scientific criteria.

- This will provide an efficient and focused process geared to help get transgenic citrus plants to the Florida industry as efficiently and cost-effectively as possible.

**Performance to Milestones**

- The current projected milestones to recruit a new MCTF manager and establish the Steering Committee have slipped one month from March (January Quarterly Report) to April. This delay could also cause some slippage in the pre-launch planning and MCTF launch dates.

What	Who	Start	End	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	2h'13	'14	'15	'16	'17	'18	'19	'20+	
<b>MCTF Ramp/Launch</b> <b>Interim MCTF Oversight</b>	CREC	Sep	Mar'13	█																		
Establish Steering Committee	CRDF/CREC	Apr'13	Apr'13							J	M											
Recruit new MCTF Manager	CRDF/	Apr'13	Apr '13							J	M											
Establish resource requirements/budgets	MCTF/ Steer Comm	Apr'13	May'13										█									
MCTF launch	MCTF/ Steer Comm	Jun'13	Jun'13										█									
<b>Commercialization</b> Mature tissue transformation into commercial cultivars	MCTF	2013	Ongoing											█								
First raw materials with desired canker traits	MCTF	2017+	2017+																			█
Field evaluations/wide area testing	CRDF/Com Partners	2017+	Ongoing																			█
Regulatory studies, permits	CRDF/Com Partners	2013	Ongoing											█								
Achieve deregulation of first new line	CRDF/Com Partners	2021	2021																			█
New cultivar budwood to nurseries	CRDF/Com Partners	2022	Ongoing																			█
Strategic partnerships	CRDF/ Steer Comm	2013	Ongoing											█								

**J = January projection M = March projection**

## 5. Citrus Gene Therapy (CTV Vectors)

### Quarterly Activity Update

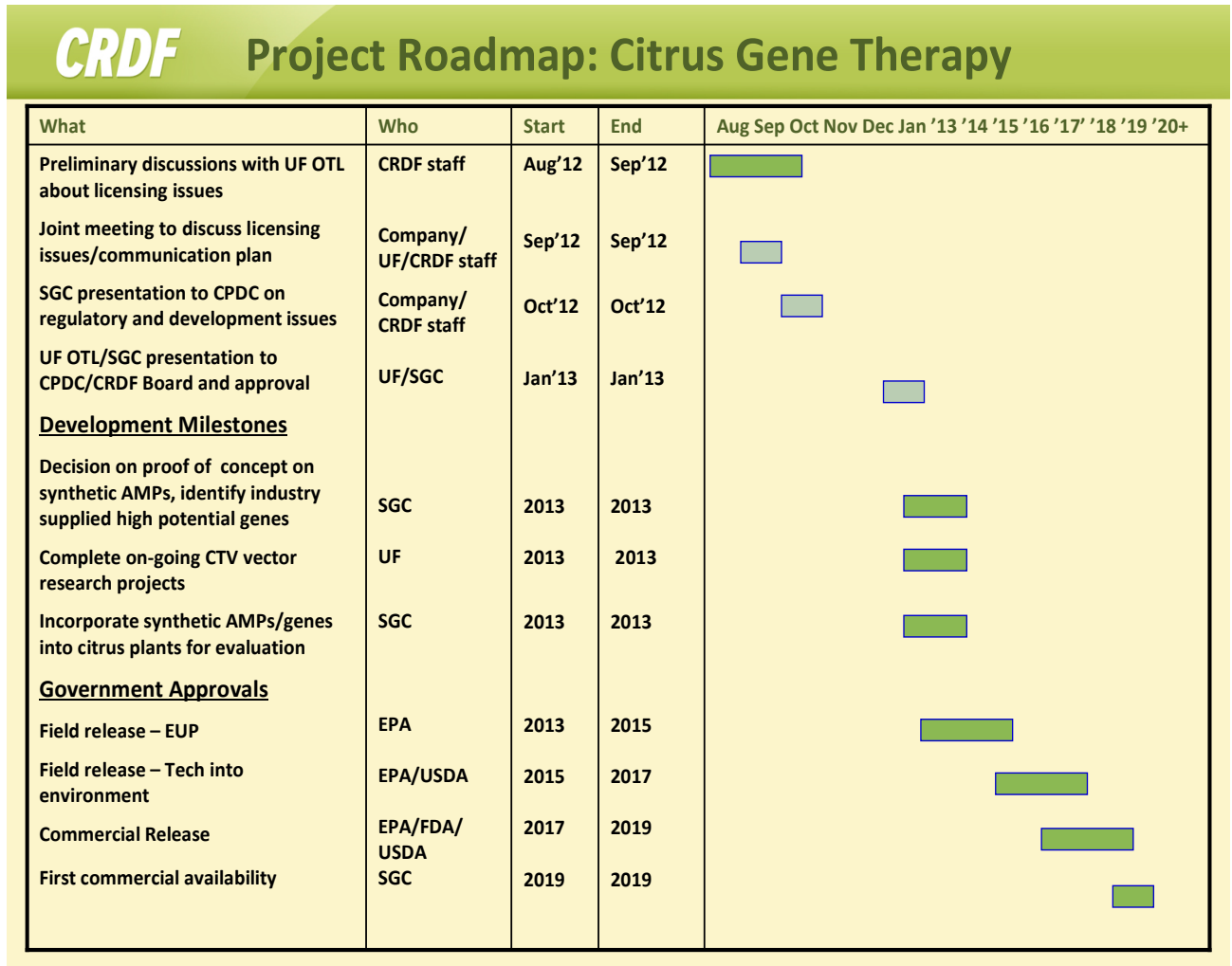
- At the January CPDC and Board meetings, the University of Florida Office of Technology Licensing (OTL) and Southern Gardens (SGC) made presentations on the background of a planned exclusive license SGC was in the final stages of negotiating covering 4 UF patents related to CTV vectors, one of which was based on CRDF-funded research.
- With the finalization of the licensing agreement, SGC is now continuing its process of tree growth and assessment moving forward.

### Issues and Gaps

- The key go-forward issues relate to execution of SGC’s roadmap shown below. Performance, cost and risk management are paramount to success.

### Performance to Milestones

- No changes from the January Quarterly Report



## 6. Advanced Citrus Production and Harvesting Systems

### Quarterly Activity Update

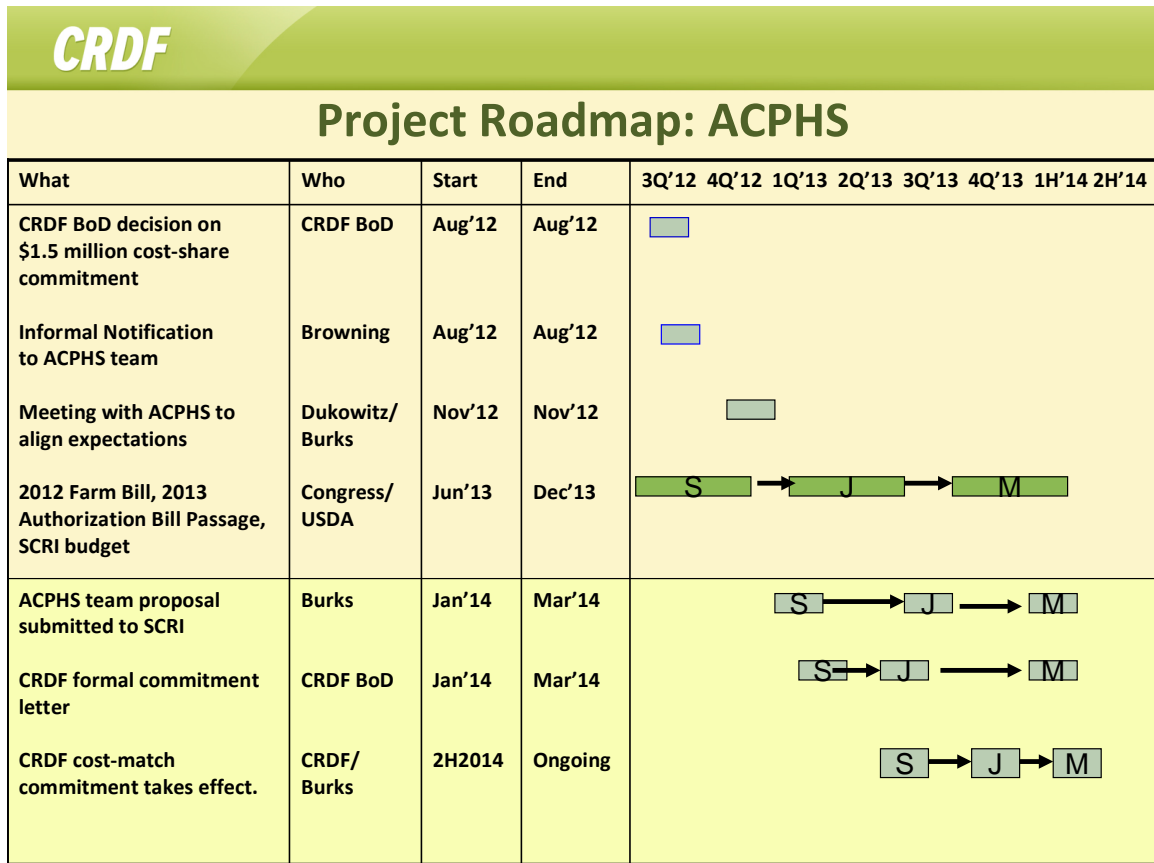
- In the January Quarterly report we discussed Dr Tom Burk’s plan to submit the ACPHS project proposal to NIFA for the 2013 round, pending passage of the 2012 Farm Bill and 2013 Appropriations Bill, since USDA does not have funding committed to the SCRI program.
- As of mid-March, Dr. Burk has indicated that he has not heard anything from Washington that encourages him that there will be an SCRI solicitation this year. He also indicated that we may not see another SCRI until late 2013 for an early 2014 submission. While it is possible that it may come earlier, with no mandatory funds and sequestration it is really uncertain when the funding will come.

### Issues and Gaps

- Once CRDF staff has better visibility on the timing, size and scope of the USDA SCRI program, and their impact on Dr. Burks’ plans for proposal submission, it can at that point revisit the CRDF Board letter of support and funding commitments,

### Performance to Milestones

- The major change from the January ACPHS team proposal submission Quarterly Report is the projected additional 4 month slippage in the projected dates for SCRI to receive funding, the ACPHS team proposal submission, and CRDF formal commitment letter and cost-match commitments.





## **7. Disease Detection: Canine Scouting (Citrus Canker)**

### **Quarterly Activity Update**

#### **Nursery Results**

- J&K Canine Academy has reported details of two successful nursery engagements during the past three months. They are measuring success by the number of state inspections passed where the nurseries had a history of failure prior to the canine inspections.
- The first example is working with a nursery with a history of failure in monthly inspections. The owners and managers requested that the teams inspect the first greenhouse where canines alerted to several plants. After the initial search, the owner advised that four of the plants identified by the canines were plants that had tested positive for canker and placed in the house as a blind test for the canine and handler. At the end of several days approximately 5000 plants were identified by the canines as having the signature odor used to ID Canker. The following week the nursery passed its state inspection. J&K has since gone through the nursery a second time and it passed another inspection.
- J&K was contacted by a second nursery, and canines were utilized to search numerous greenhouses involving thousands of plants. During this inspection the canines not only identified Canker in known greenhouses with infected plants, they also alerted to one of the workers. Upon further investigation, the worker's boot was confirmed positive, and the worker confirmed he lives at a grove that is heavily infected with canker. Two and a half days of canine inspections resulted in all but one of the greenhouses passing inspection. The inspector found one plant in a greenhouse with no known issues.

#### **HLB, Black Spot**

- J&K met with Ron Brlansky at the UF Lake Alfred. Based on his insights, J&K is in the beginning phases of training canines to identify HLB-infected plants. Preliminary results are expected within a couple of months.
- J&K met with Megan Dewdney at UF Lake Alfred to discuss Citrus Black Spot. Due to the strict quarantine requirements involving this disease, it requires further discussion before establishing protocols and procedures for canine training.

### **Issues and Gaps (Citrus Canker)**

- J&K faces the normal market acceptance and risk management challenges of an entrepreneur creating a new business in an established industry.

### **Performance to Milestones**

- No slippages from September Quarterly Report roadmap. Some new additions based on nursery activities and plans to expand to diseases beyond Canker.

**Project Roadmap: Canine Scouts**

What	Who	Start	End	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	2H2013	2014
Industry awareness progs	J&K	July'12	Ongoing	[Green bar from Jul to Jun 2014]													
Validate market demand	J&K	July'12	Mar'13	[Green bar from Jul to Mar 2013]													
Initial nursery projects	J&K	Aug'12	Mar'13		1						2	3					
Marketing roll-out	J&K	2013	Ongoing														
Meet with UF Profs re HLB, Black Spot	J&K, UF	1Q'13	1Q'13														
New market development	J&K	Sep'12	Ongoing														
Quality Assurance Certification program	J&K	2013	2013														
Business model evolution	J&K	2013	Ongoing														

## **8. Diaprepes Root Weevil Control**

### **Quarterly Activity Update**

- In early January we received notice of receipt from USDA of the patent license application and the name of the USDA project manager we will be working with on this application.
- We are still waiting for the feedback from the USDA evaluation of our licensing proposal.

### **Issues and Gaps**

- The current market is small because it is geographically limited, with a relatively slow diffusion rate due to quarantine.
- While companies have been approached, there are no commitments at this point to co-fund the Lapointe research in return for an option to license the technology.
- Once the CRDF licensing application is approved by USDA, it will be posted in the Federal Register. This should help determine the extent of additional commercial interest in the technology.
- There is on-going contact with USDA ARS regarding the need for multiple simultaneous paths and concurrent closing of the licensing, CRADA and agreements with participating companies.
- The “go-no go” decision will be made before CRDF signs a license agreement with USDA and the associated CRADA for the Lapointe field research.

### **Performance to Milestones**

- This project has slipped approximately two months from the January Quarterly report projection and a total of five months from the September Quarterly Report timetable as we await a response from USDA.

# CRDF Project Roadmap: Diaprepes Root Weevil Control

What	Who	Start	End	Sep Oct Nov Dec Jan Feb Mar Apr May Jun 2H '13 '14 '15 '16 '17 '18
Submit license application to USDA/OTT	Dukowitz	Jan'13	Jan'13	S → J
Notice of Intent in Fed Register (Secure license)	USDA	Apr'13	Apr'13	S → J → M
Negotiate consortium company option agreements	Dukowitz/Turpen	Apr'13	Jun'13	S → J → M
Negotiate CRADA/license agreement with USDA	Dukowitz/Turpen	Apr'13	Jun'13	S → J → M
Conduct field study	Lapointe	2013	2015	
Negotiate sub-licensing agreements with companies	Dukowitz/Turpen	2014	2015	
Companies develop products around licensed patent	Companies	2014	2016	
Ramp up manufacturing and marketing	Companies/CRDF	2016	2017	
Product introductions to in market	Companies	2017	2018	

S = September projection J = January Projection M = March Projection