



Citrus Research and
Development Foundation, Inc.

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

July 2013

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Overview

This Quarterly Report covers the period April through June, 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.

In order to track changes in the roadmap charts over time, I have inserted the month of the projection inside the boxes. **The box with an “S” indicates the projected date from the September report, “J” from the January report, “M” from the March report, and JI represents the projected date from this report. The arrow represents the direction of the change.**

Feedback

As always, 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 July 16 committee meeting

Thanks and regards,

Jim Dukowitz
Commercial Product Manager

CPDC PROJECT REPORTS

1. Psyllid Control (Neonicotinoid Label Modification)

Quarterly Activity Update

Neonic Labels

Imidacloprid

- No change in status from March 2013 Quarterly Report. With EPA and FDACS approvals in place Admire®.Pro is available to Florida growers.
- Additional coordination continues with registrant to ensure appropriate information is collected to support the continued availability of the product as well as any potential label modifications in the future.

Thiamethoxam

- The March 2013 Quarterly Report projected a SLN submission by registrant to FDACS in late fall. That time period may become increasingly problematic, given escalating concerns raised with respect to pollinator protection, including the lawsuit filed in March by beekeepers and environmental groups seeking the cancellation of both thiamethoxam and clothianidin.

Clothianidin

- The March 2013 Quarterly report projected a June 2013 PRIA decision on clothianidin. After encouraging signs from EPA, the agency decided to postpone a decision on clothianidin six months, apparently due to growing concerns over the second lawsuit by beekeepers and environmental groups, as well as increased political activities by these groups. Timing of the EPA decision is unclear at this point
- Dan Botts called a meeting of key stakeholders on June 5 to discuss options for near-term action, including possibly filing a Section 18 Emergency Exemption with FDACS to allow for a second application of clothianidin and increased yearly maximum dosage to juvenile citrus trees .Dan was in Washington during the week of July 8 to meet with EPA to better understand their thinking in order to plan next steps.

New Products

Sulfoxaflor

- On May 8, DOW AgroSciences announced that Closer™ SC insecticide (active ingredient sulfoxaflor) received full registration by EPA, followed by Florida registration in June. The registration covers many crops, including citrus. For citrus, applications target Asian citrus psyllids and certain scales. It is foliar applied, with Group 4C mode of action (sole member of this group). Perhaps the most important aspects of the registrations are that it allows one foliar spray application during the citrus bloom period; and that it addresses both nymphs and adult psyllids.
- The label has advisory notices regarding protection of bees. Before using the product, growers are advised to make contact with beekeepers on or next to their groves. Another advisory calls for application after 7 pm and before 7 am during blooming period, as this is the time when bees typically are not foraging. EPA expects DOW and growers to be good stewards of the

product and follow all label instructions and advisories to avoid further sensitization of bee community or jeopardize other pesticide products in the pipeline.

Cyazapyr

- It appears two new products with Cyazapyr as active ingredient may be available to Florida growers in the September-October time frame. Comment period ends in mid July, and EPA will likely approve the registration in the July-August timeframe, based on the time it will take them to respond to all comments. That will be followed by application to FDACS for approval for Florida usage.
- DuPont Verimark™ is designed specifically for soil application, and can be applied as a soil drench or injected through microsprinkler irrigation to young trees from resetting in the field up to when the trees reach a size of about 5 feet tall. DuPont Exirel is designed for 2 foliar applications per year during the period of spring and summer flush and, according to DuPont, will have high impact on honeybees if they are directly exposed to the spray application during flight; less impact when exposed to dried, foliar sprayed residues.
- There are differences of opinion among UF scientists on the efficacy of using Cyazapyr as a soil drench product. Some view it as effective when used in rotation with drench applications of neonicotinoids.. Others believe it does not prevent pathogen transmission because it takes several days to kill the psyllids and more than 24 hrs to stop feeding and, during this time, transmission still occurs.

Regulatory Relook

Dimethoate

- EPA is reportedly considering adding dimethoate no-spray buffers between citrus and residential/recreational areas to include golf courses, school yards, etc., specifically trying to reduce the risk of drift inhalation. While buffers for ground sprays would likely be minimal, aerial spray buffers could be significantly higher, perhaps as much as 100 feet. Cheminova (Tifton, GA) is providing comments to EPA, and has obtained comments from UF researchers. The company may contact CRDF if it needs assistance in assembling more information to forward to EPA.

Issues and Gaps

- The common issue for all registrants remains the perceived risk-reward associated with registrants moving forward with label expansions for neonics given the extremely small dataset that exists regarding pollinator impacts, the increased legal and political activity surrounding their use, and the increased call for additional information by EPA/ FDACS.
- There is also the issue of product stewardship. This includes following carefully the label instructions, and making every effort to observe the advisories on protecting bees.
- There is also the management of the data collection and analysis process related to impact of neonics and other pesticide products on the environment in general, and bees in particular.
- Finally, there is an ongoing issue of whether and how the Florida citrus industry can constructively engage with the beekeeper community to find common ground upon which to build.

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 for late fall 2013 time frame, and perhaps later. This is roughly in line with the March 2013 Quarterly Report projections.
- **Clothianidin.** The June 2013 PRIA projected decision date for clothianidin registration from the March Quarterly report has slipped approximately six months.

CRDF Project Roadmap: Neonicotinoid Label Modification

What	Who	Start	End	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
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			S	→				J	→							M, JI
Thamethoxam approval	FDACS	Dec'13	Dec'13			S	→				J	→							M, JI
Clothianidin Section 3 approval	EPA	Dec'13	Nov'13							S	→			J,M	→				Jl
Clothianidin 24(c) approval	FDACS	Dec'13	Dec'13							S	→			J,M	→				Jl
Additional data collection	Team	Apr'13	2014																█
Additional label changes	Team	2013	2014																█

S = September J = January M = March, Jl = July projection

2. Psyllid Control (RNAi)

Quarterly Activity Update

- The Research Agreement for follow-on work on InnoCentive dsRNA molecules that have demonstrated high toxicity to ACP was signed by CRDF and UF in April. .
- The USDA patent office has provisionally approved the Invention Disclosure by Dr. Bob Shatters (USDA-ARS, Fort Pierce,) for preparation for a patent application.. The Invention Disclosure was submitted on a subset of the InnoCentive™ materials,
- 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.

Issues and Gaps

- USDA Office of Licensing must develop a patenting approach for InnoCentive materials.
- 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

- The start-of research under the CRDF-funded research agreement is roughly in line with the March Quarterly Report, but a two month slippage from the January Quarterly report.

What	Who	Start	End	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	2H'13	'14	'15	'16	'17	'18+
InnoCentive Challenge awards selected	Turpen	Aug'12	Aug'12	█																
Comm research proposals submitted	Powell/Shatters	Aug'12	Sep'12		█															
Approve proposal for follow-on development	CPDC/BoD	Sep'12	Oct'12			█														
Conclude Research Agreement	CRDF staff/UF	Apr'13	Apr'13				S	→	J	→	M, JI									
Begin Research Project (First Year)	Powell/Shatters	May'13	May'13				▲ S	→	J	→	M, JI									
Company partnership explorations	CPDC/Companies	2013+	Ongoing																	
Regulatory roadmap	Companies	2013+	Ongoing																	
Partnerships for commercialization	Companies	2013+	Ongoing																	
Develop and optimize products	Companies TBD	2015+	Ongoing																	
Regulatory approvals (exogenous, synthetic)	Companies TBD	2016+	Ongoing																	
Regulatory approvals (plant incorp. protectant)	Companies TBD	2018+	Ongoing																	
Commercial availability	Companies	'17-'19	Ongoing																	

S = September J = January M = March JI = July projection

3. Antibacterials

Quarterly Activity Update

Research Service Agreement (RSA) Evaluations

- The one-year RSA for Dr. Powell to evaluate antimicrobial compounds (or combinations) for efficacy against HLB using the graft-based chemotherapy method, which was recommended for approval by CPDC in March, and approved by the CRDF Board in April, is operational. Currently 17 evaluations are ongoing involving combinations of InnoCentive compounds (i.e. grafts completed and observing results over time). An additional 5 compounds from 4 companies have been received at the Powell lab, with grafting underway. One product from one company will be arriving at the lab next week. The timeframe for the evaluation process is six months.
- The one year RSA for Dr. Wang to evaluate soil-based microbials against HLB is underway. Soil samples taken from areas surrounding eight “escape” trees are currently undergoing evaluation. At CRDF request, one company is providing commercial products to Dr. Wang, and evaluation will begin week of July 15.. The timeframe for the evaluation is 12 months.
- A proposed one-year RSA has been submitted for CPDC and CRDF Board approval that would provide funding to support capacity at the University of Florida (Dr. Eric Triplett) for rapid turn-around evaluation of up to 1200 promising antimicrobial compounds (or combinations) using the L.crescens assay, for efficacy in reducing C.Las titers. These compounds will be sourced by CRDF from third parties such as companies, universities and government labs. CRDF will screen and pre-approve payment for testing of submitted compounds (or combinations) within the framework of the agreement.

Patent Filings

- The University of Florida has filed a provisional patent application “Methods of Treating Candidatus Liberibacter Species Infection in Plants Using Antimicrobial Compounds”. The application covers the eleven InnoCentive compounds that were selected as contest “winners” and are undergoing continued evaluation by UF researchers (Dr. Powell and team).

Company Partnerships

- CRDF staff has established Confidentiality Agreements and has provided information to two companies. One company is interested in further evaluation of the 11 InnoCentive™ compounds and exploration of collaboration opportunities going forward. The other company is initially interested in opening up its library of proprietary antimicrobial compounds for evaluation under the proposed Research Services Agreement using the L. crescens assay .

Issues and Gaps

Accelerate Path to Market

- A major 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 defining a critical path to market as quickly and efficiently as possible.

- **Sourcing:** Efforts have focused on outreach to third parties, particularly companies with libraries of antimicrobial compounds, to greatly expand access to candidate antimicrobials.
- **Screening:** Screening capacity is being expanded through the proposed addition of the *L.crescens* screen for high volume, rapid and low cost initial screening. This RSA will complement the RSAs already approved for the graft-based assay (Powell) and soil based beneficials assay (Wang).
- **Follow-on Evaluation:** In addition to the current Research Agreement (Powell) to evaluate the InnoCentive compounds (combinations) in greenhouse and field trials, the focus is on developing grower-led field experiments that can shorten the time-frame to useful data, as well as ensure performance is measured using commercial as well as scientific criteria.
- **Product Development:** Efforts are underway to work with UF researchers who are experts in nano-droplet emulsions to explore opportunities to add promising antimicrobial compounds as add-on ingredients to commercially available nutritional or pesticide products. This is in addition to discussions with commercial partners.
- **Navigate Regulatory Channels:** Special attention is being given to those compounds that are expected to pose a somewhat lower regulatory challenge, e.g. plant essential oils, existing commercial products that may already have regulatory approval for other applications. It will also require a closer working relationship with EPA to discuss plans and understand their viewpoint and data requirements going forward.

Performance to Milestones

There are no roadmap changes from those provided in the March Quarterly Report.

What	Who	Start	End	3Q'12	4Q'12	1Q'13	2Q'13	3Q13	4Q13	2014	2015	2016	2017+
InnoCentive challenge awards selected	Turpen	Aug	Aug'12	█									
Approve amended Powell research proposal (1 Yr)	UF/Powell	April'13	Apr'13		S	→	J	→	M, JI				
Approve RSAs (Powell, Wang), RA (Powell)	CRDF/UF	Apr'13	Apr'13				█						
Approve RSA (Triplett)	CRDF/UF	Jul'13	Jul'13					█					
Source candidate compounds	CRDF	Jan'13	Ongoing										
Screen compounds with various assays	UF/TBD	Jul'13	Ongoing										
Grower-led field experiments	CPDC/ Growers	Fall'13	Ongoing										
Powell research in greenhouse/field (Y1)	UF	Apr'13	Apr'14										
Regulatory roadmap	TBD	2014+	Ongoing										
Secure Commercial Partners	CRDF	2014+	Ongoing										
Develop and optimize products	Companies	2015+	Ongoing										
Regulatory approvals (antibacterials)	Companies	2016+	Ongoing										
Regulatory approvals (antibiotics)	Companies	2017+	Ongoing										
Commercial availability	Companies	2016+	Ongoing										

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4. Genetic Disease Resistance to Citrus Canker

Quarterly Activity Update

- Dr. Janice Zale has accepted the position of MCTF Coordinator and is coming on board mid-July. Dr. Zale brings experience in plant molecular biology, breeding, plant pathology and genetic transformation of crops and model species. CRDF staff will be meeting with her in mid-July to discuss the “go forward” roadmap.
- With a lab coordinator in place, we will be in a position to establish a Steering Committee, define objectives, create an operational plan, and begin work on mature transformation of commercially important citrus scion and root stock cultivars.

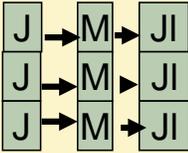
Issues and Gaps

- Formation of Steering Committee to provide oversight and support to the MCTF Coordinator.
- Finalize arrangements with Dr. Leandro Pena to provide valuable support in ensuring the facilities, tools, protocols and work plan are in place

Performance to Milestones

- Securing and having in place a new MCTF Coordinator, and associated activities of establishing a steering team, establishing resource requirements and budgets, and associated protocols and operational planning has slipped about 3 months from March projections. Long term projections remain unchanged.

What	Who	Start	End	3Q'12 4Q'12 1Q'13 2Q'13 3Q13 4Q13 '14 '15 '16' 17 '18 '19 '20 '21 '22+
<u>MCTF Ramp</u>				
Interim MCTF Oversight	CREC	Sep'12	Jul'13	
Secure new MCTF Manager	CREC	Jul'13	Jul'13	
Establish Steering Comm	CREC/CRDF	Aug'13	Aug'13	
Establish resource requirements/budgets	MCTF/Steer Comm	Aug'13	Sep'13	
Ongoing operations	MCTF/Steer Comm	4Q'13	Ongoing	
<u>Commercialization</u>				
Mature tissue transformation into commercial cultivars	MCTF	4Q'13	Ongoing	
First raw materials with desired canker traits	MCTF	2017+	Ongoing	
Field evaluations/wide area testing	CRDF/Com Partners	2017+	Ongoing	
Regulatory studies, permits	CRDF/Com Partners	2014	Ongoing	
Achieve deregulation of first new line	CRDF/Com Partners	2021	Ongoing	
New cultivar budwood to nurseries	CRDF/Com Partners	2022	Ongoing	
Strategic partnerships	CRDF/Steer Comm	2014	Ongoing	



J = January M = March JI = July projection

5. Citrus Gene Therapy (CTV Vectors)

Quarterly Activity Update

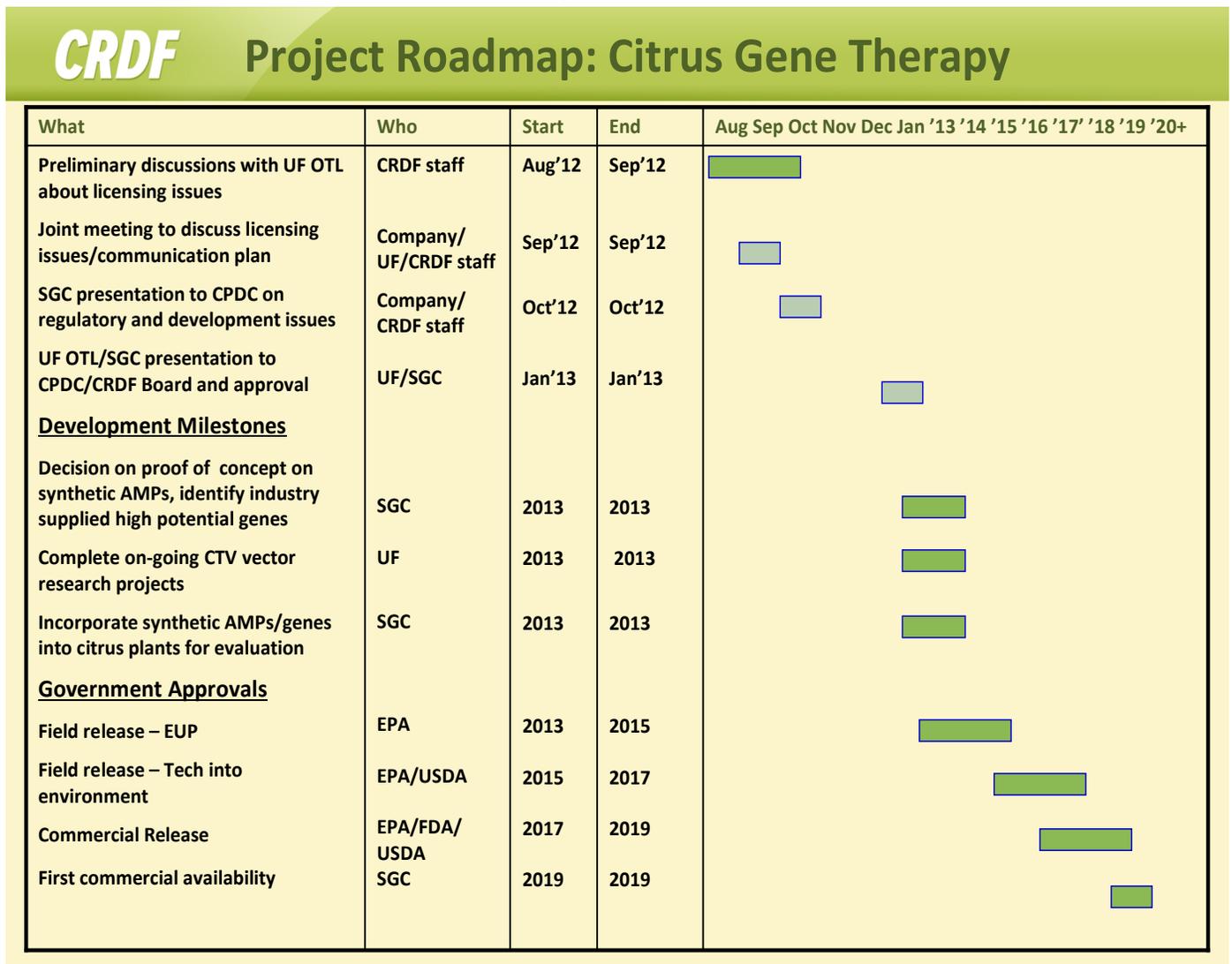
- With the finalization of the licensing agreement with UF, SGC continues its process of tree growth and assessment moving forward, with focus on performance and risk management as it executes its roadmap.

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 March Quarterly Report



6. Advanced Citrus Production and Harvesting Systems

Quarterly Activity Update

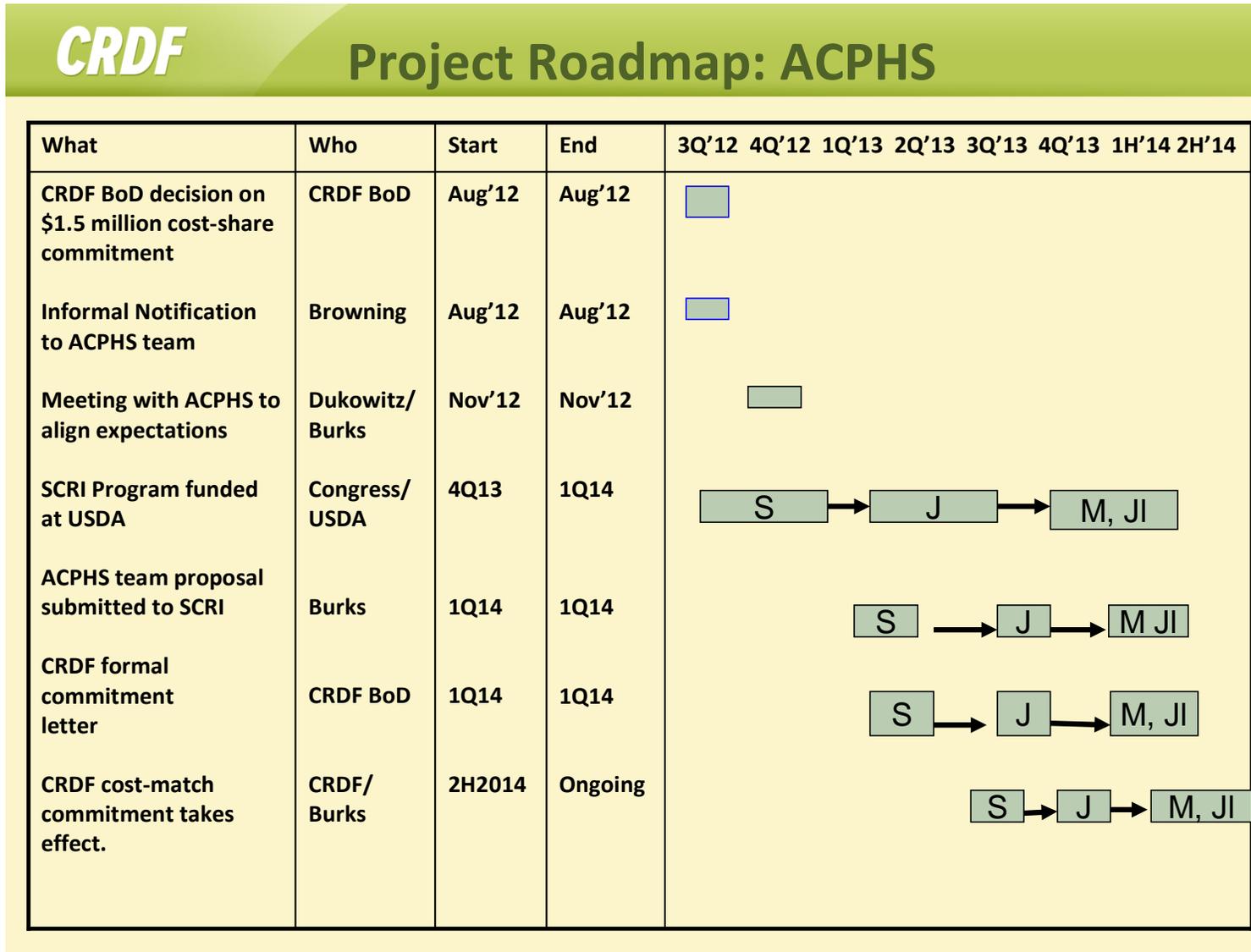
- This project is on hold until USDA has received and committed funding to the SCRI program.

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

- No changes in the projected milestones established in the March report that included projections of a late 2013/early 2014 possible timeframe for the SCRI program funding.



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7. Disease Detection: Canine Scouting (Citrus Canker)

Quarterly Activity Update

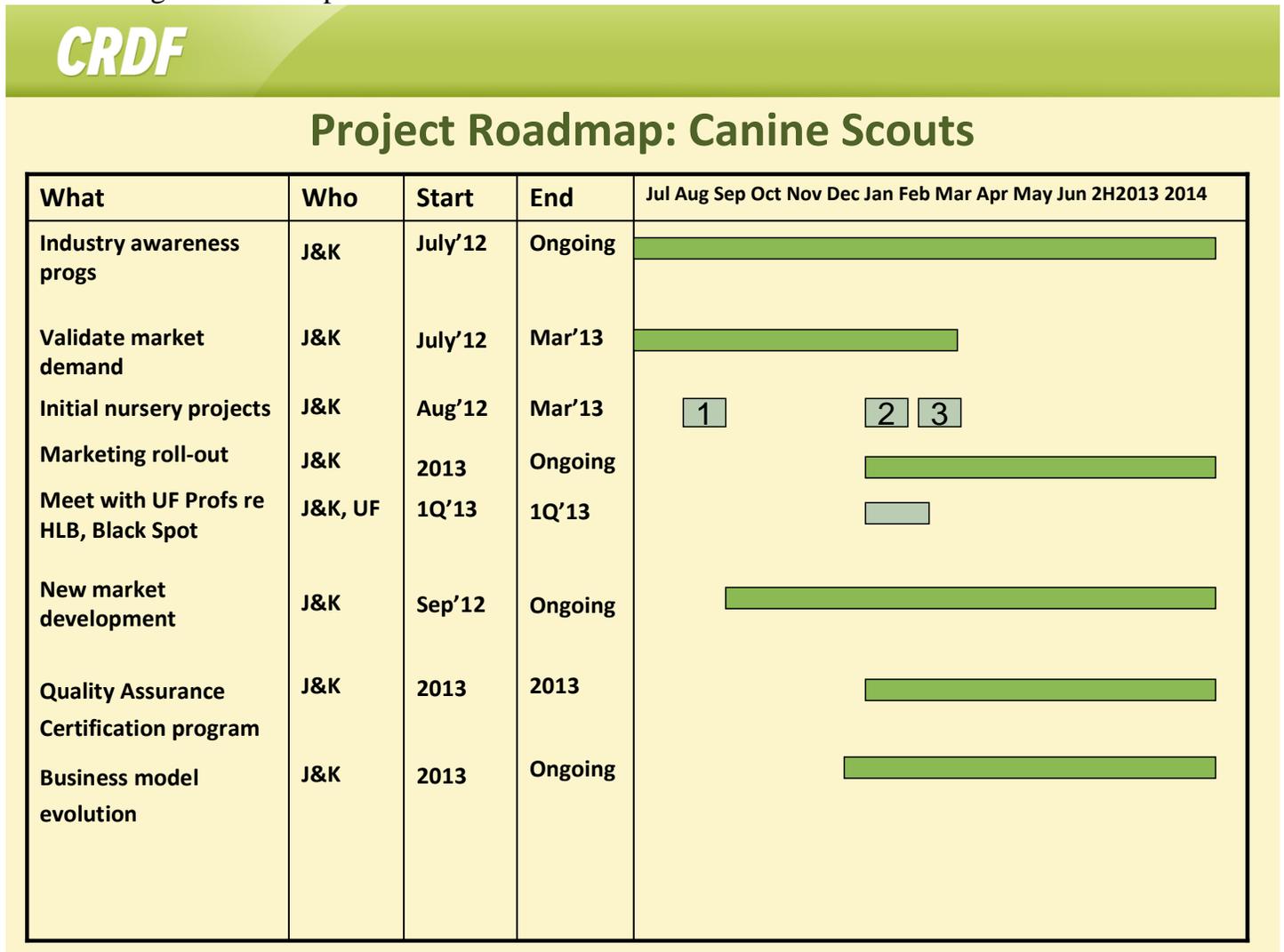
- J&K Canine Academy is continuing its focus on nursery inspections. It has conducted several inspections and has landed a six month, once a week inspection contract.
- J&K applied for a grant in California, but was turned down, apparently being told that Canker, HLB, and Black Spot were not sufficient problems to warrant canine scouting.
- J&K is continuing its education programs for growers at meetings and expos.

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 changes in roadmap from March



1=; First, 2 = Second, 3 = Third nursery project.

8. Diaprepes Root Weevil Control

Quarterly Activity Update

- On May 23 CRDF received notice from USDA, ARS Office of Technology Transfer that CRDF's license application to USDA for the Diaprepes pheromone patent has moved forward with the Federal Register Notice of Intent to Grant Exclusive License to CRDF.
- The notice was posted in the Federal Register on July 2, and comments must be received on or before August 1, 2013.
- Comments received to the Federal Register Notice should help determine the extent of additional commercial interest in the technology.

Issues and Gaps

- CRDF has communicated to USDA that the current market is small because it is geographically limited, with a relatively slow diffusion rate due to quarantine; that there are no company commitments at this point to co-fund the Lapointe research in return for an option to sub-license the technology; and that there must be multiple, simultaneous paths and concurrent closing of the licensing, CRADA and agreements with participating companies.
- There will be "go no go" hurdles and decision points along the way, and CPDC and the Board will be kept informed. Any commitments will require prior CPDC and Board approval.

Performance to Milestones

- The posting of the Federal Register Notice has slipped an additional three months from the projections in the March Quarterly Report, and a total of nine months from the projections in the September 2012 report.

What	Who	Start	End	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	2H13	'14	'15	'16	'17	'18
Submit license application to USDA/OTT	Dukowitz	Jan'13	Jan'13	S				J											
Notice of Intent in Fed Register	USDA	Jul'13	Jul'13	S				J		M									
Negotiate consortium company option agreements	Dukowitz/ Turpen	Aug'13	Nov'13	S				J		M									
Negotiate CRADA/license agreement with USDA	Dukowitz/ Turpen	Aug'13	Nov'13	S				J		M									
Conduct field study	Lapointe	2014	2016																
Negotiate sub-licensing agreements with companies	Dukowitz/ Turpen	2015	2016																
Companies develop products around licensed patent	Companies	2016	2017																
Ramp up manufacturing and marketing	Companies /CRDF	2017	2017																
Product introductions to market	Companies	2018	2018																

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