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

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TABLE OF CONTENTS

Overview

The Commercial Product Development Committee's inaugural quarterly report, issued in September 2012, provided a first look at all eight committee projects in detail, providing an overview for each project along with its goals, benefits, targeted completion, available resources, current status, issues and gaps and project roadmap. That report also included a first look at 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.

This second quarterly report to the Committee tracks progress the Committee has made over the period October through December 2012 in establishing new processes, procedures and approaches needed to facilitate commercialization, as well as documents\our progress in achieving milestones on each of the eight committee projects.

For ease of reading, I have focused this report on the activity highlights of the past quarter, issues and gaps that have been identified, and performance against milestones. On the roadmap charts, changes from the September Quarterly Report are highlighted in yellow. **The box with an "S" indicates the projected date from the September report, while the "J" box represents the January Quarterly reports projected date. The arrow represents the direction of the change.**

On the procedural side, the Committee took an important step by establishing priorities among the eight projects in terms of industry impact and time allocation of CPDC staff. This process began at our September 26 CPDC meeting, where the Committee reviewed in depth each of the eight CPDC projects and associated budgets. During our October 23 CPDC meeting we requested Committee feedback on project priorities in terms of importance to Florida citrus growers, as well as how Committee staff should allocate time among the projects. This prompted a useful discussion at the November 30 Committee meeting. that provided guidance on how to allocate staff time over the contract extension period ending May 31, 2013.

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 January 22 committee meeting

Thanks and regards,

Jim Dukowitz
Commercial Product Manager

PROJECT REPORTS

1. Psyllid Control (Neonicotinoid Label Modification)

Quarterly Activity Update

Imidacloprid

- This project had a notable success with the October 5 FDACS conditional approval of the 24(c) Special Local Need (SLN) label change for Bayer Admire®.Pro.
- On January 14, FDACS received the letter of acceptance for the Admire® Pro SLN for protection of young citrus trees in Florida. The label, as negotiated stands.
- This approval allows a second full rate basal application at established maximum levels for trees three to five years old (5 to 9 feet tall), but restricts application during the period November 1 through completion of petal fall the following year for 3 to 5 year old citrus trees
- There are still outstanding pollinator issues, and EPA's recent SAP report suggested the need for additional information to allow these risks to be more accurately assessed.
- Additional discussions with the registrant will continue to assure the appropriate information is collected to allow refinement of this label in the future.

Thiamethoxam

- Due to concerns over pollinator issues, label expansion associated with 5 to 9 foot trees is problematic and will require additional discussion with registrant to fully resolve. In discussions with the registrant, we are encouraging them to proceed with a revised 24(c) label.
- With the publication of the SAP report and the pending review and decision on expansion of the current label, the specific process and best avenue to accomplish the needs of the industry in the short term are still being assessed., and movement forward on this labeling will continue to depend on resolution of the bee mitigation language required. Hopefully these issues can be resolved over the next couple of months.

Clothianidin

- The registrant was notified in early January of EPA's need to address comments received concerning the litigation on the petition by several environmental groups to cancel the seed treatment uses of Clothianidin prior to moving forward with Valent's label expansion for a multitude of crops, including establishment and publication of the tolerances necessary to allow the use on bearing citrus.
- This led to a negotiated extension of the PRIA decision date until mid June.
- In meetings with the registrant in California on January 15, a pathway forward was discussed to move this action forward as expeditiously as possible. There are no indications at this point of further problems, other than anticipated additional data needs for pollinator risk assessment. It would be best if this need was addressed through the registration review process and not b ecome an impediment to the pending actions. Expansion of the label to conclude the projected increase of materials allowed per year is dependent on these discussions. We anticipate it will be lat e spring before these issues are fully resolved.

Issues and Gaps

Need for Pollinator Impact Data

- The common issue for all registrants has been the perceived risk-reward associated with moving forward with a label expansion given the extremely small dataset that exists for this use, and the increased call for additional information by EPA/ FDACS.

Performance to Milestones

- **Imidacloprid:** The September Quarterly Report projected the Bayer Admire®Pro 24(c) label modification would be approved by FDACS in November. This was achieved in October, ahead of the timetable projected in the September report. The October approval was critical given the label restriction on product use between November and after petal fall the next year.
- **Thiamethoxam**: The September Quarterly Report projected the 24(c) label modification would be submitted to FDACS in October, with conditional approval in December. This has slipped at least five months as registrant determines its go-forward plans for the 24(c) submission.
- **Clothianidin**: The September Quarterly report projected the EPA registration would be complete in January, the 24© submission to FDACS would promptly follow in January with approval projected in February. Based on recent developments, the Section 3 approval date is projected to slip until late spring, with the FDACS approval coming shortly thereafter.

2012-13 Project Roadmap: Neonicotinoid Label Modification

What	Who	Start	End	Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun July Aug+
FDACS/EPA Meetings	Team	2011	2013	
Registrant mtgs/package prep	Team	Jan'12	Jun'13	
Submit 24(c) package for Imidacloprid	Bayer	Sep'12	Sep'12	
Imidacloprid approval	FDACS	Oct'12	Oct'12	
Submit 24 (c) package for Thiamethoxam	Syng-enta	Mar13	Mar'13	S → J
Thiamethoxam approval	FDACS	Apr'13	Apr'13	S → J
Clothianidin Section 3 approval	EPA	Jun'13	Jun'13	S → J
Submit 24(c) package for Clothianidin	Valent	Jun'13	Jun'13	S → J
Clothianidin approval	FDACS	Jul'13	Jul'13	S → J
Additional data collection	Rogers	Apr'13	Jul'13+	
Additional Label Changes	Team	Jul'13+	Jul'13+	

2. Psyllid Control (RNAi)

Quarterly Activity Update

Approve Commercial Research Proposal

- At its October 23 meeting, the CRDF Board approved the first year of the two-year proposed commercial research project submitted by Dr. Charles Powell (UF, Ft. Pierce) and Dr. Bob Shatters (USDA, Ft. Pierce). This proposal had been reviewed and recommended for funding approval by CPDC at the September committee meeting.
- 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.

Prepare Commercial Research Agreement Template

- As a commercial research project, the intent is to facilitate interest among prospective commercial partners to join in and ultimately drive the commercialization process/
- For that reason, a new commercial research agreement template was created by CRDF staff, was reviewed by the CRDF Governance Committee and Board of Directors, and is currently under review by the University of Florida Office of Sponsored Research and Office of Technology Licensing.
- Once the template is agreed to, the next step is to finalize the commercial research agreement so that CRDF funding can be released.

Facilitate Company Partnerships (Monsanto)

- At the end of November, CRDF was notified by Bob Shatters (USDA Ft. Pierce) that Monsanto was prepared to synthesize large quantities of two of the dsRNA gene targets for greenhouse and field testing. Monsanto and USDA (Dr. Wayne Hunter) have an existing agreement which can be modified to allow Monsanto to proceed.
- USDA requested and, after investigation, CRDF provided a letter indicating CRDF has no claims to that portion of the IP that belongs to the U.S. government related to the two specific gene targets. This has paved the way for USDA and Monsanto to modify their CRADA to allow this work to proceed, thereby advancing the science and (hopefully) increasing the possibility of a long term Monsanto partnership..

Issues and Gaps

Invention Disclosures

- One of the near-term actions that needs to be taken by UF/USDA is to complete invention disclosures (IDs) for some or all of the 14 gene targets. CRDF has been advised that USDA intends to take the lead to complete the RNAi-related IDs and turn them over to the appropriate technology licensing activity to develop a patenting approach.
- CRDF is monitoring this closely and is in regular communications with USDA ARS researchers to ensure this is completed in a timely fashion.

Terms of the Commercial Research Agreement

- The new CRDF commercial research agreement template is currently under review by the University of Florida Office of Sponsored Research and Office of Technology Licensing. Some of the elements of the template related to confidentiality, data ownership, good laboratory practices, and contract flexibility are creating special challenges for the culture and established practices at the university.
- CRDF staff will create the best agreement template possible with the University and, as required, find alternative approaches to ensure that the conduct of the commercial research will move forward on the right commercialization path.

Company Partnerships

- There are relatively few companies conducting development work in this space, with Monsanto being the most important. The modified USDA-Monsanto CRADA for synthesizing large quantities of two of the dsRNA gene targets can be an important first step toward developing a long term commercial relationship with Monsanto.

Regulatory Roadmap.

- Navigating the regulatory process will require an understanding of the concerns and information needs of regulators, and data collection requirements under GLP conditions that meets these needs. CRDF staff will begin conversations with regulatory authorities to gain perspective on these issues.

Performance to Milestones

- The major change in milestones is the slippage of the start of the commercial research project. The September Quarterly Report listed October as the start date. This has slipped by at least 3-4 months until CRDF and UF reach agreement on the commercial research template, and finalize the agreement for the first year of the follow-on commercial research project.

Project Roadmap: Psyllid Control (RNAi)

What	Who	Start	End	Aug Sep Oct Nov Dec 2013 2014 2015 2016 2017 2018+
InnoCentive Challenge awards selected	Turpen	Aug	Aug	
Comm research proposals submitted	Powell/ Shatters	Aug	Sep	
Approve proposal for follow-on comm research	CPDC/ CRDF BoD	Sep	Oct	
Prepare comm research template	CRDF Staff/ BoD	Oct	Dec	
Conclude comm research agreement	**CRDF Staff/ UF**	**Feb'13**	**Feb'13**	S → J
Begin research project (first year)	**Powell/ Shatters**	**Feb'13**	**Feb'14**	S → J
Company partnership explorations	Turpen/ Dukowitz	Sep'12	Ongoing	
Regulatory roadmap	CPDC/comp	2013	Ongoing	
Partnerships for prod devt/commercialization	CPDC/comp	2013	Ongoing	
Develop and optimize products	Companies	2015	Ongoing	
Regulatory approvals (exogenous, synthetic)	Companies/ TBD	2016+	Ongoing	
Regulatory approvals (plant incorp. protectant)	Companies/ TBD	2018+	Ongoing	
Commercial availability	Companies	2017-2019	Ongoing	

3. Antibacterials

Quarterly Activity Update

Approve Commercial Research Proposal

- At its October 23 meeting, the CRDF Board approved the first year of a three-year proposed commercial research project submitted by Dr. Charles Powell (UF, Ft. Pierce).The proposal had been reviewed and recommended for funding approval by CPDC at the September committee meeting.
- This project continues CRDF-funded research performed the prior year to evaluate candidates as part of the InnoCentive™ Challenge. This research takes the 11 winners, 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.

Prepare Commercial Research Agreement Template

- The Commercial Research Agreement Template that was described in Project 2 , once finalized, will be used for the Antibacterials research agreement.

Facilitate Company Partnerships

- In parallel, work continues on developing company partnership arrangements. Current focus is on two companies with complementary competencies.

Issues and Gaps

Patents/IP Management

- One of the near-term actions that needs to be taken is for UF to complete invention disclosures (IDs) for some or all of the 11 compounds being evaluated. CRDF has been advised that UF intends to take the lead to complete the Antibacterial-related IDs and turn them over to the UF Office of Technology Licensing to develop a patent approach for each of the compounds.
- CRDF is monitoring this closely and is in regular communication with UF researchers to ensure this is completed in a timely fashion.

Company Partnerships

- 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.
- At this point we have identified two companies that have strong interest in commercializing antibiotics/antibacterials for citrus HLB management, and we are in

discussions to explore their interests and capabilities.. The intent is to develop a partnership to complete development, regulatory and "take to market" activities.

Regulatory Roadmap:

- Navigating the regulatory process will require understanding of the concerns and information needs of regulators, and data collection under GLP conditions that meets these needs.
- In general, antibacterials (biopesticides) such as plant essential oils are expected to have an easier regulatory path than antibiotics. There is an interesting mix of compounds: some are naturally occurring, some are registered for agricultural use in Asia, others are predominately in veterinary medicine, and one is even used to enhance the efficacy of cancer chemotherapy in humans.
- CRDF staff is working through the list and will plan a pre-registration visit with EPA to discuss our plans and understand their viewpoint and data requirements.

"Target of Opportunity" Compounds:

- 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.
- CRDF staff is examining these opportunities and determine whether it may be possible to get a relatively quick regulatory approval, e.g. a Section 3 label expansion, 24(c) special local need, or Section 18 emergency approvals.

Performance to Milestones

- The major change in milestones is the slippage of the start of the commercial research project. The September Quarterly Report listed October as the start date. This has slipped by at least 3-4 months until CRDF and UF reach agreement on the commercial research template, and finalize the agreement for the first year of the follow-on commercial research project.

Project Roadmap: Antibacterials

What	Who	Start	End	Aug Sep Oct Nov Dec 2013 2014 2015 2016 2017
InnoCentive challenge awards selected	Turpen	Aug	Aug	
Comm research proposals submitted	Powell	Aug	Sep	
Approval proposal for follow-on comm research	CPDC/ CRDF BoD	Sep	Oct	
Prepare/approve comm research template	CRDF Staff/ BoD	Oct	Dec	
Conclude comm research agreement	CRDF Staff/ UF	Feb'13	Feb'13	S → J
Begin follow-on comm research (first year)	Powell/Team	Feb'13	Feb'14	S → J
Company partnership explorations	CPDC staff/ companies	2013	Ongoing	
Regulatory roadmap	CPDC/ comp	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	

4. Genetic Disease Resistance to Citrus Canker

Quarterly Activity Update

Interim Oversight of MCTF

- With the departure in September of Dr. Zapata to accept a position in industry, the most immediate need was to work with CREC Director Dr. Jackie Burns to arrange interim oversight until a new Mature Citrus Transformation Facility (MCTF) manager can be hired. Dr. Burns has put in place interim management to maintain the facility in a caretaker status.

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 prepared a description and posted a job announcement on the UF system, have placed ads in targeted journals, and are proactively reaching out to prospective candidates to determine their interest in applying fort the position. This includes discussions with three Plant Transformation Lab Directors at different universities to gain their perspective and access to their networks of potential candidates.

Steering Committee

- We are also working closely with Dr. Burns to establish a Steering Committee for the MCTF to aid in selecting the new leader and to provide strategic oversight to MCTF activities. The MCTF Manager will be accountable to the Steering Committee. To date, two UF Gainesville candidates have been identified to serve on the Steering Committee along with Jackie Burns, Tom Turpen, and Jim Dukowitz. Jackie Burns is contacting these individuals to determine their availability and willingness to serve.

Issues and Gaps

Secure a Qualified MCTF Manager

- Management of the MCTF will deal with outside scientists and companies, budgeting, personnel and meeting development timelines It is recognized that there are only a small number of individuals that have knowledge of and experience in both the scientific and industry side of plant transformation processes, operations and management in a commercially-oriented, high throughput environment..
- For that reason, we are taking a proactive approach to network with the small community of individuals who are either interested themselves, or can provide connections to those who may be interested.

Pre-Launch Planning

- Once the MCTF manager is in place, he or she 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.

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

- There are no changes to the roadmap from the September Quarterly report.
- There is risk in the current milestone to secure a new MCTF manager by the March timeframe/ If that milestone slips, the June timeframe for re-launch of the MCTF is also at risk.

Project Roadmap: Genetic Disease Resistance (Canker)

What	Who	Start	End	2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
MCTF Ramp/Launch				
Interim MCTFoversight	CREC	Sep	Mar'13	
Recruit new MCTF mgr	CRDF/CREC	Oct	Mar'13	
Establish Steering Committee	CRDF/ CREC	Nov	Mar'13	
Establish resource requirements and budget	MCTF/Steer Comm	Mar'13	May'13	
MCTF Launch	MCTF/Steer Comm	Jun'13	Jun'13	
Commercialization				
Mature tissue transformation into commercial cultivars	MCTF	2013	Ongoing	
First raw materials with desired canker traits	MCTF	2017+	2017+	
Field evaluation/ wide area testing	CRDF/Com Partners	2017+	Ongoing	
Regulatory studies, permits	CRDF/Com Partners	2013	Ongoing	
Achieve deregulation of first new line	Companies	2021	Ongoing	
New cultivar budwood to nurseries	Companies	2022	Ongoing	
Strategic partnerships	CRDF	2013	Ongoing	

5. Citrus Gene Therapy (CTV Vectors)

Quarterly Activity Update

- Efforts over the past quarter have focused on work with University of Florida Office of Technology Licensing and Southern Gardens (SGC) to develop a process for CPDC and CRDF board review of the licensing agreement that is being finalized between SGC and University of Florida.
- The agreement covers 4 UF pa tents related to CTV vectors, one of which was based on CRDF-funded research.
- After the September 23 CRDF Board meeting, representatives of CRDF staff, SGC and UF OTL met to scope out the issues, and begin to define a process to move toward a "decision" presentation to the CRDF Board.
- CRDF Board member Rick Kress of SGC presented an overview of the regulatory process and other issues associated with commercializing CTV technology at the October 23 CPDC meeting.
- UF OTL and SGC have indicated that they will have completed, or be near completion of the licensing agreement in January, so the decision was made to have representatives of University of Florida OTL and SGC present to CPDC and the CRDF board at the January 22 meetings.
- In preparation for the meeting, UF has forwarded a copy of the template used by UF for license agreements, as well as the development plan and milestones associated with the licensing agreement. The development plan and milestones are being provided to the CPDC and CRDF Board of Directors in advance of the January 22 meeting as useful background to help members prepare for the meetings.
- CRDF staff has requested and received from UF OTL a redacted copy of the actual license agreement between UF and SGC. Harold, Tom and Jim are reviewing the document under a confidentiality agreement. This will allow CRDF staff to be able to offer informed opinion on the key issues known to be of concern to the CRDF Board.

Issues and Gaps.

Research Agreement Provisions

- Based on the terms of the standard CRDF-UF research agreement, OTL may not execute any exclusive licenses for IP developed using CRDF funding without the prior written consent of CRDF. The agreement also states that:written consent may not be unreasonably withheld or delayed; that no license may be granted on more favorable terms than those offered to the U.S. citrus industry; and the license agreement must contain commercial development milestones and due diligence provisions that allow the license agreement to be terminated if the licensee is not diligently developing the technology.

Potential Board Considerations

The following are potential issues for Board consideration that were developed by CRDF staff, and reflect discussions over time with Board members as well as the UF Office of Technology Licensing:

- **Approach to licensing**: CRDF must determine how to balance the desire to obtain royalties from its sponsorship of research that created the IP; and the desire to see the technology commercialized and in the hands of growers as quickly and efficiently as possible, and then offered to growers at a price that is affordable and usable.
- **Most favored nation terms:** Will the timing and terms of the deal offered to Florida growers be at least as good as those offered to others, particularly licensees outside the U.S.?
- **Commitment to commercialization:** Doe SGC development plans and milestones represent a strong commitment to commercialization?
- **Performance clauses/default terms**: Will there be adequate me chanisms in the agreement so that UF can regain control of the technology if SGC does not commercialize and perform to milestones in a reasonable time frame?
- **Market accessibility**: How will the technology be productized and delivered to the market?
- **Limitations on existing research**: Will this agreement pose any restrictions in terms of continued use of the licensed CTV vector technology as a research tool in projects funded by CRDF?
- **Commercialization costs**: Commercializing CTV technology will require multiple years of product development, regulatory approvals and "take to market" efforts that may be more than any single company in the Florida citrus industry can bear. The regulatory approvals may be complicated because the regulated article is a new biologic. Additional external funding sources and collaborations may be needed to successfully commercialize this technology.

Performance to Milestones

- A near milestone was added based on finalization of the plan to present to CPDC and CRDF Board in January.
- There are also a number of "tweaks" to the longer-term commercialization roadmap based on additional information gathered over the past quarter as part of the planning process for the January CPDC and CRDF Board meetings.

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Project Roadmap: Citrus Gene Therapy

What	Who	Start	End	Aug Sep Oct Nov Dec 2013 2014 2015 2016 2017 2018 2019+
Preliminary discussions with UF OTL about licensing issues	CRDF staff	Aug	Sep	
Joint meeting to discuss licensing issues/ communication plan	SGC/ UF/ CRDF staff	Sep	Sep	
SGC presentation to CPDC on regulatory and development issues	SGC	Oct	Oct	
UF OTL/SGC presentation to CPDC/CRDF Board	UF/SGC	Jan'13	Jan'13	
Development Milestones				
Decision on proof of concept on synthetic AMPs, identify industry supplied high potential genes	SGC	2013	2013	
Complete on-going CTV vector research projects	UF	2013	2013	
Incorporate synthetic AMPs/genes into citrus plans for evaluation	SGC	2013	2013	
Governmental Approvals				
Field release – EUP	EPA	2013	2015	
Field release – Tech into envt.	EPA/USDA	2015	2017	
Commercial release	EPA/FDA/ USDA	2017	2019	
First commercial availability	SGC	2019	2019	

6. Advanced Citrus Production and Harvesting Systems

Quarterly Activity Update

- In August the CRDF Board agreed to support Dr. Tom Burks' planned 2013 submission of the ACPHS project proposal with a cost-match commitment of $1.5 million over five years, composed of $1 million in cash and $500 thousand of in-kind cost-share. This is the same amount that was approved by the CPDC and CRDF Board in December 2011 in support of the 2012 NIFA SCRI application
- The CRDF Board requested CRDF staff meet with Tom Burks before the end of 2012 to review the revised proposal to insure the scope of work is not redundant with currently funded CRDF projects, and will benefit the industry in a way that warrants its cost share commitment.
- In late November, CPDC staff met with Tom Burks to review issues associated the planned submission in January'13 of the proposal, and to align project expectations with those of CRDF. This provided needed background in support of the Board commitment letter, as well as a roadmap for future interactions.
- While Dr. Burks and his team are still planning to submit the proposal to NIFA for the 2013 round, he is somewhat concerned about his ability to secure the same level of cost share commitments ($10 million) as last year. He indicated the proposal will be essentially the same as last year, differing primarily in "cosmetic" improvements that better communicate how all the tasks within the overall project fit together.

Issues and Gaps

SCRI Program Funding

- The timing of the proposal submission will depend on the passage of the 2012 Farm Bill, and the 2013 Appropriations Bill, since USDA does not yet have funding committed to the SCRI program. Burks' assessment is that this could come any time in the next 6 months, or it may not come until 2014.

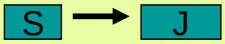
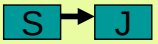
Letter of Support

- 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,

Performance to Milestones

- The major change from the September Quarterly Report is the slip in the projected dates for the Board letter of support and the submission date of the proposal by Burks and his team.

Project Roadmap: ACPHS

What	Who	Start	End	Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep 2014
CRDF BoD decision on $1.5 million cost-share commitment	CRDF BoD	Aug	Aug	
Informal Notification to ACPHS team	Browning	Aug	Aug	
Meeting with ACPHS to align expectations	Dukowitz/ Burks	Nov	Nov	
2012 Farm Bill, 2013 Authorization Bill passage, SCRI budget	Congress USDA	Jan'13?	June'13+	
ACPHS team proposal submission to SCRI	Burks	Jun'13+	Sep'13+	
CRDF formal commitment letter	CRDF BoD	May'13+	Sep'13+	
CRDF cost-match commitment takes effect	CRDF/ Burks	2013+	Ongoing	

7. Disease Detection: Canine Scouting (Citrus Canker)

Quarterly Activity Update

- During the last quarter Pepe Peruyero, CEO of J&K Canine Academy, has been actively marketing his canine scouting program within Florida as well as exploring interest in other citrus growing states as well as internationally. He has been targeting growers who are purchasing new plantings from nurseries and want to be assured they are canker free before planting; fresh fruit exporters who want to increase the likelihood that they will obtain harvesting permits; and pre-packing house collection points at which he can provide additional screening services before the fruit is sent to packing houses.
- He is also taking steps to upgrade his marketing activities, including additional information on his website.
- Because this is entrepreneur-driven, the program is largely on auto-pilot, and we are monitoring and providing mentoring and other assistance upon request.
- J&K Canine Academy plans to expand to other diseases, and has submitted a proposal to CRDF under CATP 12 for training canines to detect both HLB and citrus black spot.

Issues and Gaps (Citrus Canker)

Marketing Approach

- Despite widespread interest, J&K faces the normal challenges of creating a new business in an established industry. He is experimenting with different marketing approaches, and enhanced website and business models to find the right combination.

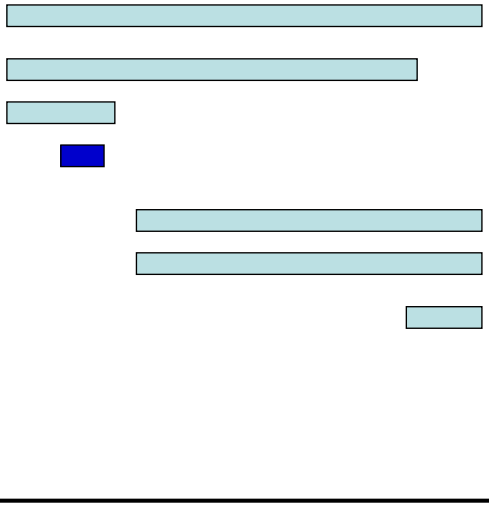
Other Diseases

One of the key issues that can be addressed with CATP 12 research funding is the extent pre-symptomatic detection of HLB will be possible while the disease is s till latent. The proposed 8 month program could enable HLB detection services to be available to Florida growers by the end of 2013.

Performance to Milestones

- No changes to September Quarterly Report roadmap.

Project Roadmap: Canine Scouts

What	Who	Start	End	Jul Aug Sep Oct Nov Dec 2013
Industry awareness progs	J&K	July	Ongoing	
Validate market demand	J&K	July	Dec+	
Business model evolution	J&K	July	Aug	
Nursery pilot project	J&K	Aug	Aug	
Nursery program rollout	J&K	Sep	Ongoing	
Grower program rollout	J&K	Sep	Ongoing	
Quality Assurance Certification program	J&K, Industry	2013	Ongoing	

8. Diaprepes Root Weevil Control

Quarterly Activity Update

- At the October and November CPDC meetings the Committee discussed the relative priority of the eight CPDC projects in terms of value to industry and level of project management support that should go to each project.
- This project was ranked low by the Committee primarily because of the Committee's desire to focus on HLB, and the small market size, limited geographical locations and slow diffusion rate of Diaprepes root weevil.
- CRDF staff had already been working with USDA ARS Office of Technology Licensing to prepare and submit an application to USDA for an exclusive license for the patent and associated intellectual property associated with Dr. Steven Lapointe's research on pheromone attractants for Diaprepes Root Weevil.
- CRDF had also made contact with candidate companies about taking out an option to sublicense the technology in return for company co-funding of a two year field trial by Dr. Lapointe to further the progress in pheromone development and delivery.
- This overall approach was discussed with USDA as a model for future USDA-CRDF cooperation on other projects.
- Based on these considerations, the Committee decided to take this project to the next step of submitting the CRDF license application to USDA, which will be followed by a posting in the Federal Register. This will provide other companies an opportunity to express interest in the license.
- In December, CRDF staff signed a confidentiality agreement with USDA, viewed the relevant provisional patent and draft regular patent application, provided inputs on geographical markets of interest, and submitted the license application to USDA.
- In early January we received notice of receipt of the application and the name of the USDA project manager we will be working with on this application.

Issues and Gaps

Market opportunity.

- The current market is small because it is geographically limited, with a relatively slow diffusion rate due to quarantine.
- Diaprepes is currently a major problem in the Caribbean, especially Puerto Rico, and in Florida, where it impacts over 30,000 acres in 21 counties, affecting both citrus and ornamental plants.
- In 2000, Diaprepes was first reported in the Texas Rio Grande Valley in Hidalgo County, with a second detection site in 2008 in Cameron County. Diaprepes was also found in southern California in 2005, where it is limited to urban areas and a small number of citrus orchards in the Los Angeles, Orange and San Diego counties. It also has been found in Louisiana.
- Because of quarantine, the spread of Diaprepes has been relatively slow to date. Should it spread to the agricultural areas of California, or move south into Mexico,

Central and South America, the problem and market opportunity would both expand dramatically.

Securing Commercial Partners

- 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.

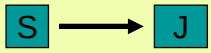
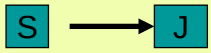
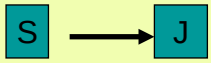
Risk Mitigation

- 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.
- We should know within 3-4 months after submitting the license application to USDA whether there will be sufficient company interest to proceed with the project. Sufficient interest means commitment to co-fund the two year Lapointe field trials in exchange for an option to license the technology in the future.
- 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 three months from the September Quarterly Report timetable pending resolution of Committee project priorities.

Project Roadmap: Diaprepes Root Weevil Control

What	Who	Start	End	Sep Oct Nov Dec Jan Feb Mar 2013 2014 2015 2016 2017 2018
Submit license application to USDA/OTT	Dukowitz	Jan	Jan	
Notice of Intent in Fed Register (Secure license)	USDA	Feb	Mar	
Negotiate consortium company option agreements	Dukowitz/ Turpen	Feb	Mar	
Negotiate CRADA/license agreement with USDA	Dukowitz/ Turpen	Feb	Mar	
Conduct field study	Lapointe	2013	2015	
Negotiate sub-licensing agreements with companies	Dukowitz/ Turpen	2013	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