

REVIEW OF  
LOUISIANA STATE UNIVERSITY SYSTEM'S AFFILIATE  
RELATIONSHIP WITH THE LOUISIANA HEALTH  
INFORMATION TECHNOLOGY FOUNDATION

LOUISIANA STATE UNIVERSITY SYSTEM



FINANCIAL AUDIT SERVICES  
ISSUED JUNE 6, 2019

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LOUISIANA LEGISLATIVE AUDITOR  
DARYL G. PURPERA, CPA, CFE

June 6, 2019

The Honorable John A. Alario, Jr.  
President of the Senate  
The Honorable Taylor F. Barras,  
Speaker of the House of Representatives

The Louisiana State University System (LSU) President requested that the Louisiana Legislative Auditor review the relationship between LSU and a not-for-profit entity named Louisiana Health Information Technology Foundation (LaHIT). The report contains our findings, conclusions, and recommendations.

We would like to express our appreciation to the management and staff of LSU and other associated parties for their assistance during this engagement.

Sincerely,

A handwritten signature in blue ink that reads "Daryl G. Purpera".

Daryl G. Purpera, CPA, CFE  
Legislative Auditor

DGP/aa

LAHIT



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# Louisiana Legislative Auditor

Daryl G. Purpera, CPA, CFE



## Review of Louisiana State University System's Affiliate Relationship with the Louisiana Health Information Technology Foundation

June 2019

Audit Control # 80180129

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### Introduction

The Louisiana State University System (LSU) President requested that the Louisiana Legislative Auditor review the relationship between LSU and a not-for-profit entity named Louisiana Health Information Technology Foundation (LaHIT). LaHIT was used to license LSU intellectual property for commercial use. The request indicated that the LSU Office of Internal Audit conducted a thorough investigation and discovered a number of potentially concerning policy and procedural issues. The purpose of this engagement was to examine these matters.

### Background

LSU management directed the creation of an LSU-affiliated, non-profit corporation, LaHIT, to serve as the licensee for the CLinical InQuiry (CLIQ) software. This software was developed to support clinical decision-making and to optimize patient safety. LaHIT was incorporated on September 30, 2014. LSU's intention was that LaHIT would sublicense the software to a for-profit corporation, HarmonIQ Health Systems Corporation (HarmonIQ), which would be responsible for the development and commercialization of the software. The following summarizes the events from the development of CLIQ in the late 1990s to the present.

**CLinical InQuiry (CLIQ)** is an LSU-developed software application comprising an electronic medical record and clinical data infrastructure and repository. The software enables a web-based portal that allows healthcare practitioners secure access to electronic patient information, which includes visit history, laboratory results, allergies, medications, immunization history, preventive health reminders, etc.

**Late 1990s through 2011.** The development of the software began in the late 1990s at the LSU Healthcare Network and LSU Health Sciences Center - New Orleans (LSUHSC-NO). It was designed to facilitate communication of clinical data among health care providers at the Charity Hospital in New Orleans. As this software further developed, it became what is today called CLIQ. By 2006, CLIQ had been deployed to all the LSU hospitals and clinics. A team of LSU employees developed CLIQ. Once the software was complete, the developers transitioned to supporting CLIQ at the LSU hospitals. Documentation indicates that LSU began efforts to license the software at least as far back as 2011 through LSUHSC-NO's Office of Technology Management (OTM).

**August 2012 through 2017.** In August 2012, Dr. Frank Opelka was appointed as LSU's Executive Vice President for Health Care and Medical Education Redesign. Dr. Opelka managed

the effort to commercialize CLIQ, including an attempted joint venture with the Harris Corporation. This effort was unsuccessful, and LSU subsequently licensed the software to LaHIT in February 2016. LaHIT sublicensed the software to a for-profit company, HarmonIQ, which was responsible for its commercialization. LSU eventually terminated the license agreement with LaHIT in March 2017 for failure to meet milestones specified in the license agreement, specifically failing to achieve the first commercial sale through HarmonIQ on or before September 30, 2016. LSU entered into a new license agreement directly with HarmonIQ on March 27, 2017.

**2018 – Present.** As of March 2019, LaHIT still exists as a non-profit foundation but is listed as inactive by the Louisiana Secretary of State. Based on documentation obtained by auditors, attempts to dissolve LaHIT have been unsuccessful due to LaHIT's apparent debt (salary/legal fees) and uncertainty regarding the current makeup of LaHIT's Board of Directors. The license agreement with HarmonIQ, dated March 27, 2017, was terminated by LSU on December 31, 2018, because of HarmonIQ's failure to pay \$164,000 in IT infrastructure debt due to LSU. According to LSU, no royalties were paid to (or are owed to) LSU relating to the commercialization of the CLIQ software.

The objective of our work was to review the relationship between LSU and LaHIT, as well as LSU's licensing process for CLIQ. We evaluated LSU's licensing process through interviews of LSU employees and officials, interviews of other persons as appropriate, review of LSU policies and procedures, review of applicable state laws and regulations, and review of appropriate documents and records. Our review included:

- (1) the creation of LaHIT as licensee,
- (2) the creation of HarmonIQ and its relationship to LSU,
- (3) compliance with LSU's licensing process for intellectual property,
- (4) LSU Board of Supervisors (Board) oversight of the licensing process, and
- (5) potential conflicts of interests in the licensing process.

The weaknesses we identified in these areas are summarized on the next page and discussed in more detail throughout the remainder of this report. Appendix A contains management's response to this report. Other individuals were given opportunities to respond and, for those who chose to respond, their response is included at Appendix B. In addition, Appendix C provides a timeline of events related to licensing of the CLIQ software.

## **Objective: To review the affiliate relationship between LSU and LaHIT, related to the licensing of CLIQ.**

Overall, we found that LSU did not follow its own procedures and by-laws, or ensure proper oversight by the LSU Board, when forming LaHIT and licensing CLIQ for commercial use. As a result, the terms of the license agreements may have been less favorable to LSU, the legal costs paid for creating and/or for the benefit of the associated corporations may have violated the Louisiana Constitution, and potential conflicts of interest involving an LSU official and employees were created. Specifically, we identified the following issues:

- **LSU management did not follow its own established practice and by-laws when creating LaHIT as a licensee for LSU technology transfer or for the commercialization of intellectual property.** This gave LaHIT control over licensing proceeds and the terms of the sublicense agreement, and may have prevented the LSU developers of the software from receiving the full amount of royalties owed to them.
- **While not prohibited by LSU policy, such policies do not clearly define the circumstances under which LSU can assist non-LSU entities in the commercialization of LSU technology.** In addition, legal costs paid for the creation of and/or for the benefit of corporations may have violated Article VII Section 14 of the Louisiana Constitution.
- **LSU management did not adhere to its process for licensing intellectual property when licensing the CLIQ software for commercial use.** As a result, LSU's control over aspects of the commercialization and the LSU President's and Board's ability to make appropriate decisions was weakened, resulting in conflicts of interest.
- **LSU management failed to bring three LSU agreements related to the licensing of the CLIQ software before the LSU Board for formal approval.** As a result, the LSU Board was not able to review, recognize, and approve to ensure proper Board oversight.
- **Arrangements adopted by LSU to license the CLIQ software created potential conflicts of interest involving an LSU official and employees.** Specifically, an LSU official who stood to gain from the success of CLIQ entered into contracts with HarmonIQ and HarmonIQ's President.

These issues are discussed in more detail throughout the remainder of the report, along with recommendations to assist LSU in addressing them.

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#### Departure from Established Practice on Technology Transfers

LSU failed to use the Offices of Technology Management (OTMs) located at the various LSU campuses, which normally manage technology transfers. These OTM offices are responsible for ensuring that the technology is protected and marketable, for identifying potential licensees, and for drafting license agreements. The staff of the OTM offices is experienced at performing technology transfers and documents them using standard forms and templates. The procedures governing technology transfers are specified in the LSU Board Regulations. Prior to 2012, the OTM at LSUHSC-NO was managing LSU's efforts to license CLIQ.

As stated previously, in August 2012 Dr. Frank Opelka was appointed as LSU's Executive Vice President for Health Care and Medical Education Redesign. This position gave him authority over LSU's Health Care Services Division (HCSD) and the responsibility to oversee the proposed joint venture with Harris Corporation to commercialize the CLIQ software. Instead of relying on OTM, he relied on contract attorneys from Taylor, Porter, Brooks & Phillips L.L.P. (Taylor Porter) to assist with the licensing process.

Dr. Opelka briefed the LSU Board of Supervisors on the efforts to commercialize CLIQ and the role of LaHIT in these efforts. While employed by LSU, he also served as a Director on the LaHIT Board and in this capacity signed the licensing agreement with LSU and hired a Director for LaHIT.

#### Licensing Proceeds and Sublicense Terms Controlled by LaHIT

LSU management incorrectly believed that the executed sublicense agreement included LaHIT receiving equity in HarmonIQ. The sublicense agreement, dated February 25, 2016, between LaHIT and HarmonIQ specified that HarmonIQ was to pay LaHIT royalties of 5% of net sales. However, a draft license agreement dated November 11, 2015, specified LaHIT was to receive a 40% equity stake in HarmonIQ in addition to a 5% royalty. Dr. Opelka stated he was not sure why the final license agreement did not include the equity stake in HarmonIQ. He added that the purpose of the equity stake was to ensure that LSU benefited fully in the event that HarmonIQ was bought out by another company. In addition, email correspondence in August 2016 indicates that LSU management thought that the 40% equity stake was included in the executed sublicense agreement.

According to Dr. Opelka, LaHIT's equity position meant that a substantial portion of proceeds from a buyout of HarmonIQ would go to LaHIT. LaHIT could then distribute all or a portion of the proceeds to LSU. Dr. Opelka further stated that if all proceeds were distributed to LSU, then LSU may have simply had its budget cut with no gain to LSU, and that proceeds that stayed at LaHIT would not be subject to budget cuts and, therefore, could be used for programs that benefited LSU.

An attorney for Taylor Porter stated that the proceeds to LaHIT from a buyout of HarmonIQ was where LSU expected to get the most financial benefit from the software and indicated that part of the motivation for licensing the software to LaHIT was to protect these proceeds from resulting in possible budget cuts.

### Royalties Owed to LSU Developers Potentially Reduced

The potential for LaHIT to retain proceeds from a buyout of HarmonIQ rather than LSU may also have affected the royalty distribution to the LSU developers who created the CLIQ software. LSU Board Regulations state that the developers of LSU's intellectual property are entitled to 40% of all distributed royalties<sup>1</sup> earned from LSU intellectual property. According to Dr. Opelka, developers' royalty distributions could only be based on proceeds received by LSU. Royalties could not be calculated on the basis of proceeds retained by LaHIT, as these were not LSU funds. As a result, the LSU developers potentially could have not received the royalties owed them under this arrangement had a buyout occurred.

**Recommendation 1:** LSU should ensure that all technology transfers are managed by the appropriate OTM office to ensure a uniform process and adherence to established policies and procedures. A uniform process reduces the risk of noncompliance, protects the interests of LSU and LSU developers, and minimizes the perception of possible conflicts of interest.

**Recommendation 2:** LSU should ensure that all proceeds received for licenses of intellectual property are placed under control of LSU rather than LSU-affiliated entities. Since the LSU-affiliated entities are separate legal entities, their assets are not owned by LSU and are not subject to LSU's system of internal control. Directing proceeds to an LSU-affiliated entity may limit control, transparency, and accountability.

**Summary of Management's Response:** Management concurs and is charging the President's Committee on Technology Transfer with reviewing LSU's current bylaws, regulations, policies, and processes regarding intellectual property and technology transfer and making recommendations for change or enhancement as appropriate (see Appendix A, pages 2-3).

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<sup>1</sup> Distributed royalty means "any consideration, whether in the form of money, corporate stock or other equity in a business organization, or any other thing of value, actually received by and in the control of the University pursuant to an authorized agreement granting any rights in any LSU Intellectual Property..."

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**While not prohibited by LSU policy, such policies do not clearly define the circumstances under which LSU can assist non-LSU entities in the commercialization of LSU technology. In addition, legal costs paid for the creation of and/or the benefit of corporations may have violated Article VII Section 14 of the Louisiana Constitution.**

On October 1, 2014, LSU entered into a \$45,000 consulting contract with Mr. Oscar Diaz,<sup>2</sup> President of HarmonIQ, as discussed later in this report. The consulting contract was for Mr. Diaz to assess the commercial potential of the CLIQ software and provide advice on the resource requirements and other considerations for making the technology commercially viable.

On October 6, 2014, Harmoniq Health Systems Corp. (Harmoniq), a for-profit corporation, was created by LSU. An attorney for Taylor Porter was the incorporator and registered agent. Its Articles of Incorporation show that its corporate purpose was to “develop, license, market and support certain software applications and related technology within the healthcare industry...” Harmoniq was created while LSU was in negotiations to commercialize the CLIQ software through a joint venture with Harris Corporation. Harmoniq was to be the vehicle for this joint venture using the CLIQ software provided by LSU and proprietary cloud technology provided by Harris Corporation. The proposed joint venture between LSU and Harris Corporation was never finalized because the parties could not reach an agreement. Harmoniq was dissolved on December 17, 2014.

On December 17, 2014, an entity with a similar name, HarmonIQ Health System Corporation (HarmonIQ), was incorporated with Mr. Diaz as Director and later President. The incorporator of HarmonIQ was an attorney that was recommended by Taylor Porter. LSU licensed CLIQ to LaHIT, which sublicensed it to HarmonIQ in February 2016. E-mail correspondence indicates that LSU management expected HarmonIQ to develop its own cloud technology to help commercialize the CLIQ software.

Mr. Diaz stated that HarmonIQ had no assets at its creation and obtained a line of credit from a bank in April 2016 after it signed the sublicense agreement with LaHIT. This line of credit was supported, in part, by the assignment of LSU’s Accountable Care Service (ACS) contracts with the public/private hospital partnerships to HarmonIQ in February 2016.

Dr. Opelka confirmed that HarmonIQ was to be funded by the public/private hospital partnerships through the ACS contracts LSU had in place with these partners. The value of the LSU ACS contracts at the time of their assignment to HarmonIQ was approximately \$8.8 million per year, and the payments to HarmonIQ were based on HarmonIQ’s contributions toward meeting the required terms of the contracts. LSU paid approximately \$954,000 to HarmonIQ

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<sup>2</sup> Mr. Diaz had previously worked for Harris Corporation and was experienced in healthcare information technology. Several years earlier, Mr. Diaz, as a founder, minority stock holder, and employee of Carefx, had negotiated with LSU to commercialize the CLIQ software, but an executed license agreement did not materialize. Carefx was acquired by Harris Corporation in 2011.

related to the assignment of the ACS contracts. In May 2016, HarmonIQ hired several LSU programmers who had previously worked on the development and support of the CLIQ software.

Records show that LSU paid Taylor Porter approximately \$410,000 for legal services related to the licensing of the CLIQ software. However, the exact portion of this amount associated with the formation of Harmoniq and/or for the benefit of HarmonIQ could not be determined due to lack of itemization of those costs.

LSU did not enter into an agreement with HarmonIQ, outlining the reciprocal obligations between the parties and benefits LSU would receive in return for the attorney fees expended by LSU to assist in the formation of HarmonIQ.

LSU Board Regulations do not prohibit LSU from assisting with commercialization efforts following a technology transfer. However, efforts to assist in the commercialization of LSU technology transferred to non-LSU entities can lead to increased risk of fraud, potential conflicts of interest, and the perception of impropriety. Furthermore, LSU may have violated the provisions of Article VII, Section 14 of the Louisiana Constitution of 1974 by using public funds to pay legal services in the creation of and/or for the benefit of private, for-profit corporations that do not act for the sole benefit of LSU, but for their shareholders. If any LSU employees' time was spent working on the creation of Harmoniq or HarmonIQ while on LSU payroll, those payroll costs may have also violated Article VII, Section 14 of the Louisiana Constitution of 1974.

**Recommendation 3:** LSU should develop policies that clearly define the circumstances under which LSU can assist in the commercialization of LSU technology subsequent to a technology transfer. These policies should require LSU management to justify in writing the necessity for its assistance in the commercialization efforts and include controls that provide reasonable assurance that any LSU funds or assets are used solely for the commercialization of the technology and no other purpose.

**Recommendation 4:** LSU should enter into written agreements, that clearly outline reciprocal obligations and benefits with parties, to ensure LSU does not violate Article VII, Section 14 of the Louisiana Constitution of 1974.

**Summary of Management's Response:** Management concurs and is charging the President's Committee on Technology Transfer with reviewing LSU's current bylaws, regulations, policies, and processes regarding intellectual property and technology transfer and making recommendations for change or enhancement as appropriate (see Appendix A, page 3).

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**LSU management did not adhere to its process for licensing intellectual property when licensing the CLIQ software. As a result, LSU’s control over aspects of the commercialization and the LSU President’s and Board’s ability to make appropriate decisions was weakened, resulting in conflicts of interest.**

The LSU Board Bylaws & Regulations<sup>3</sup> outline a uniform process governing transfers of LSU intellectual property. According to these regulations (1) all license agreements must be approved by the President, (2) the licensee is expected to be directly active in developing and commercializing the intellectual property, (3) the licensing process relies on standard templates and deviations from these templates must be justified, (4) actions related to the commercialization of LSU intellectual property shall be reported to the President and the LSU Board, and (5) all license agreements shall be accompanied by a certification and checklist from appropriate campus officials.

The licensing process outlined above was not adhered to by LSU management in the licensing of the CLIQ software in the following respects: (1) the licensee “brokered” the technology to a sublicensee that developed and commercialized the technology, (2) deviations from standard templates were made that were not justified, and (3) the appropriate campus officials did not certify the license agreement as required.

#### Brokerage of the Technology

The license agreement between LSU and LaHIT states that LaHIT’s responsibility is to identify a suitable sublicensee to commercialize the software. This agreement represents a departure from LSU’s standard process for licensing intellectual property since LSU does not ordinarily permit the “brokerage” of its intellectual property. Chapter VII, Section 7-5(e) of the LSU Board Regulations states that LSU expects the licensee to be “directly active in developing and commercializing licensed LSU Intellectual Property.” Exceptions to this policy must be supported with a written finding showing that exceptional circumstances make the brokerage of the intellectual property in the best interests of the university and authorized by the President or his designee.

According to Dr. Opelka, it was his understanding based on advice from attorneys that, part of the reason LSU licensed the software to an intermediary (LaHIT) was because licensing the software directly would have subjected the process to the state’s public bid law. Dr. Opelka explained that under a public bid, potential bidders might not have understood the true value of the software and LSU may have received less for the software than by licensing the software to an LSU-affiliated entity. However, the Public Bid Law does not apply to LSU. Instead, LSU is subject to the University Pilot Procurement Code (UPPC). The UPPC exempts technology transfers from the competitive solicitation process. *LAC tit. 34, pt. XIII, Sec. 525.*

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<sup>3</sup> The LSU Board Bylaws & Regulations were revised June 19, 2015. This version of the LSU Board Bylaws & Regulations was in effect at the time LSU licensed CLIQ in February 2016. This and subsequent references to the LSU Board Bylaws & Regulations are based on this June 19, 2015 version.

Nevertheless, since LSU could provide no written finding showing the necessity to license the software to an entity not involved in the development and commercialization of the software, LSU management may have violated LSU Board Regulations.

In addition, by allowing LaHIT to “broker” the software, LSU was not able to ensure that the 40% equity stake, as described previously on page 4 of the report and again below, was included in the sublicense agreement. The sublicense agreement between LaHIT and HarmonIQ, dated February 25, 2016, required HarmonIQ to pay a royalty of 5% of net sales to LaHIT as consideration for the LSU software. The license agreement between LaHIT and LSU required LaHIT to pay to LSU 90% of those royalties received from HarmonIQ. Although this license agreement was signed in February 2016, attempts to license the software goes back to at least 2011. Documentation from these prior licensing efforts<sup>4</sup> show terms considerably more favorable to LSU than the license agreement signed in February 2016.

For example, an unsigned term sheet between LaHIT and HarmonIQ, dated November 11, 2015, includes a 40% equity stake to LaHIT in addition to a 5% royalty. Although these term sheets and draft agreements were tentative, they show consideration significantly higher than the 5% royalty agreed to in the signed license and sublicense agreements of February 2016. In addition, as noted previously on page 4, by allowing LaHIT to broker LSU’s intellectual property, LSU was not in a position to identify that the 40% equity stake, which LSU management thought was included, was actually not included in the sublicense agreement.

#### Deviations from Standard Templates

LSU relies on standard templates to manage its licensing process for intellectual property. Chapter VII, Section 7-6(b)1 of the LSU Board Regulations requires that these standard templates must be used in all transactions related to the commercialization of intellectual property. Included in these templates is a standard licensing agreement. During our review of the license agreement between LSU and LaHIT, we noted that changes were made to the standard language. These changes included the addition of an option to purchase the software and the deferral of royalty payments owed to LSU for a period of two years. Chapter VII, Section 7-6(b)1 of the LSU Board Regulations requires a justification for significant deviations from the language in this standard template. LSU management was unable to provide us documentation of the justification for these deviations from the standard license template, which may violate LSU Board Regulations.

#### License Agreement Not Certified

Chapter VII, Section 7-6(b)3 of the LSU Board Regulations requires that “all license agreements shall be accompanied by a certification from appropriate campus officials and a checklist which provides a description of (a) potential conflicts of interest, (b) due diligence of the commercial potential of the intellectual property and (c) due diligence activities performed to evaluate the

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<sup>4</sup> LSU records, for example, show a signed term sheet between LSU and Carefx Corporation (Carefx), dated December 6, 2011, which provided for a royalty of 50% of all licensing revenues and fees to LSU in consideration for the software. A 2013 draft license agreement between LSU and Harris Corporation shows a 25% royalty to LSU on net sales up to \$750,000 and a 50% royalty to LSU on net sales exceeding \$750,000.

proposed licensee, and (d) a description of any significant deviations from standard templates and justification for such changes.” The certification is documented through a standard template.

The certification checklist in the LSU Board Bylaws also requires that “appropriate due diligence has been conducted on the valuation of the LSU Intellectual Property to be licensed...” The checklist requires LSU management to describe the methodology used to value the licensed technology. LSU was unable to provide us with the certification checklist or other documentation related to the valuation of the software and the basis on which the royalty amount was determined. As a result, we cannot definitively state whether the royalty amount LSU was to receive under the February 2016 license agreement was sufficient consideration for the software. However, the steep decline in the royalty amount and the removal of a proposed 40% equity stake to LSU shortly before execution of the sublicense agreement suggests that LSU’s software may have been undervalued. This may be further evidenced by the fact that LSU’s agreement with HarmonIQ, dated March 27, 2017, gives LSU a minimum 20% equity stake in addition to 5% royalties.

LSU management was unable to provide us with this certification and accompanying checklist, which may violate LSU Board Regulations. Also, without the certification and supporting checklist, the LSU President and Board may not have had all necessary information needed to properly evaluate the proposed license agreement.

**Recommendation 5:** LSU should ensure that agreements for licensing LSU intellectual property are made directly with the companies responsible for commercializing the intellectual property rather than intermediary companies. The use of intermediary companies involves brokering of the intellectual property, which could weaken LSU’s control over the commercialization, and is prohibited by LSU policy absent specified exceptions and President, or his designee, approval.

**Recommendation 6:** LSU should adhere to its licensing procedures for intellectual property including using standard templates and justifying significant deviations from these standard templates; requiring certifications are obtained; and ensuring appropriate documentation is maintained. Failure to adhere to these procedures weakens internal control, accountability, and transparency. It also weakens the LSU President and the LSU Board’s ability to make appropriate decisions for the University and could create an appearance of impropriety.

**Recommendation 7:** LSU should obtain formal estimates of the value of any intellectual property that it intends to license. These estimates should be properly documented and should be made available to the LSU President and the LSU Board as part of their review of proposed license agreements that represent “Significant Board Matters.”

**Summary of Management's Response:** Management concurs and is charging the President's Committee on Technology Transfer with reviewing LSU's current bylaws, regulations, policies, and processes regarding intellectual property and technology transfer and making recommendations for change or enhancement as appropriate (see Appendix A, pages 3-4).

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### **LSU management failed to bring three LSU agreements related to the licensing of the CLIQ software before the LSU Board for formal approval.**

During our review, we identified three LSU agreements related to the licensing of the CLIQ software, which required formal Board recognition or approval. Although LSU management presented information about the commercialization of CLIQ to the Board, as outlined in Appendix C, LSU management failed to bring these three agreements before the Board. These agreements include: (1) the affiliation agreement between LSU and LaHIT, (2) the license agreement between LSU and LaHIT, and (3) the assignment of ACS contracts to HarmonIQ.

#### Affiliate Agreement between LSU and LaHIT

LSU and LaHIT entered into an affiliation agreement on February 24, 2016. LSU affiliates are private entities that, although separate from LSU, are closely identified with the University and support its mission. Chapter VIII, Section 8-2 of LSU Board Regulations states that "All affiliated organizations, such as alumni associations, foundations, and other nonprofit groups, whose principal interest is to provide public support to enhance the programs, facilities, and research and educational opportunities offered by University campuses must be officially recognized by the Board." We reviewed LSU Board minutes and found no evidence that the affiliation agreement was ever presented to or recognized by the Board as required by LSU Board Regulations.

During our review, we also noted modifications to the standard affiliation agreement, such as removing the requirement that "The President of the University, or his designee, shall be a non-voting ex officio member of the Affiliate's Board and of the Executive Committee, and any other committee responsible for review and approval of Affiliate's budgets, of such Board." Removing this language weakens LSU's ability to be able to control its interest on the Board, and no justification was given for this change. Also, language giving the Affiliate's Board and Executive Committee "prompt access [to] all books and records of Affiliate..." was softened to "reasonable access to all books and records of Affiliate..." These changes reduced LSU's ability to provide appropriate oversight of LaHIT.

#### License Agreement between LSU and LaHIT

LSU and LaHIT entered into a license agreement on February 24, 2016. The license agreement was never formally approved by the Board. Article VII, Section 8D of the LSU Board Bylaws require formal Board approval for all "Significant Board Matters," which include any "matter having significant fiscal (primary or secondary) or long-term educational or policy impact on the

University or any of its campuses or divisions.” The CLIQ software was valued at potentially \$15 million based on a preliminary term sheet from September 2015, and a HarmonIQ business plan, dated September 14, 2015, estimated the value of LaHIT’s 40% of shares to be \$174 million after year four. Therefore, the licensing of this software clearly had a potentially significant fiscal impact on the University. As such, it was a significant Board matter and should have been presented to the Board for formal approval in accordance with the LSU Board Bylaws.

#### Assignment of ACS Contracts to HarmonIQ

LSU entered into ACS contracts with operators of five of the public-private partnership hospitals in 2014 and 2015 following the privatization of the LSU hospitals. The contracts were designed to “make the healthcare organization’s data ...more accessible, usable and actionable for process and quality improvement.” LSU charged the operators approximately \$8.8 million for ACS services in fiscal year 2015/2016. On February 24, 2016, LSU assigned these ACS contracts to HarmonIQ in three assignment agreements and eventually made payments to HarmonIQ totaling approximately \$954,000 related to the agreements. All five operators that entered into these ACS agreements sent notices of termination between July and September 2016.

Due to the value of these contracts and their significance to LSU operations, the transfer of these contracts to HarmonIQ was clearly a “Significant Board Matter” and should have been brought before the Board and formally approved in accordance with the LSU Board Bylaws. We reviewed LSU Board minutes and determined that the assignment of these ACS contracts was not brought before and formally approved by the Board.

**Recommendation 8:** LSU management should ensure that all significant actions taken regarding the licensing of LSU intellectual property and the approval of affiliated organizations are brought to the attention of the LSU Board for its review and recognition or approval as required by the LSU Board Bylaws & Regulations. These actions represent an important part of the Board’s oversight responsibilities.

**Summary of Management’s Response:** Management concurs and will send communication to leadership of all research campuses reinforcing the need to be compliant with current requirements regarding intellectual property and approval of affiliated organizations included in the LSU bylaws and regulations. Management will also request LSU Office of Internal Audit include a review of compliance with these bylaws and regulations as part of its annual work plan (see Appendix A, page 4).

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**Arrangements adopted by LSU to license the CLIQ software created potential conflicts of interest involving an LSU official and employees.**

During our review, we noted potential conflicts of interest as described below.

Dr. Wayne Wilbright

Dr. Wayne Wilbright was appointed Chief Executive Officer (CEO) of the LSU HCSD in August 2014. He previously worked as the HCSD Chief Medical Information Officer (CMIO) but left LSU in 2012. He returned to LSU upon his appointment as HCSD CEO. In his position as HCSD CEO, he oversaw the team of LSU programmers at HCSD that developed the CLIQ software and supported its use in the LSU hospitals.

Dr. Wilbright stated that he is unsure if he is owed royalties because he was not one of the programmers who actually created the software. However, LSU records show that Dr. Wilbright is on the list of LSU employees owed royalties from the commercialization of the CLIQ software, and he signed as an inventor of CLIQ on the LSU Technology Disclosure Form in July 2009.

In January 2015, LSU HCSD entered into a membership contract with the Healthcare Services Platform Consortium (HSPC). HSPC's CEO was Mr. Diaz. The contract was signed by Dr. Wilbright in his capacity as CEO of LSU HCSD. Under this contract, LSU HCSD paid \$240,000 in "benefactor" and other dues to the HSPC covering two years of membership. The benefactor members are given more rights than other classes of members. According to the contract, HSPC's mission is to improve clinical and financial efficiency through industry-wide collaboration in the development of information technology applications. According to Dr. Wilbright, the HSPC was created to ensure standardization of electronic health care data. Records show that LSU management viewed the HSPC's efforts as supportive of CLIQ's commercialization. Dr. Wilbright may have violated the Louisiana Code of Governmental Ethics by signing a contract as CEO of LSU HCSD with the HSPC since that contract contributed to LSU's efforts to commercialize the CLIQ software and Dr. Wilbright was entitled to royalties based on the success of that commercialization effort.<sup>5</sup>

On December 1, 2016, LSU's HCSD entered into a contract with HarmonIQ under which HarmonIQ expanded HCSD's clinical data warehouse and analytical reporting capabilities so it could better support its LSUHSC-NO providers. Dr. Wilbright signed the contract with HarmonIQ in his capacity as CEO of the LSU HCSD. HCSD made payments to HarmonIQ totaling \$282,668. Dr. Wilbright may have violated the Louisiana Code of Governmental Ethics by signing a contract with HarmonIQ while it was attempting to commercialize the CLIQ software, since he was entitled to royalties based on the success of that commercialization effort.

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<sup>5</sup> Louisiana Revised Statute 42:1112(A) states, "No public servant, except as provided in R.S. 42:1120, shall participate in a transaction in which he has a personal substantial economic interest of which he may be reasonably expected to know involving the governmental entity."

However, the applicability of the Ethics Code to specific factual circumstances is within the exclusive jurisdiction of the Ethics Board.

### LSU Programmers

According to Mr. Diaz, in May 2016 HarmonIQ hired five of the LSU programmers who developed the CLIQ software. One of the programmers we interviewed stated that he and the other programmers worked on research/development and commercialization efforts at HarmonIQ and not the technical support work they performed at LSU. He added that he and the other programmers also performed no CLIQ-related work for LSU after they left LSU employment.

The LSU programmers that were hired by HarmonIQ were involved in the development and technical support of the CLIQ software during their employment at LSU and appear to have helped in the further development of the CLIQ software while employed at HarmonIQ. To the degree the actions of the programmers were compensated by their new employer, HarmonIQ, they may constitute a violation of the Louisiana Code of Governmental Ethics. However, the applicability of the Ethics Code to specific factual circumstances is within the exclusive jurisdiction of the Ethics Board.<sup>6</sup>

**Recommendation 9:** LSU management should ensure that transactions/situations are reviewed prior to completion for possible conflicts of interests so that potential conflicts can be identified and prevented. Ethics opinions should be requested in advance of entering into questionable situations to avoid conflicts of interest.

**Recommendation 10:** LSU management should consider appropriate corrective action, such as notifying the Board of Ethics, if they are aware or become aware that any public employees involved in the commercialization of CLIQ received anything of value that would not have been allowed by law or policy.

**Summary of Management's Response:** Management concurs and will be directing the Office of General Counsel to review the specific actions by LSU employees noted in this report and to inform State Board of Ethics and other appropriate authorities as necessary if warranted by the review (see Appendix A, pages 4-5).

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<sup>6</sup> **Louisiana Revised Statute 42:1121(B)1** states, "No former public employee shall, for a period of two years following the termination of his public employment, assist another person, for compensation, in a transaction or in an appearance in connection with a transaction **in which the former public employee participated at any time during his public employment** and which involves his former public employer..."

## **APPENDIX A: MANAGEMENT'S RESPONSE**





April 24, 2019

Mr. Daryl G. Purpera  
Legislative Auditor  
Louisiana Legislative Auditor  
1600 North Third Street  
P.O. Box 94397  
Baton Rouge, 70804-9397

Dear Mr. Purpera,

The purpose of this letter is to provide the University's response to the Louisiana Legislative Auditor's (LLA) Review of Louisiana State University System's Affiliate Relationship with the Louisiana Health Information Technology Foundation ("Report"). As noted in the Report, I requested this review in April 2018 as the result of potentially concerning information provided to me by the LSU Office of Internal Audit regarding the operations of the Louisiana Health Information Technology Foundation ("LaHIT"). Given that various aspects of LaHIT and its relationship to LSU went beyond the legal authority of LSU Internal Audit to pursue, the LSU Board of Supervisors ("Board") and I believed that a thorough review and examination of LaHIT by LLA was the most appropriate path forward to resolving the related issues. After reviewing the final report, it is clear that the findings of this review will be beneficial in enhancing LSU's policies and practices regarding technology transfer and intellectual property commercialization and strengthening transparency and control over these important activities.

It is unfortunate that the actions of one individual (LSU's former Executive Vice President for Health Care and Medical Education Redesign) operating at various times outside of the boundaries of his position led to a situation where LSU was placed at potential risk for conflicts of interest and other potential liabilities. However, we have since adjusted our administrative and governance structures in a manner that will prevent this from occurring again. I would like to highlight three specific actions LSU has taken to strengthen management control and oversight:

- ***Established a new Board of Supervisors committee with the specific charge of affiliated organization oversight.*** The University has had a Uniform Affiliation Agreement ("UAA") which sets the terms and expectations for its relationship with affiliated organizations and which requires Board approval for several years and which was last updated in 2009. However, there has been no formal, standing process for ongoing Board review and oversight of LSU's affiliated organizations. To remedy this deficiency, the Board created a new Affiliated Organizations Oversight Committee ("Committee") which was memorialized in the Board's Bylaws in October 2018. The charge of the Committee is oversight of matters relating to the University's relationship with affiliated organizations including agreements (e.g., UAA), leases, financial issues, and any other matters relevant to the relationship of the University to the organizations. Additionally, the University is currently revising the UAA to further strengthen and clarify its oversight of affiliated organizations and responsibilities of both the University and affiliated

organizations in that regard. It is anticipated that these revisions will be brought forward to the Board for consideration and approval in May 2019. Once approved, all current and future LSU-affiliated organizations will be required to execute this new UAA.

- ***Moved the LSU Health Care Services Division (“HCSD”) under the direct purview of the Chancellor of the LSU Health Science Center – New Orleans.*** Prior to July 2016, HCSD was (organizationally) a separate entity within the LSU System reporting to LSU’s Executive Vice President for Health Care and Medical Education Redesign (“Executive Vice President”). At the time, this organizational structure was appropriate given HCSD’s responsibility for managing the state’s public hospital system, though the advent of the public-private hospital partnerships in 2013 substantially reduced HCSD’s role in this regard. As highlighted throughout the Report, this organizational structure also fostered a number of vulnerabilities regarding overall management control and oversight by the LSU President and Board. With the separation of the prior Executive Vice President from LSU in June 2016, I placed HCSD under the direct management of the Chancellor of the LSU Health Science Center – New Orleans to consolidate health care operations and ensure proper oversight and management control.
- ***Created a comprehensive Office of General Counsel that reports directly to the President of LSU.*** Prior to 2015, LSU’s internal legal matters were overseen by a General Counsel and one staff lawyer, a structure that was inadequate for a public university of LSU’s scope and size. As a result, the more complicated and specialized legal matters at LSU such as the LaHIT venture were regularly assigned to outside counsel as a matter of necessity and standard operating practice. In turn, outside counsel often viewed the offices and individuals at LSU for whom they regularly performed legal work as their “client” rather than the University’s General Counsel, which presented significant risks to the University regarding institutional oversight and control over legal matters. To correct this situation, the University has made a conscious investment in strengthening its internal legal capacity since 2015, enhancing the capacity of the Office of General Counsel (“OGC”) in terms of personnel and specialized expertise in order to reduce its reliance on outside counsel. While it is still necessary at times to outsource legal services for certain specialized matters, the OGC has also implemented much more stringent controls over this process to ensure stronger oversight over outside counsel.

I believe that these actions have collectively strengthened management control and oversight with regard to both affiliated organizations and initiatives such as LaHIT, and, along with the actions LSU will take regarding the specific recommendations presented in the Report, will mitigate against the possibility of these problems in the future.

Our responses to the 10 recommendations presented in the Report are addressed below in the order and grouping in which they were presented in the Report.

**Recommendation 1:** LSU should ensure that all technology transfers are managed by the appropriate OTM office to ensure a uniform process and adherence to established policies and procedures. A uniform process reduces the risk of noncompliance, protects the interests of LSU and LSU developers, and minimizes the perception of possible conflicts of interest.

**Recommendation 2:** LSU should ensure that all proceeds received for licenses of intellectual property are placed under control of LSU rather than LSU-affiliated entities. Since the LSU-affiliated entities are separate legal entities, their assets are not owned by LSU and are not subject to LSU's system of internal control. Directing proceeds to an LSU-affiliated entity may limit control, transparency, and accountability.

**Management's Response:** Management concurs and is charging the President's Committee on Technology Transfer ("PCTT") with reviewing LSU's current bylaws, regulations, policies, and processes regarding intellectual property and technology transfer with respect to these two recommendations and making recommendations for change or enhancement as appropriate.<sup>1</sup> It is anticipated that the PCTT will engage the OGC in assisting with this review.

**Anticipated Completion Date:** December 31, 2019.

**Recommendation 3:** LSU should develop policies that clearly define the circumstances under which LSU can assist in the commercialization of LSU technology subsequent to a technology transfer. These policies should require LSU management to justify in writing the necessity for its assistance in the commercialization efforts and include controls that provide reasonable assurance that any LSU funds or assets are used solely for the commercialization of the technology and no other purpose.

**Recommendation 4:** LSU should enter into written agreements, that clearly outline reciprocal obligations and benefits with parties, to ensure LSU does not violate Article VII, Section 14 of the Louisiana Constitution of 1994.

**Management's Response:** Management concurs and is charging the PCTT with reviewing LSU's current bylaws, regulations, policies, and processes regarding intellectual property and technology transfer with respect to these two recommendations and making recommendations for change or enhancement as appropriate. It is anticipated that the PCTT will engage the OGC in assisting with this review.

**Anticipated Completion Date:** December 31, 2019.

**Recommendation 5:** LSU should ensure that agreements for licensing LSU intellectual property are made directly with the companies responsible for commercializing the intellectual property rather than intermediary companies. The use of intermediary companies involves brokering of the intellectual property, which could weaken LSU's control over the commercialization, and is prohibited by LSU policy absent specified exceptions and President, or his designee, approval.

**Recommendation 6:** LSU should adhere to its licensing procedures for intellectual property including using standard templates and justifying significant deviations from these standard templates; requiring

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<sup>1</sup> The PCTT was created in 2013 for the purpose of providing guidance to the President and Board on matters regarding intellectual property and technology transfer across LSU's six research campuses (LSU A&M, LSU Ag Center, LSU Health Sciences Center – New Orleans, LSU Health Sciences Center – Shreveport, Pennington Biomedical Research Center, and LSU Shreveport). The PCTT includes representatives from each of these campuses.

Mr. Daryl Purpera

April 24, 2019

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certifications are obtained; and ensuring appropriate documentation is maintained. Failure to adhere to these procedures weakens internal control, accountability, and transparency. It also weakens the LSU President and the LSU Board's ability to make appropriate decisions for the University and could create an appearance of impropriety.

**Recommendation 7:** LSU should obtain formal estimates of the value of any intellectual property that it intends to license. These estimates should be properly documented and should be made available to the LSU President and the LSU Board as part of their review of proposed license agreements that represent "Significant Board Matters."

**Management's Response:** Management concurs and is charging the PCTT with reviewing LSU's current bylaws, regulations, policies, and processes regarding intellectual property and technology transfer with respect to these three recommendations and making recommendations for change or enhancement as appropriate. It is anticipated that the PCTT will engage the OGC in assisting with this review.

**Anticipated Completion Date:** December 31, 2019.

**Recommendation 8:** LSU management should ensure that all significant actions taken regarding the licensing of LSU intellectual property and the approval of affiliated organizations are brought to the attention of the LSU Board for its review and recognition or approval as required by the LSU Board Bylaws & Regulations. These actions represent an important part of the Board's oversight responsibilities.

**Management's Response:** Management concurs and: (1) will be sending a communication to the leadership of all LSU research campuses reinforcing the need to be compliant with the current requirements regarding intellectual property and approval of affiliated organizations included in the LSU bylaws and regulations; and (2) will request that the LSU Office of Internal Audit include a review of research campus compliance with these bylaws and regulations as part of their annual work plan beginning with FY 2020.

**Anticipated Completion Date:** Action #1 above will be completed by May 15, 2019. Action #2 above will be completed annually beginning in FY 2020.

**Recommendation 9:** LSU management should ensure that transactions/situations are reviewed prior to completion for possible conflicts of interests so that potential conflicts can be identified and prevented. Ethics opinions should be requested in advance of entering into questionable situations to avoid conflicts of interest.

**Recommendation 10:** LSU management should consider appropriate corrective action, such as notifying the Board of Ethics, if they are aware or become aware that any employees involved in the commercialization of CLIQ received anything of value that would not have been allowed by law or policy.

Mr. Daryl Purpera

April 24, 2019

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**Management's Response:** Management concurs and will be directing the OGC to review the specific actions by LSU employees noted in the Report and to inform the State Board of Ethics and other appropriate authorities as necessary if warranted by this review.

**Anticipated Completion Date:** June 1, 2019.

Thank you again for your thorough review of this matter and your helpful recommendations.

Sincerely,

A handwritten signature in blue ink that reads "F. King Alexander". The signature is written in a cursive style.

F. King Alexander  
LSU President

Cc: Mr. James Williams, Chairman, LSU Board of Supervisors  
Ms. Mary Werner, Chair-Elect, LSU Board of Supervisors  
Mr. Stephen Perry, Past Chair, LSU Board of Supervisors  
Mr. Lee Mallett, Chairman, LSU Board of Supervisors Audit Committee  
Dr. Dan Layzell, LSU Executive Vice President for Finance & Administration/CFO  
Mr. Tom Skinner, LSU Vice President for Legal Affairs and General Counsel  
Mr. Chad Brackin, LSU Chief Auditor  
Mr. Jim Buras, LSU Assistant Vice President for Finance and Administration and PCTT Chair



## APPENDIX B: OTHER RESPONSE



April 15, 2019

Daryl G. Purpera, CPA, CFE, Legislative Auditor  
P.O. Box 94397  
Baton Rouge, LA 70804-9397

Dear Mr. Purpera,

I have received and reviewed the confidential draft report – “Review of Louisiana State University System’s Affiliate Relationship with Louisiana Health Information Technology Foundation.” Please consider this letter my response.

I agree with the recommendation that LSU should ensure that transactions/situations are reviewed for possible conflicts of interest prior to completion. LSU policies and procedures related to technology transfer should be improved to assist management in clarifying and identifying situations where possible conflicts of interest might exist regarding potential royalties and/or commercialization of LSU intellectual property. Ethics opinions regarding potential conflicts of interest should be requested in advance of finalizing technology transfer agreements or contracts.

The strengthening and assurance of adherence to policies and procedures related to technology transfer will serve to inform and protect current and future staff as well as the institution.

I appreciate the opportunity to review and respond to the draft report.

Sincerely,



Wayne A. Wilbright, MD, MS  
Chief Executive Officer  
LSU Health Care Services Division



## APPENDIX C: TIMELINE OF EVENTS RELATED TO LICENSING OF CLIQ SOFTWARE

July 13, 2009 – Completion of LSU’s Technology Disclosure Form for the CLIQ software. This is the first step in LSU’s process for commercializing intellectual property.

December 6, 2011 – Signed term sheet between LSU and Carefx, a once privately-held corporation founded in part by Oscar Diaz and acquired by Harris Corporation in 2011, under which LSU granted Carefx the exclusive rights to market and distribute the CLIQ software in return for 50% of all licensing revenue and fees. These terms never materialized to an executed license agreement.

2013 (unspecified date) – License agreement between LSU and Harris Corporation for licensure of the CLIQ software is drafted by the Office of Technology Management at the LSU Health Science Center in New Orleans. Draft agreement was never finalized or signed. Under terms of this draft agreement, LSU licenses the CLIQ software to Harris for royalties of 25% of net sales up to \$750,000 and royalties of 50% of net sales after \$750,000.

June 24, 2014 – LSU enters into an Accountable Care Service (ACS) contract with the University Medical Center Management Corporation in New Orleans, the partner operating the state hospital in New Orleans.

September 12, 2014 – Dr. Opelka gives presentation to the LSU Board of Supervisors’ Health Committee that discusses formation of a joint venture between LSU and Harris Corporation called Harmoniq supported through an LSU Foundation named LaHIT. No official recognition of LaHIT from the LSU Board of Supervisors was requested or given.

September 30, 2014 – LaHIT incorporated as a Louisiana, non-profit corporation.

October 1, 2014 – LSU HCSD and nGENEX7, entered into a \$45,000 contract (signed by Oscar Diaz in his capacity as Vice President/General Manager) under which nGENEX7 was to provide an assessment of the legal considerations and resource requirements for developing LSU Medical Informatics assets (i.e., CLIQ) into a commercially scalable and marketable platform.

October 6, 2014 – Harmoniq incorporated as a Louisiana, for-profit corporation.

December 17, 2014 – Dissolution of Harmoniq.

December 17, 2014 – Incorporation of HarmonIQ.

February 27, 2015 – LSU pays Healthcare Services Platform Consortium (HSPC) \$220,000 for “benefactor” dues.

May 8, 2015 – Dr. Opelka gives presentation to LSU Board of Supervisors on the transfer of LSU’s CLIQ technology to LaHIT and then to HarmonIQ, which indicates that LaHIT will hold a 31% equity stake in HarmonIQ.

June 2015 – LSU Board of Supervisors Board Meeting Agenda includes request from LSU HCSD for approval to sell its technology asset to LaHIT and for review of the LaHIT and HarmonIQ term sheet. The agenda is subsequently revised and this request is removed from the agenda.

July 1, 2015 – LSU enters into ACS contracts with Our Lady of the Lake Hospital, Inc., the partner operating the state clinics in Baton Rouge; Our Lady of Angels Hospital, Inc., the partner operating the state hospital in Bogalusa; and the Chabert Operational Management Co. LLC., Southern Regional Medical Corporation, and the Hospital Service District #1 of the Parish of Terrebonne, the partners operating the state hospital in Houma.

December 7, 2015 – LSU enters into an ACS contract with University Hospital & Clinics, Inc. in Lafayette.

February 24, 2016 – Affiliate Agreement signed between LSU and LaHIT.

February 24, 2016 – Licensure agreement signed between LSU and LaHIT for the CLIQ software. Per the agreement, LSU grants LaHIT the exclusive rights to license the software to a suitable sublicensee in return for 90% of the royalties received from the sublicensee.

February 24, 2016 – ACS contracts between LSU and the hospital partnerships assigned to HarmonIQ through three separate agreements. Per the agreements, LSU continues to receive payment from the hospital partnerships and, in turn, pays HarmonIQ based on its contribution to the support of these contracts.

February 25, 2016 – Sublicense agreement signed between LaHIT and HarmonIQ. Per the agreement, LaHIT grants HarmonIQ the exclusive rights to further develop, market, and distribute commercially the software in return for a royalty of 5% of net sales.

March 30, 2016 – LSU pays HSPC \$20,000 for yearly membership fees.

April 2016 – HarmonIQ obtains line of credit supported, in part, by ACS agreements.

June – September 2016 – ACS agreements between LSU and hospital partnerships expire or are cancelled by the hospital partnerships.

December 1, 2016 – LSU HCSD enters into contract with HarmonIQ to expand HCSD’s clinical data warehouse and analytical reporting capabilities to better support LSUHSC-NO healthcare providers.

March 22, 2017 – LSU terminates its license agreement with LaHIT. The termination is for cause and is based on the failure to meet certain milestones specified in the license agreement.

March 27, 2017 – LSU enters into a new license agreement directly with HarmonIQ. Under the terms of the new license agreement, LSU receives a royalty of 5% of net sales as well as a minimum 20% equity position in HarmonIQ in return for use of the CLIQ software.

October 1, 2018 – A letter from LSU Health Sciences Center – New Orleans dated October 1, 2018, was sent to Oscar Diaz, HarmonIQ, explaining that failure to pay \$164,000 within 90 days for IT infrastructure debt would automatically terminate the Exclusive License Agreement.

January 10, 2019 – A letter from LSU Health Sciences Center – New Orleans dated January 10, 2019, was sent to Oscar Diaz, HarmonIQ, explaining that the Exclusive License Agreement was terminated on December 31, 2018.