

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

March 28, 2024
Date of Report (date of earliest event reported)

QT Imaging Holdings, Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-40389
(Commission
File Number)

86-1728920
(I.R.S. Employer
Identification Number)

3 Hamilton Landing, Suite 160
Novato, CA 94949
(Address of principal executive offices)

(650) 276-7040
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	QTI	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Definitive Material Agreement

Feasibility Study Agreement

On March 28, 2024, QT Imaging Holdings, Inc., a Delaware corporation (the “Company”), entered into a Feasibility Study Agreement (the “Feasibility Study Agreement”) with Canon Medical Systems Corporation, a company organized and existing under the laws of Japan (“Canon”). The term of the Feasibility Study Agreement commenced on March 28, 2024 and shall remain in force until the end of December 2024 or until the execution of a definitive agreement that clearly supersedes the Feasibility Study Agreement, whichever comes earlier. In connection with the Feasibility Study Agreement, Canon will initiate studies to evaluate the business, technical, and clinical values of the Company’s ultrasound breast scanner (the “QT Scanner”) including product quality validation, development and manufacturing studies, clinical evaluation, regulatory investigation, and market validation. Canon has no right to reverse engineer the QT Scanner and may only modify and disassemble the QT Scanner as necessary to conduct the feasibility study.

Under the terms of the Feasibility Study Agreement, the Company shall provide support for the feasibility study as agreed with Canon from time to time during the term of the Feasibility Study Agreement and shall use its commercially reasonable efforts to facilitate the feasibility study. Both parties confirm that the support provided by the Company will not result in significant costs to the Company, as it will only provide technical materials and knowledge that it already possesses and will not involve the creation of new materials or engineering. Each party will be responsible for covering its own expenses related to the feasibility study and the support, except if the parties agree in writing otherwise, one party shall pay to the other party an amount reasonable under the circumstances.

All know-how and intellectual property embodied in QT Scanner are owned by the Company and all rights not expressly granted by the Company are reserved.

During the term of the Feasibility Study Agreement, the Company shall give Canon first priority in any negotiations for collaborations, including joint development, contract manufacturing, and marketing, with respect to ultrasound breast scanners. The Company will notify Canon of its intent to enter into negotiations for any such similar collaboration but is under no obligation to identify the other party to such anticipated negotiations nor any of the financial terms of such collaboration; the Company’s only obligation is to notify Canon in writing that it intends to enter into negotiations for a collaboration similar to the feasibility study contemplated under the Feasibility Study Agreement and in such notice, include a general description of the subject matter of the collaboration. Canon may notify the Company in writing that it desires to enter into negotiations with the Company for the same collaboration. If Canon fails to give the Company such written notice within twenty-one calendar days after the Company’s written notice to Canon, the Company will have no further first priority obligations. If Canon gives the Company timely notice of its desire to enter into negotiations with the Company, the Company will prioritize the negotiations with Canon for such collaboration; provided, however, that nothing will be construed as an obligation on the Company to negotiate exclusively with Canon for such collaboration. The Company will have sole discretion to determine whether or not to enter into the collaboration with Canon or with another third party. Canon’s rights will extend to negotiations for each collaboration that the Company proposes to commence so long as the Company reasonably determines that such proposed collaboration has similar objectives to the feasibility study.

Either party may terminate the Feasibility Study Agreement in the event that: (a) proceedings are instituted by the other party in bankruptcy, reorganization, receivership, or dissolution; or (b) proceedings are instituted against the other party in bankruptcy, reorganization, or receivership, or dissolution and such proceedings have not been dismissed or otherwise terminated within sixty days following the date they were initiated; (c) if the other party makes an assignment for the benefit of creditors; or (d) a breach of the non-disclosure agreement between the parties with respect to any confidential information exchanged in connection with this Feasibility Study Agreement.

The foregoing description is qualified in its entirety by reference to the Feasibility Study Agreement, a copy of which is attached hereto as Exhibit 10.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit	Description
10.1	Feasibility Study Agreement, dated as of March 28, 2024, by and between QT Imaging Holdings, Inc. and Canon Medical Systems Corporation.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: April 1, 2024

QT Imaging Holdings, Inc.

By: /s/ Dr. Raluca Dinu
Name: Dr. Raluca Dinu
Title: Chief Executive Officer

Feasibility Study Agreement

THIS Feasibility Study Agreement (“**Agreement**”) is made by and between Canon Medical Systems Corporation, a company organized and existing under the laws of Japan with its registered office at 1385 Shimoishigami Otawara-shi, Tochigi 324-0036, Japan (hereinafter “**Canon**”) and QT Imaging Holdings, Inc., a company organized and existing under the laws of Delaware with its registered office at 3 Hamilton Landing Suite 160, Novato, CA 94949 (hereinafter “**QTI**”).

The above-mentioned parties are, where applicable, also hereinafter jointly referred to as “**Parties**” or individually as a “**Party**.”

THIS AGREEMENT is effective on the date of the last signature (“**Effective Date**”).

RECITALS

WHEREAS, the Parties have entered into the Mutual Nondisclosure Agreement on January 16, 2023 (the “**Original NDA**”) to discuss a potential business and/or technical relationship;

WHEREAS, the Parties held a meeting on December 1, 2023, and the meeting minutes were prepared to clarify matters agreed upon and matters for further discussion;

WHEREAS, the Original NDA was superseded and replaced by that certain Amended and Restated QT Imaging, Inc. Mutual Nondisclosure Agreement on February 12, 2024 (hereinafter “**NDA**”)

WHEREAS, as agreed on the meeting minutes, Canon has placed purchase orders for two (2) quantities of QTI’s product: ultrasound breast scanner (hereinafter “**QT Scanner**”); and

WHEREAS, Canon desires to conduct a Feasibility Study (as defined below) to evaluate the possibility to proceed on further collaboration with QTI, and QTI is willing to provide information, documents, and support for the purpose of Feasibility Study.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE 1. DEFINITIONS

The terms, as defined herein, shall have the same meanings in both their singular and plural forms.

- 1.1 “**Affiliate**” means any entity that directly or indirectly , owns or controls a Party, or is owned or controlled by a Party, or is under common control with a Party and “control” means the direct or indirect ownership of majority of the stock entitled to vote in an election of directors (or of persons performing similar functions), or the direct or indirect ownership of the maximum percentage of such stock permitted under local laws or regulations in those countries where 50% ownership by a foreign entity is not permitted.
- 1.2 “**Feasibility Study**” means the project described in paragraph 2.1.
- 1.3 “**Intellectual Property Rights**” means patents, trademarks, registered or unregistered designs, copyrights, database rights and any other intellectual property rights recognized from time to time in any jurisdiction, including any applications for such rights.

- 1.4 “**Know-How**” means specific, detailed and identifiable technical or similar information (including but not limited to information relating to inventions, discoveries, concepts, methodologies, models, research, development and testing procedures, the results of experiments, tests and trials, manufacturing processes, techniques and specifications, quality control data, analyses and reports) which is not in the public domain and which may have commercial or scientific value for the owner or holder of such information.
- 1.5 “**Sites**” mean third party entities used for external evaluation of the performance of QT Scanner.
- 1.6 “**Site Agreements**” mean the agreements entered into between Canon and the Sites described in paragraph 2.3.
- 1.7 “**Support**” means the works supporting the Feasibility Study as described in paragraph 2.2.

ARTICLE 2. FEASIBILITY STUDY

2.1 Scope of the Feasibility Study

Canon will initiate studies to evaluate business, technical, and clinical values of QT Scanner including product quality validation, development and manufacturing studies, clinical evaluation, regulatory investigation, and market validation. For the avoidance of doubt, Canon has no right to reverse engineer QT Scanner and may only modify and disassemble the QT Scanner as necessary to conduct the Feasibility Study.

Canon’s use of QT Scanner and Support is at Canon’s own risk and QTI makes no express, implied or statutory warranties regarding QT Scanner and Support, and hereby disclaims the implied warranties of merchantability, fitness for a particular purpose and non-infringement with respect to QT Scanner and Support.

QTI has no liability for any indirect, consequential, incidental, special and exemplary damages or lost profits, loss of use, loss of data or loss of business arising out of or related to this Agreement, regardless of the legal theory on which any such damages or losses may be based and even if QTI has been advised of the possibility of such damages or losses. Except for (i) personal injury or death, and/or property damage arising out of QT Scanner, and (ii) the General Terms and Condition as attached in the Quotation for Products and Services issued by QTI to Canon for two (2) quantities of QT Scanner, QTI’s aggregate liability arising out of or related to the Feasibility Study conducted under this Agreement is limited to \$[1000.00].

2.2 Support

QTI will provide support for the Feasibility Study as agreed with Canon from time to time during the term of this Agreement and shall use its commercially reasonable efforts to facilitate the Feasibility Study. Both Parties confirm that the Support provided by QTI will not result in significant costs to QTI, as it will only provide technical materials and knowledge that QTI already possesses and will not involve the creation of new materials or engineering. The Support may include but not limited to the following:

1. Quality validation
 - a. 3D CAD, Assembling drawings
 - b. Nationally Recognized Testing Laboratories (NRTL) report and/or other, IEC, EMC, etc., reports
 - c. System specification, duration design and examination report of durability
2. Procurement, Manufacturing, Cost
 - a. Transducer Technical Information (Acoustic Performance, etc.)
 - b. Parts List, Vender Information, Price, Lead Time
 - c. Manufacturing Tools

- d. Inspection instructions and reports
- e. Printed Circuit Board Information
3. Regulatory approval (FDA, J-FDA, MDR)
 - a. 510K submission document
 - b. IEC62304, ISO 14971
4. Support for clinical evaluation at Site (Keio University)
 - a. Q&A support
5. Parts, maintenance, and training
 - a. QTI will provide initial training (Maintenance, Calibration, etc..) to Canon at a location, date, time, and cost as mutually agreed
 - b. QTI will prepare and have service parts in stock[, which will be available for Canon to purchase in accordance with QTI's then current standard terms and conditions of sale and at QTI's then current list price]
 - c. Service Documentation

Each Party shall be responsible for covering their own expenses related to the Feasibility Study and the Support, except that if the Parties agree in writing otherwise, one Party shall pay to the other Party an amount reasonable under the circumstances.

2.3 Site Agreements

Canon is entitled to designate evaluation Sites in Japan and enter into the agreement with the Sites that are as protective of QTI's Know-How and Intellectual Property Rights in and to QT Scanner as the terms that Canon would use with respect to its own Know-How and Intellectual Property Rights and otherwise in form and substance reasonably acceptable to QTI.

ARTICLE 3. OWNERSHIP

3.1 Ownership

All Know-How and Intellectual Property embodied in QT Scanner are owned by QTI and all rights not expressly granted by QTI are reserved.

ARTICLE 4. EXPORT CONTROL

QTI shall comply with all applicable US, Japanese and foreign laws with respect to its transfer of related technical data to foreign countries, including, without limitation, the International Traffic in Arms Regulations, and the Export Administration Regulations.

ARTICLE 5. TERM AND TERMINATION

5.1 Term

The term of this Agreement shall commence upon the Effective Date and shall remain in force (a) until the end of December 2024 or (b) until the execution of a definitive agreement that clearly supersedes this Agreement, whichever comes earlier. The term shall only be extended through mutual written agreement of both Parties.

5.2 Termination

Either Party may terminate this Agreement, effective immediately upon notice, in the event that: (a) proceedings are instituted by the other Party in bankruptcy, reorganization, receivership, or dissolution; or (b) proceedings are instituted against the other Party in bankruptcy, reorganization, or receivership, or dissolution and such proceedings have not been dismissed or otherwise terminated within sixty (60) days following the date they were initiated; (c) if the other Party makes an assignment for the benefit of creditors; or (d) a breach of the NDA with respect to any Confidential Information exchanged in connection with this Agreement.

5.3 Survival on Termination.

Notwithstanding termination for any reason, such articles and paragraphs which by their nature are intended to survive termination shall continue in force.

ARTICLE 6. USE OF NAMES AND TRADEMARKS

Nothing contained in this Agreement confers any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of either Party (including contraction, abbreviation or simulation of any of the foregoing), without the prior written approval of such Party.

ARTICLE 7. MISCELLANEOUS PROVISIONS

7.1 Confidentiality.

- (a) All Information exchanged during the Feasibility Study shall be governed by the NDA. For purposes of this Agreement and for clarity, the Feasibility Study and the existence of this Agreement shall be deemed as part of the Business Relationship as defined in the NDA. Notwithstanding anything in the NDA to the contrary, QTI may disclose this Agreement and file as a material agreement for purposes of any filing or reporting requirement required by the rules or regulations of the Securities and Exchange Commission, provided however, QTI shall promptly notify Canon.
- (b) Canon will prepare the designated folder in the cloud storage service "Box" that can only be accessed by the limited persons as Canon and QTI mutually agreed upon. All Confidential Information and Trade Secret respectively as defined in the NDA shall be exchanged via such designated folder.

7.2 **Assignability.** Neither Party may assign or transfer this Agreement or any rights granted under this Agreement except to an Affiliate of a Party or a successor of a Party's business (whether through a stock, asset or other sale of a substantial part of a Party's business). Subject to the limitations on assignment herein, this Agreement shall be binding upon and inure to the benefit of any successors in interest and assigns of the Parties.

7.3 **No Waiver.** No waiver by either Party of any breach or default of any covenant or Agreement set forth in this Agreement shall be deemed a waiver as to any subsequent and/or similar breach or default.

7.4 **Governing Laws and Arbitration.** This Agreement shall be governed by and construed in accordance with the laws of the State of Singapore without regard to, or application of choice-of-law rules or principles. All disputes, controversy or difference which may arise between the Parties out of or in relation to, or in connection with this Agreement or any breach thereof shall, unless resolved by good faith negotiation, be finally settled by arbitration conducted under the Rules of the Arbitration of the Singapore International Arbitration Centre, by a single arbitrator selected in accordance with such Rules. The award of the arbitration shall be final and binding on the Parties. The seat of arbitration shall be Singapore. The language to be used in the arbitration proceeding shall be English. Notwithstanding the foregoing, a Party may seek equitable relief from any court of competent jurisdiction in order to enforce or preserve its Know-How and Intellectual Property Rights.

7.5 **Force Majeure.** A Party may be excused from any performance required herein if such performance is rendered impossible or unfeasible due to any catastrophe or other major event beyond its reasonable control, including, without limitation, war, riot, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and floods, fires, explosions, or other natural disasters. When such events have abated, the non-performing party's obligations herein shall resume.

- 7.6 **Headings.** The headings of several articles and paragraphs are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.
- 7.7 **Entire Agreement.** This Agreement, together with the NDA, embodies the entire understanding of the Parties and supersedes all previous communications, representations or understandings, either oral or written, between the Parties relating to the subject matter hereof.
- 7.8 **Amendments.** No amendment or modifications of this Agreement shall be valid or binding on the Parties unless made in writing and signed on behalf of each Party.
- 7.9 **Severability.** In the event that any of the provisions contained in this Agreement is held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as is the invalid, illegal, or unenforceable provisions had never been contained in it.
- 7.10 **First Priority.** During the term of this Agreement, QTI shall give Canon first priority in any negotiations for collaborations, including joint development, contract manufacturing, and marketing, with respect to ultrasound breast scanners. QTI will notify Canon of its intent to enter into negotiations for any such similar collaboration but is under no obligation to identify the other party to such anticipated negotiations nor any of the financial terms of such collaboration; QTI's only obligation is to notify Canon in writing that it intends to enter into negotiations for a collaboration similar to the Feasibility Study contemplated under this Agreement and in such notice, include a general description of the subject matter of the collaboration. Canon may notify QTI in writing that it desires to enter into negotiations with QTI for the same collaboration. If Canon fails to give QTI such written notice within twenty-one (21) calendar days after QTI's written notice to Canon, QTI will have no further obligations under this Section 7.10. If Canon gives QTI timely notice of its desire to enter into negotiations with QTI, QTI will prioritize the negotiations with Canon for such collaboration; provided, however, that nothing in this Section 7.10 will be construed as an obligation on QTI to negotiate exclusively with Canon for such collaboration. QTI will have sole discretion in determine whether or not to enter into the collaboration with Canon or with another third party. Canon's rights under this Section 7.10 will extend to negotiations for each collaboration that QTI proposes to commence so long as QTI reasonably determines that such proposed collaboration has similar objectives to the Feasibility Study.
- 7.11 **Subsequent Agreements.** Unless both Parties separately execute the definitive agreement, this Agreement shall not give rise to any commitment nor obligation by either Party to any collaboration beyond the Feasibility Study, nor does it bind either Party to execute any subsequent agreements.

Canon Medical Systems Corporation

Signature: /s/ Akihiro Sano
Name (print): Akihiro Sano
Title: Ultrasound Geberal Manager
Date: March 28, 2024

QT Imaging Holdings, Inc.

Signature: /s/ Dr. Raluca Dinu
Name: Dr. Raluca Dinu
Title: Chief Executive Officer
Date: March 26th, 2024