

OncoCyte Corp  
Form 424B5  
February 07, 2019

**Filed Pursuant to Rule 424(b)(5)**

**Registration No. 333-220769**

**The information in this preliminary prospectus supplement is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission and is effective. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and they are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED FEBRUARY 7, 2019**

**PRELIMINARY PROSPECTUS SUPPLEMENT**

**(To Prospectus dated October 2, 2017)**

**Shares**

**Common Stock**

We are offering shares of our common stock.

Our common stock is listed on the NYSE American under the symbol "OCX." The last reported sale price of our common stock on February 6, 2019 was \$4.52 per share.

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus supplement, the accompanying prospectus and our filings with the Securities and Exchange Commission.

**Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page S-6 of this prospectus supplement, as well as the documents incorporated by reference in this prospectus supplement, for a discussion of the factors you should carefully consider before deciding to purchase our common stock.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

<sup>(1)</sup> See “Underwriting” beginning on page S-20 of this prospectus supplement for additional information regarding underwriting compensation.

*We have granted the underwriters an option for a period of 30 days to purchase up to an additional \_\_\_\_\_ shares of common stock at the public offering price.*

The underwriter expects to deliver the shares of common stock on or about \_\_\_\_\_, 2019.

*Sole Book-Running Manager*

**Piper Jaffray**

*Co-Manager*

**Janney Montgomery Scott**

**Prospectus Supplement dated                      , 2019**

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**ABOUT THIS PROSPECTUS SUPPLEMENT**

This document is in two parts. The first part is the prospectus supplement, including the documents incorporated by reference, which describes the specific terms of this offering. The second part, the accompanying prospectus, including the documents incorporated by reference, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. Before you invest, you should carefully read this prospectus supplement, the accompanying prospectus, all information incorporated by reference herein and therein, as well as the additional information described under “Where You Can Find Additional Information” on page S-26 of this prospectus supplement. These documents contain information you should consider when making your investment decision. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document filed after the date of this prospectus supplement and incorporated by reference in this prospectus supplement and the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectuses we may provide to you in connection with this offering. We have not, and the underwriters have not, authorized any other person to provide you with any information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein or in the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

**MARKET, INDUSTRY AND OTHER DATA**

This prospectus contains estimates, projections and other information concerning our industry, our business and the markets for our products, including data regarding the estimated size of those markets and their projected growth rates, as well as market research, estimates and forecasts prepared by our management. We obtained the industry, market and other data throughout this prospectus from our own internal estimates and research, as well as from publicly available information, industry publications and research, surveys and studies conducted by third-parties, including governmental agencies.

Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information based on various factors, including those discussed under the heading “Risk Factors” and elsewhere in this prospectus. We believe that these sources and estimates are reliable but have not independently verified them and cannot guarantee their accuracy or completeness. We caution you not to give undue weight to such projections, assumptions and estimates.

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**PROSPECTUS SUPPLEMENT SUMMARY**

*This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all the information you should consider before investing in our securities pursuant to this prospectus supplement and the accompanying prospectus. Before making an investment decision, to fully understand this offering and its consequences to you, you should carefully read this entire prospectus supplement and the accompanying prospectus, including “Risk Factors” beginning on page S-6 of this prospectus supplement, the financial statements and related notes, and the other information incorporated by reference herein, including our most recent Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and our other filings with the Securities and Exchange Commission, or the SEC, that we file from time to time.*

*Unless the context otherwise requires, all references in this prospectus to “OncoCyte,” “we,” “us,” “our,” “the Company” or similar words refer to OncoCyte Corporation, together with our consolidated subsidiaries.*

**Overview**

Our mission is to develop highly accurate, easy to administer, non-invasive molecular diagnostic tests to improve the standard of care for cancer diagnosis to better meet the needs of patients, physicians and payers. Our initial focus is developing confirmatory diagnostics, utilizing novel liquid biopsy technology, for use to help confirm suspicious imaging results with an initial focus on lung nodules. In the future, we may study whether our technology and interrogation approach could have applications in other intended uses, indications or therapeutic areas both inside and outside oncology. Our lead product is DetermaVu™, which is a laboratory-developed blood test we are developing in our clinical laboratory as a non-invasive confirmatory diagnostic test to aid in the diagnosis of lung cancer. DetermaVu™ is being developed using proprietary sets of gene expression markers in a test that we have designed and are in the process of validating as an aid in identifying suspicious lung nodules which may help make decisions about invasive biopsies.

Our liquid biopsy diagnostic tests, for which DetermaVu™ currently is our sole product candidate, will be confirmatory diagnostics and are being developed to help reduce false positive results associated with current screening imaging and diagnostic protocols. These new tests are intended to help:

Reduce unnecessary and sometimes risky procedures, as well as lower the cost of care through the avoidance of more expensive diagnostic procedures, including invasive biopsies;



Improve the quality of life for cancer patients by reducing the anxiety associated with non-definitive diagnoses; and  
Improve health outcomes through avoidance of unnecessary invasive procedures

Our strategic focus is to develop diagnostic tests that are supportive clinical tools in areas of high unmet need, including lung cancer, breast cancer and bladder cancer detection. We have prioritized our efforts on DetermaVu™ and lung cancer because we believe that lung cancer has one of the greatest unmet needs. In addition, we may in the future develop additional diagnostics in the lung cancer field.

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We believe there are many people who would benefit from a diagnostic test such as DetermaVu™. The U.S. Preventive Services Task Force recommended in 2013 that individuals aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the previous 15 years should be screened annually for lung cancer. We estimate that there are about 7 million such individuals in the United States. In addition, approximately 5 million people undergo incidental scans outside of screening each year. Given the prevalence and gravity of lung cancer, we believe a noninvasive aid to support patient care and diagnostic treatment decisions would attract meaningful market interest.

We plan to develop any initial tests with a focus on the U.S. market as a category of diagnostics called “laboratory-developed tests” and plan to market any tests we develop under that regulatory framework. As this area of law and regulation is evolving, we may have to adjust our future development and marketing plans and may need to pursue U.S. Food and Drug Administration premarket review and clearance or approval of our tests.

## **Recent Developments**

On January 29, 2019, we announced positive results from our key R&D Validation study, demonstrating the accuracy of DetermaVu™, our confirmatory liquid biopsy test for lung nodules suspicious for cancer that is intended to provide clinicians and doctors with information that can aid in patient care and diagnosis.

The R&D Validation study demonstrated a sensitivity of 90% (95% CI 82%-95%) and specificity of 75% (95% CI 68%-81%) of DetermaVu™ on a prospectively collected cohort of 250 patient blood samples that were blinded to laboratory operators. Sensitivity is the percentage of malignant nodules that are correctly identified and specificity is the percentage of benign nodules correctly identified (with correct identification in our study confirmed by biopsy results or serial imaging). A 95% confidence interval (CI) suggests that there is a 95% chance that final test performance will be within the stated range.

We believe the results show that DetermaVu™ exceeds the needs of clinicians and payers because its high specificity could help better inform clinical decisions, which could help avoid unnecessary invasive biopsies, related complications and their costs. Based on the results of the R&D Validation study, we believe that DetermaVu™ can become a best-in-class lung cancer confirmatory liquid biopsy diagnostic test to help aid in clinical decision-making about lung nodules identified through screening imaging protocols. We plan to make DetermaVu™ commercially available through our clinical laboratory in the second half of 2019, with the goal of helping fundamentally change the way lung cancer is diagnosed.

Notably, we obtained these results without including any clinical factors in the OncoCyte-designed DetermaVu™ algorithm, underscoring what we believe is the biological strength of this laboratory-developed test. DetermaVu™ measures biomarkers of the immune system's response to cancer to differentiate between suspicious and likely benign lung nodules in early stage lung cancer. Specifically, DetermaVu™ has been designed for use in patients with lung nodules ranging from 5-30mm in size detected initially in a computerized tomography (CT) scan or incidentally through other imaging. Because clinical data points, such as lung nodule size, provide a significant amount of the diagnostic power for liquid biopsy lung cancer tests developed by other companies, we believe the superior accuracy range we have seen, to date, for DetermaVu™ independent of any clinical factors reinforces its strength as a confirmatory diagnostic tool for aiding early lung cancer detection, and provides physicians with significant biologic information that has not been available prior to DetermaVu™.

We believe DetermaVu™ has the potential to significantly reduce U.S. healthcare costs each year by eliminating unnecessary invasive biopsies, which, according to an analysis of Medicare data, cost on average \$14,634 each. In addition, DetermaVu™ may improve health outcomes by providing information that may help avoid invasive biopsies and the complications that arise in up to 24% of such procedures, and deaths that occur in a small number of cases.

In clinical practice, physicians could use a DetermaVu™ blood test to help determine whether or not a patient's lung nodule in the 5-30mm range should be biopsied for cancer. If the DetermaVu™ test indicates a likely benign result, we believe clinicians or doctors could choose to monitor the patient through serial imaging (follow-up low-dose computed tomography) rather than ordering a biopsy. With 75% specificity (the percentage of benign nodules correctly identified in the R&D validation study), we anticipate that physicians could use DetermaVu™ to help prevent up to three quarters of unnecessary invasive biopsies and their associated complications and, in rare instances, deaths. Currently, for many patients, a lung biopsy has a higher likelihood of leading to a serious complication than of confirming lung cancer. These anticipated reduced costs and potential for improved patient outcomes highlight DetermaVu™'s value proposition for payers such as Medicare and health insurance companies.

The R&D Validation study utilized the optimized biomarkers and algorithm that were previously identified in our recently completed algorithm development study, based on 700 patient samples. The R&D Validation study used a blinded set of 250 samples, including samples from 44 clinical sites, to validate the classifier performance.

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***R&D Validation Study Highlights:***

DetermaVu™ demonstrated sensitivity of 90% (95% CI 82%-95%), and specificity of 75% (95% CI 68%-81%) in a prospectively collected cohort of 250 patient blood samples including patients with nodules of 5 to 30 mm that were blinded to laboratory operators, and without the use of clinical factors such as nodule size.

Results are the first ever in a blinded prospective study to confirm our approach of utilizing the immune system's response to early stage cancer to provide a robust biological signal in blood that supports physicians in differentiating between malignant and benign lung nodules.

Results are consistent with earlier studies that led to our selection of biomarkers included in DetermaVu™, without requiring the use of clinical factors such as nodule size, further confirming the strength and robustness of the biomarkers in the assay.

We believe our immune system interrogation approach overcomes significant challenges and limitations associated with aiding early stage lung cancer detection using other liquid biopsy approaches, such as circulating tumor cell and cell free DNA detection, which have failed to demonstrate sensitivity and specificity characteristics comparable to those seen in the DetermaVu™ R&D Validation study, particularly in early stage lung cancer patients.

***Next Steps***

Having achieved successful R&D Validation utilizing the robust clinical grade and reproducible Thermo Fisher Ion GeneStudio S5 next-generation sequencing platform, we are working to complete the remaining steps to make DetermaVu™ commercially available in the second half of 2019.

The remaining steps to having a diagnostic that can be offered to patients are:

Analytical Validation – a series of studies, as specified in guidelines for labs under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, to establish the analytical performance of the test system, based on the Thermo Fisher Ion GeneStudio S5 next-generation sequencing platform's operating performance.

CLIA Validation – which consists of running approximately 100 samples, previously run in the R&D Validation study, in the CLIA laboratory using the systems that are now validated analytically. The intent would be to demonstrate that the systems as being run in the CLIA lab are providing the equivalent results to those observed in the R&D Validation study.

Clinical Validation – an analysis of running approximately 350 prospectively collected, blinded samples in the CLIA laboratory. The results of the Clinical Validation will establish the assay’s performance in the CLIA laboratory using the fully validated test systems.

In addition to these steps, we plan to conduct a post-launch Clinical Utility study for the purpose of meeting the reimbursement requirements of public and commercial payers, including Medicare, insurance companies and integrated delivery networks. This Clinical Utility study design will be part of the data package that will be submitted to Medicare in 2020 in hopes of receiving a coverage decision in 2020, and the results of the Clinical Utility trial will be part of the data package provided to commercial payers.

### ***Commercial Focus***

Our commercial focus will be on pulmonologists. With the increased focus of health care workers and advocacy groups on earlier diagnoses, we believe that more high-risk patients will be screened for lung cancer. Many of these patients see, or will be referred for follow up with, a pulmonologist. The American Association of Medical Colleges estimates that there are approximately 4,830 practicing pulmonologists in the United States. We believe that a specialty sales force can cover the number of practicing pulmonologists.

### **Corporate Information**

We were incorporated in September 2009 in the state of California. Our principal executive offices are located at 1010 Atlantic Avenue, Suite 102, Alameda, California 94501. Our telephone number is (510) 775-0515. Our website is [www.oncocyte.com](http://www.oncocyte.com). Information contained on, or that can be accessed through, our website, is not, and shall not be deemed to be, incorporated in this prospectus supplement or considered a part thereof.

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**THE OFFERING**

Common Stock offered by us                      shares

Common stock to be outstanding immediately after this offering<sup>(1)</sup>                      shares (or                      shares if the underwriters exercise in full their option to purchase additional shares of common stock).

Option to purchase additional common stock                      We have granted the underwriters an option to purchase up to                      additional shares of common stock from us at the offering price. The underwriters can exercise this option at any time, but not more than once, within 30 days following the effective date of the purchase agreement between us and the underwriters.

Use of proceeds                      We expect to receive net proceeds from this offering of approximately \$                      (or \$                      if the underwriters exercised their option to purchase additional shares of common stock in full), after deducting the underwriting discounts and commissions and the expenses of this offering payable by us. We currently intend to use the net proceeds from this offering to support DetermaVu™ commercialization efforts and additional clinical studies to support reimbursement and adoption, to initiate future product development, and for general corporate and working capital purposes. See “Use of Proceeds.”

Risk factors                      Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page S-6 of this prospectus supplement and page 4 of the accompanying prospectus, as well as the documents and other information incorporated by reference in or included in this prospectus supplement, for a discussion of the risks you should carefully consider before investing in our common stock.

NYSE American symbol for our common stock                      OCX

(1) The number of shares of our common stock to be outstanding immediately after this offering as shown above is based on 40,664,496 shares of our common stock outstanding as of September 30, 2018, and excludes:

4,035,339 shares of our common stock issuable upon exercise of warrants outstanding as of September 30, 2018, with a weighted-average exercise price of \$3.70 per share;

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4,540,000 shares of our common stock issuable upon exercise of options outstanding under our 2010 Stock Option Plan as of September 30, 2018, with a weighted-average exercise price of \$2.94 per share, of which options to acquire 575,000 shares of our common stock have been exercised for net proceeds to us of \$942,500 subsequent to September 30, 2018;

230,000 shares of our common stock issuable upon exercise of options outstanding under our 2018 Equity Incentive Plan as of September 30, 2018, with a weighted-average exercise price of \$2.40 per share; and

4,770,000 shares of our common stock available for future grants under our 2018 Equity Incentive Plan as of September 30, 2018.

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**RISK FACTORS**

*Investing in our securities involves a high degree of risk and uncertainty. You should carefully consider these risk factors, together with all of the other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus, as modified and superseded, before you decide to invest in our securities. The occurrence of any of the following risks could harm our business. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our operations. You should also refer to the other information contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus, including our financial statements and the notes to those statements and the information set forth in the section entitled “Special Note Regarding Forward-Looking Statements.”*

**Risks Related to our Business Operations**

*We have limited capital, marketing, and sales resources and no distribution resources for the commercialization of DetermaVu™.*

If we are successful in completing the remaining steps of Analytical Validation, CLIA Validation, and Clinical Validation for DetermaVu™, we will need to build our own marketing and sales capability, which will require the investment of significant financial and management resources to recruit, train, and manage a sales force and build-out a health care regulatory compliance program. In the alternative, due to our limited capital resources, we may need to enter into marketing arrangements with other diagnostic companies for DetermaVu™. Under such marketing arrangements we may license marketing rights to one or more other companies or to one or more joint venture companies formed to market DetermaVu™, and we might receive only a royalty on sales of DetermaVu™ or an equity interest in a joint venture company. As a result, our revenues from the sale of DetermaVu™ may be substantially less than the amount of revenues and gross profits that we might receive if we were to market DetermaVu™ ourselves.

*We may experience delays in conducting the additional validation studies necessary for the commercialization of DetermaVu™, or we may encounter unanticipated results or findings.*

Having concluded our R&D validation study, our next step prior to commercialization of DetermaVu™ will be to conduct an analytical validation study, and, assuming successful completion, a CLIA validation and clinical validation study thereafter. Clinical validation is the final step prior to commercial launch of a laboratory-developed test, or LDT, and we are targeting completion of a clinical validation during the second half of 2019. If these studies are completed successfully, we plan to commercialize or to arrange for the commercialization of the test as a



laboratory-developed test to be run solely in our clinical laboratory in Alameda, CA. Until we perform these studies, we will not know whether we can successfully complete the development of DetermaVu™. We have limited experience conducting analytical and clinical validation and have not yet performed a clinical utility demonstration in our lab. We may not be able to successfully complete this testing for DetermaVu™ or any other test we may develop. While we plan to make DetermaVu™ commercially available in the second half of 2019, there can be no assurance that there will be no delays in the successful completion of the clinical validation study and commercialization of DetermaVu™, due to any number of factors some of which may not be within our control. Any delays in the successful completion of the additional validation studies for DetermaVu™ could cause us to incur significant additional costs and delay the completion of development and commercial launch of DetermaVu™. We may encounter unanticipated results or findings in the studies subsequent to our R&D validation study; our earlier test results may not be predictive of future test results with DetermaVu™ or any other future candidate tests. We have performed only limited R&D work for any other test or for any other intended patient population outside of lung cancer, and we have conducted no R&D work outside of cancer. Our immune system interrogation approach and technology may not ultimately have application in any other population, and we may be unable to identify any future candidates and tests for any other cancer or any other disease population.

***Our testing of DetermaVu™ is conducted in a single, CLIA-certified laboratory. Our operations as a clinical laboratory are subject to oversight by the Centers for Medicare & Medicaid Services, or CMS, under the Clinical Laboratory Improvement Amendments, or CLIA, as well as certain state agencies, and any failure to maintain our CLIA or applicable state permits and licenses may affect our ability to commercialize DetermaVu™.***

We are subject to CLIA, a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratory must be certified under CLIA in order for us to perform testing on human specimens. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate under CLIA to perform routine chemistry. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make periodic inspections of our clinical laboratory outside of the renewal process.

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