

**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

Date of Report (Date of earliest event reported): **November 11, 2021**

GBS INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-39825

(Commission
File Number)

82-1512711

(IRS Employer
Identification No.)

**420 Lexington Ave, Suite 300
New York, NY 10170**

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **Telephone: (646) 828-8258**

(Former name or former address, if changed since last report)

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:

- 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 Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value	GBS	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 2.02 Results of Operations and Financial Condition

On November 11, 2021, GBS Inc. (the “Registrant”) issued a press release announcing financial results for the three months ended September 30, 2021, and the hosting of a conference call and webcast on November 11, 2021, to discuss the financial results. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K, and a transcript of the conference call and webcast is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information contained herein and in the accompanying exhibits shall not be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this report, including the exhibit hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits.

Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated November 11, 2021.
99.2	Transcript of November 11, 2021 Conference Call and Webcast.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

Dated: November 17, 2021

GBS INC.

By: /s/ Spiro Sakiris

Name: Spiro Sakiris

Title: Chief Financial Officer



GBS Inc. Reports First Quarter 2022 Financial Results and Recent Business Highlights

November 11, 2021

– Announced Pre-Submission Package sent to the FDA for its Glucose Biosensor Test –

– Clinical Validation Study Results for SARS CoV2 Ab Test –

– Evaluating site locations for build out of high-tech manufacturing facility supported by \$4.7 Million Grant Funding from Australian Government –

– \$12.6 Million in Cash, Cash Equivalents, and Marketable Securities as of September 30, 2021, Provides Estimated Runway into H1 2023 –

– To Host Conference Call and Webcast Today at 4:30 p.m. ET –

NEW YORK, Nov. 11, 2021 (GLOBE NEWSWIRE) — GBS Inc. (Nasdaq: GBS), a life sciences company developing non-invasive, real-time diagnostic testing in the hands of patients and their primary health practitioners at point-of-care, today announced its financial results for the first quarter ended September 30, 2021, and provided a recent business update. Management will host a webcast and conference call at 4:30 p.m. today after market.

“We are thrilled with our team’s progress for the first quarter and believe the recently announced changes to our executive leadership team will elevate GBS into a new chapter focused on product development and planned manufacturing. Our team remains laser focused on advancing the development, clinical studies and regulatory approvals needed to bring our biosensor technology into the testing market while also consolidating our partnerships opportunities in Asia,” interim Chief Executive Officer of GBS, Dr. Steven Boyages said.

“Specifically, in the United States we recently submitted on behalf of our group the pre-submission package to the FDA for their review of our clinical trial plans and protocols so they can offer guidance and foster an open and productive communication channel. In the APAC region, GBS is reviewing commercial partner opportunities in China from the shortlist of suitable partners provided by our consulting team in Hong Kong and we look forward to progressing ahead in the next quarter. We are well on our way and proud of our success this quarter as we remain driven to provide non-invasive, real-time diagnostics testing solutions to patients and their healthcare providers at point-of-care.”

New Development- Clinical Validation Study Results

A clinical validation study was conducted at the Wyss Institute for Biologically Inspired Engineering at Harvard University. The objective of this study was to develop an electrochemical assay to detect SARS-CoV-2 IgG in human plasma. The statistical design of the study was powered in accordance with this study objective. Preliminary findings were:

- The SARS-CoV-2 Antibody biosensor assay was 100% sensitive and 100% specific using positive and negative SARS CoV-2 human plasma samples.
- The time in obtaining results was less than 10 minutes.

The study is a key milestone towards validating a rapid point-of-care diagnostic test intended to quantify the measurement of antibodies against SARS-CoV-2 in saliva, and will assist in the preparation for clinical trials.

Q1 2022 & Recent Highlights

- GBS has prepared its clinical trial strategy and protocols and accordingly filed a Pre-Submission package on behalf of the group with the United States (US) Food and Drug Administration (FDA). The purpose of this pre-submission is to confirm with the FDA the GBS regulatory strategy and proposed clinical studies enabling it to develop the glucose biosensor according to the FDA regulatory standards.
- In July, the Company engaged L.E.K. Consulting Hong Kong Pty Limited to deliver a shortlist of suitable commercial partners for distribution in China. Management is currently evaluating the shortlist for suitable partners.
- In July, GBS was awarded a \$4.7 Million Medical Products Priority Grant by the Australian government to fund a high-tech manufacturing facility;

Anticipated Events and Targeted Milestones for 2022

- Finalize clinical salivary collection and clinical trial protocols with Johns Hopkins Bloomberg School of Public Health Secure strategic partnership opportunities for sales and distribution in the APAC region
- Complete SARS-CoV-2 Antibody Biosensor submission for FDA EUA
- Progressing the design transfer to manufacture phase for Saliva Glucose Biosensor

First Quarter 2022 Financial Results

As of September 30, 2021, the Company's cash, cash equivalents and marketable securities totaled approximately \$12.6 million, compared to approximately \$12.57 million on June 30, 2021.

For the quarter ended, September 30, 2021 the Company had a preliminary net loss of \$1.4 million or \$0.10 per share compared to a net loss of \$1.0 million or \$0.12 per share for same period last year. This is predominantly due to the acceleration of development and commercialization expenditures.

As of September 30, 2021, the Company had 14.88 million shares outstanding.

GBS is of the view that based on the current operating plan and financial resources, its cash, cash equivalents and marketable securities at September 30, 2021, are estimated to be sufficient to cover expenses and capital requirements into H1 2023. Cash runway does not include exercising the glucose North American license option agreement.

Conference Call and Webcast

To participate in today's conference call, please dial 877-407-3982 (Domestic/Toll-Free) or 201-492-6780 (International) and reference the conference ID: 13724335.

To participate via a webcast, please visit: <https://78449.themediaframe.com/dataconf/productusers/vvdb/mediaframe/47098/index1.html>

The webcast will be archived for approximately 30 days and will be available at <https://investors.gbs.inc/news-and-events/investor-calendar>.

About GBS Inc.

GBS Inc. is a life sciences company developing non-invasive, real-time monitoring and diagnostic tests for patients and their primary health practitioners. With the world-first Biosensor Platform, GBS Inc. is developing and launching diagnostic tests urgently needed to help people living with diabetes.

For more information, please visit GBS.inc or follow [GBS Inc.](#) on [Twitter](#) and [LinkedIn](#).

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, GBS Inc.'s ability to develop and commercialize its diagnostic tests, realize commercial benefit from its partnerships and collaborations, and secure regulatory approvals, among others. Although GBS, Inc. believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. GBS Inc. has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, included in the Company's public filings filed with the Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

For more information, please contact: Investor Contact:

Tim McCarthy – Managing Director
LifeSci Advisors, LLC
Tim@LifeSciAdvisors.com

Company Contact:

Spiro Sakiris – Chief Financial Officer
GBS, Inc.
Investor.Relations@gbs.inc

GBS, INC.
PRELIMINARY CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)
(Amounts in \$)

	Three Months Ended September 30,	
	2021	2020
Revenues:		
Other income:		
Government support income	\$ -	\$ 55,427
Total revenues	-	55,427
Operating expenses:		
General and administrative expenses	1,332,520	521,003
Development and regulatory approval expenses	106,799	30,938
Prospectus and capital raising expenses	-	166,481
Total operating expenses	1,439,319	718,422
Loss from operations	(1,439,319)	(662,995)
Other income (expense):		
Interest expense	-	(85,828)
Loss from unconsolidated equity method investment	-	(135,692)
Realized foreign exchange loss	(3,118)	(192,470)
Interest income	4,597	70
Total other income (expense)	1,479	(413,920)
Loss before income taxes	(1,437,840)	(1,076,915)
Income taxes	-	-
Net loss	(1,437,840)	(1,076,915)
Net loss attributable to non-controlling interest	(5,188)	(4,405)
Net loss attributable to GBS, Inc.	\$ (1,432,652)	\$ (1,072,510)
Other comprehensive loss, net of tax:		
Foreign currency translation loss	\$ (67,482)	\$ (50,568)
Total other comprehensive loss	(67,482)	(50,568)
Comprehensive loss	(1,505,322)	(1,127,483)
Comprehensive loss attributable to non-controlling interest	(5,188)	(4,405)
Comprehensive loss attributable to GBS, Inc.	\$ (1,500,134)	\$ (1,123,078)
Net loss per share, basic and diluted	\$ (0.10)	\$ (0.12)
Weighted average shares outstanding, basic and diluted	14,006,127	8,630,000

GBS, INC.
PRELIMINARY CONSOLIDATED BALANCE SHEETS
(Unaudited) (Amounts in \$)

	September 30, 2021	June 30, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,608,468	\$ 12,573,685
Grant receivable, current portion	-	2,098,884
Research and development tax incentive receivable	982,898	1,025,455
Other current assets	2,268,771	2,509,017
Total current assets	15,860,137	18,207,041
Grant receivable, net of current portion	2,743,337	3,148,328
Other non-current assets	504,000	504,000
TOTAL ASSETS	\$ 19,107,474	\$ 21,859,369
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 808,736	\$ 1,467,968
Related party payables	68,808	13,323
Current portion of deferred grant income	1,828,891	2,098,884
Current employee benefit liabilities	126,139	102,475
Total current liabilities	2,832,574	3,682,650
Employee benefit liabilities	30,264	21,770
Long-term deferred grant income	2,743,337	3,148,328
Total liabilities	5,606,175	6,852,748
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, \$0.01 par value, 10,000,000 shares authorized, 0 and 1,300,000 shares issued and outstanding at September 30, 2021 and June 30, 2020, respectively	-	13,000
Common stock, \$0.01 par value, 100,000,000 shares authorized, 14,882,522 and 13,582,122 shares issued and outstanding at September 30, 2021 and June 30, 2020, respectively	148,825	135,821
Additional paid-in capital	38,440,085	38,440,089
Accumulated deficit	(24,302,455)	(22,869,803)
Accumulated other comprehensive loss	(728,742)	(661,260)
Total consolidated Group equity	13,557,713	15,057,847
Non-controlling interest	(56,414)	(51,226)
Total shareholders' equity	13,501,299	15,006,621
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 19,107,474	\$ 21,859,369

GBS Inc. (GBS) CEO Steven Boyages on Q1 2022 Results - Earnings Call Transcript

Start Time: 16:30 January 1, 0000 4:53 PM ET

GBS Inc. (NASDAQ:[GBS](#))

Q1 2022 Earnings Conference Call

November 11, 2021, 16:30 PM ET

Company Participants

Steven Boyages - CEO

Spiro Sakiris - CFO

Tim McCarthy - LifeSci Advisors, IR

Conference Call Participants

John Vandermosten - Zacks

Operator

Greetings, and welcome to the GBS Inc. First Quarter 2022 Earnings Conference Call. Currently, all participants are on a listen-only mode. A question-and-answer session will follow the formal presentation. [Operator Instructions]. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Tim McCarthy of LifeSci Advisors, Investor Relations for GBS Inc. Thank you. You may begin.

Tim McCarthy

Thank you, operator, and good afternoon. Joining us today from the company are Dr. Steven Boyages, Interim CEO and Chairman of the Board; and Spiro Sakiris, Chief Financial Officer. A press release announcing the results and the update was issued this afternoon and is available now on the GBS Web site. If you haven't received this news release or if you'd like to be added to the company's distribution list, please send an email to Investor.Relations@gbs.inc.

I will now read the company's Safe Harbor statement. Some of the statements on this conference call are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements on this call include, without limitation, GBS Inc.'s ability to develop and commercialize its diagnostic tests, realize commercial benefit from its partnerships and collaborations, and secure regulatory approvals, among others. Although GBS Inc. believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements.

GBS Inc. has attempted to identify forward-looking statements by terminology, including believes, estimates, anticipates, expects, plans, projects, intents, potential, may, could, might, will, should, approximately or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, included in the company's public filings filed with the Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

During this conference call, the company may refer to EBITDA, a non-GAAP measure. EBITDA does not and should not be considered an alternative to net income loss, income loss from operations or any other measure for determining operating performance. EBITDA is normally calculated by adding back income tax, depreciation and amortization to net income loss.

I would like now to turn the floor over to Dr. Steven Boyages, Interim CEO of GBS Inc. Steven, please go ahead.

Steven Boyages

Thank you, Tim. Good afternoon and thank you for joining us on our quarterly business and financial update call today. We issued our first financial year quarter 2022 preliminary financial and operating results after the close of the market today, and I hope you've been able to review them.

On today's call, I'll begin with an update on our leadership changes and highlight GBS achievements to date that were announced last week. I'll then turn the call over to Spiro for a more detailed review of our financials, including our preliminary first quarter results and our forecasted cash burn.

As GBS announced last week, we've accelerated and prioritized product development and manufacturing, which have resulted in changes to our organization and leadership structures, which I'd like to walk you through now.

The Board strongly believes a key element to ensuring that we set up for long-term success is to have the best possible leadership. By ensuring that we have the best team to execute our strategic product and operational plans, we can continue to drive shareholder value in the long run.

As such, and in order to bolster the company's existing management capabilities, the Board announced that Harry Simeonidis has transitioned his role over to President of Asia Pac, Sales and Marketing to focus on the emerging Asia Pac markets due to his vast experience and skill set developed over his 25 years tenure in the region. Harry has been instrumental in this planned transition and will remain supportive as the Board finalizes the transition.

The Board is initiating a search process with leading executive search firms to identify a permanency. Until that time, I'm committed to working with our management team as Chief Executive and Chairman to drive GBS forward. On behalf of the Board and management team, I want to thank Harry for his work in advancing our company and we appreciate his continued support.

Now on a brief business overview before getting into the quarter's performance. GBS is committed to developing and commercializing innovative biosensors for point of care monitoring and diagnostic tests. Our proprietary technologies revolve around saliva-based testing approaches, which we intend to demonstrate are as accurate as other fluid-based methods such as serum, blood and urine.

We believe by offering patients an affordable, convenient and disposable test strips, we can drive increased compliance and frequency of testing to drive better outcomes among people living with diabetes.

One of the key differentiating factors of GBS' biosensor is that this platform technology uses a proprietary organic thin film transistor technology or abbreviated OTFT, which can be applied across different testing modalities.

As such, we have identified approximately 130 additional diagnostic tests and evaluated the commercial potential in multiple geographic areas around the world. GBS holds exclusive rights and the OTFT is patented and protected till the year 2033.

As we look out into 2022 and analyze our forward-looking portfolio, GBS is prioritizing two lead product candidates towards commercialization. Firstly, our flagship product candidate is the novel saliva glucose biosensor, a convenient point of care test expected to substitute for the invasive finger pricking blood glucose monitoring for patients living with diabetes.

Secondly, our saliva SARS-CoV-2 antibody test candidate which will provide real-time quantitative detection of SARS-CoV-2 (COVID-19) virus antibodies. I want to turn my attention now to review some of our key highlights on these two candidates over the last quarter.

Firstly, saliva glucose biosensor. In the subsequent quarter, we made significant advancements in the development of the clinical action plan. At a very high level, this three-step prospective clinical action plan comprises the following.

Firstly, to define the relationship between saliva and plasma glucose as well as the time course between the two; secondly, the development of the algorithm between plasma and saliva glucose; and thirdly, to validate the algorithm and generate prospective data for full regulatory approval.

This clinical action plan was included in a pre-submission package by the group with the FDA to confirm the approach and provide a forum for feedback on these clinical studies as regulatory approval is pursued.

The second exciting development is the awarding of a manufacturing grant to GBS. GBS was recently identified for a competitive grant award by the Australian government under its Modern Manufacturing Strategy, MMS.

This US\$4.7 million grant awarded by the Australian Federal Government is specifically to fund the build-out of a high-tech biosensor manufacturing facility. This non-dilutive capital is incredibly important to the next phase of manufacturing development, in which GBS can accelerate product development through the purchase of several important technical machinery and equipment.

The third area that I want to highlight is the engagement of L.E.K. Consulting in Hong Kong who will deliver a shortlist of suitable commercial partners for distribution in China as we prepare for initial discussions with potential collaborators in this region. We look forward to progressing this in the next quarter.

Finally, I want to return to our second key biosensor strategy which is the saliva SARS-CoV-2 antibody test. A preliminary clinical study conducted at the Wyss Institute for Biologically Inspired Engineering at Harvard University demonstrated important confirmatory findings.

The plasma SARS-CoV-2 antibody biosensor assay demonstrated comparable specificity and sensitivity to well known commercially available tests using positive and negative SARS-CoV-2 patient plasma samples.

Sample to answer time to obtain test results was less than 10 minutes. This study is a key milestone towards validating a rapid point of care diagnostics intended to quantify the measurement of antibodies against the SARS-CoV-2 in saliva.

Turning to GBS' financial year first quarter financial results, which our CFO, Spiro Sakiris, will discuss in greater detail shortly, I just want to highlight that we continue to exercise fiscal restraint and responsibility as we emerge from the COVID-19 pandemic.

With that, I would now like to turn the call over to our CFO, Spiro Sakiris, for a more detailed review of our Q1 financials. Spiro?

Spiro Sakiris

Thank you, Steven. As Steven mentioned, Q1 was an impressive period of advancement and development of GBS' biosensor-based point of care tests but also for GBS' growing organization.

For the quarter ended September 30, 2021, the company had a preliminary net loss of 1.4 million or \$0.10 per share compared with a net loss of 1 million or \$0.12 per share in the same period last year. This is predominantly due to the acceleration of development and commercialization expenditure.

Government support income was zero for the first three months ended September 30, 2021, a decrease of \$55,427 for the same period ended 2020. As of September 30, 2021, the company's cash, cash equivalents and marketable securities totaled approximately 12.6 million compared with approximately 12.57 million as of June 30, 2021. As of September 30, 2021, the company had 14.88 million shares outstanding.

Management continues to be fiscally responsible and has multiple strategies to extend its runway through potential sublicensed and distributor agreements and collaborations which provide a diverse set of funding options for the company.

GBS is of the view that based on the current operating plan and financial resources, its cash, cash equivalents and marketable securities at September 30, 2021 will be sufficient to cover expenses and capital requirements into the first half of 2023.

We will now open the call for questions. Operator, please open the floor for questions.

Question-and-Answer Session

Operator

Thank you. Ladies and gentlemen, at this time, we will be conducting a question-and-answer session. [Operator Instructions]. Our first question is coming from the line of John Vandermosten with Zacks. Please proceed with your questions.

John Vandermosten

Hello, there. Dr. Boyages, good to meet you. And Spiro, good to hear your voice as well. I wanted to start out with a question on just a change in management. Is the change in the CEO role expected to have any effect on the strategic direction of the company, or is it more something in terms of execution?

Steven Boyages

Look, it's a good question and it's good to be able to talk to you directly. The Board was clear in the sense that this was a strategic focus. I have an extensive clinical research, technological, IT background. And as we're moving now into our next phase beyond our establishment, we wanted to bring a greater focus on the execution of our two key clinical programs, as well as our relationships with other partners. So we see this as building on what has been achieved to date, rather than a distraction or a changing direction. It's generally an acceleration of effort, and we believe that we should be able to put forward a superb team going forward into the next quarter and beyond.

John Vandermosten

Okay. And is there a set timeline for how long it might take to find a permanent CEO?

Steven Boyages

Look, my view is that we should be doing this in the next three to six months. We're looking for high caliber candidates. Given our focus, particularly in the U.S., we'd be particularly looking for a U.S. candidate to work with our teams there on site. But again, we're not going to compromise quality for timeliness. We are in the holiday period, particularly in Australia, but that's not going to slow us down. The Board is very committed to pursuing this. And I've already had discussions with our management team here on site about progressing them out.

John Vandermosten

Okay. Thank you. And I wanted to pivot towards some of the studies that you're going to be performing. There's that data correlation study between blood and saliva. When do you expect results from that? And can you talk about how that process is going with that test?

Steven Boyages

Yes. Look, that's a key milestone for us. I was talking to Head of Clinical Affairs this morning in the U.S. He's been physically on site in Seattle yesterday talking to some of the clinical research groups there. And today, he is in California, two clinical research facilities, looking to build relationships to begin that key work of correlation between not only saliva, but gingival fluid as well as comparison to gold standards of venous blood, capillary blood and interstitial fluid. We expect those results by the end of March 2022.

John Vandermosten

Okay. And I assume that that's also been submitted to the FDA what you're doing right now in the package that was recently announced?

Steven Boyages

Right, and we're very excited by that pre-submission package to the FDA. And again, that's going to give us guidance right around most of the regulatory jurisdictions as to what they're looking for, what we need to perform? But we believe that our clinical correlation action plan that I outlined in our presentation will fulfill most of those requirements.

John Vandermosten

And are there any other studies that are required? I think there is at least one more that you have to perform as well before you're --

Steven Boyages

Look, the studies are there in the development of the algorithm in terms of being able to present that data to the device, so that the patients will hold. That will require the product development, the production model of the sensor, but it's currently being prototyped. But that will build on the clinical correlation study. So that would be -- we're expecting that to be in the third quarter of next year.

John Vandermosten

Okay. I wanted to pivot again towards the manufacturing facility. How was that coming along? And when do you expect to break ground?

Steven Boyages

Look, I might just make some comments [ph] and then pass it across to Spiro. But I think people need to understand that this grant is one of the first ones to be awarded in Australia. It's highly competitive. It may not sound like a lot of dollars from a U.S. perspective, but \$4.6 million grant in Australian terms is a huge amount of funding. So we're very proud of that achievement. It's going to be a major step towards the prototype and product development. But I'll hand across to Spiro to talk about the specifics. Spiro?

Spiro Sakiris

Okay. Thank you. Thanks, Steve. So what we're looking at that, since the grant's been announced, we've been concentrating on finalizing the site. So we're expecting to be finalizing that with the potentials in by quarter one calendar year for 2022. And with that process, the important part of that process is that the role of the manufacturing facility -- it has a few roles. The first one is that we're looking -- it plays an important part for the transfer to manufacturing. And this allows us to get together the processes, and most importantly, the quality control. Once we've then put these protocols together, this will then give us a blueprint in relation to manufacturing that we need to do in our other territories, be it contract manufacturing, be it direct manufacturing. And then the important part of this too, which Steve touched on before, is the equipment. So we're looking to be fast tracking to bring the equipment across and start commissioning the equipment. So then we can get the benefits of progressing along with our commercialization strategy in an efficient manner.

John Vandermosten

Okay. And how much of the total cost will that 4.7 million take care of?

Spiro Sakiris

The cost we've got on there is budgeted. The 4.7 that's coming in, we've got that -- the grant is based on dollar-for-dollar matching. Okay. And with that cost, it's included in our budget equipment, you've got the labor component, because the job creation is a very important part of the grant. And that's basically a dollar-for-dollar match.

John Vandermosten

Okay. So about \$10 million total expected cost for the facility?

Spiro Sakiris

In the ballpark, correct.

John Vandermosten

Okay, great. And then just last question on that. And my last question is just on how long you anticipate it will take to build and you'll finally have things operational at that facility?

Steven Boyages

Yes, I'll have those details in Q1, which is in the process Q1 next year before March. So we'll release that to the market once we've locked those timelines in. We're actually in discussions on that now as we speak.

John Vandermosten

Okay, great. Well, thank you both for the answers. I appreciate it.

Steven Boyages

Thank you, John.

Operator

Thank you. [Operator Instructions]. At this time, there are no further questions. And I'd like to turn the floor back over to Dr. Boyages for closing remarks.

Steven Boyages

Thank you. I just wanted to finally say that we're extremely proud of the progress we've made this quarter. We're very excited. We look forward to reporting on our progress at the midyear earnings presentation. Thank you very much for joining us on our call today. We look forward to the developments that we've outlined. We appreciate your support and thank you again for joining our quarterly conference update call.

Operator

Thank you for your participation. You may disconnect your lines at this time. Have a great day.