

**From:** Zachary Clarke  
**Sent:** Monday, 1 March 2021 8:54 AM  
**To:** Michael Contaldo; Simon Rae  
**Subject:** Fwd: brief update 4  
**Attachments:** Update report 4.pdf

FYI

---

**From:** Nidish Nair <[nidish.nair@biocellcorp.co.nz](mailto:nidish.nair@biocellcorp.co.nz)>  
**Sent:** Sunday, February 28, 2021 4:06:52 PM  
**To:** Zachary Clarke <[Zachary.Clarke@mbie.govt.nz](mailto:Zachary.Clarke@mbie.govt.nz)>  
**Subject:** brief update 4

Hello Zachary,

I trust you are doing well.

We are all keeping safe and are getting prepared to work in compliance with Auckland's level 3 guidelines.

Please find attached the next update report.

Cheers,

---

Nidish



Update report 4

28 February 2021

Hello Zachary,

Now that most orders are in with the suppliers, we are in continued discussion with them to approve various designs, drawings and automation controls.

As an example, we have cited and discussed the piping and instrumentation diagrams of the 5,000 L bioreactor and have organised fortnightly meetings with the team in Europe to get regular updates on the progress of the reactor manufacturing.

Simultaneously, we are working with contactors and consultants in NZ to look at the regulatory aspects of installing the reactor at our facility in Auckland. <sup>9(2)(b)(ii)</sup> [REDACTED], the global quality certification provider, is working directly with our supplier <sup>9(2)(b)(ii)</sup> [REDACTED] to certify our bioreactor after ensuring that it meets NZ's pressure vessel and seismic compliance standards.

We have engaged <sup>9(2)(b)(ii)</sup> [REDACTED] to ensure that our site is prepared to handle the pressure and seismic compliance requirements of the 5000 L bioreactor.

In other matters, we will be taking delivery of one of the smaller disposable bioreactors from <sup>9(2)(b)(ii)</sup> [REDACTED] in the next two weeks.

We will continue to work with these suppliers and keep you posted on our progress.

Cheers,

Nidish



**From:** Zachary Clarke  
**Sent:** Thursday, 1 April 2021 10:13 AM  
**To:** Simon Rae; Michael Contaldo  
**Subject:** Fwd: brief update 5  
**Attachments:** Update report 5.pdf

Get [Outlook for iOS](#)

---

**From:** Nidish Nair <[nidish.nair@biocellcorp.co.nz](mailto:nidish.nair@biocellcorp.co.nz)>  
**Sent:** Wednesday, March 31, 2021 9:58:29 PM  
**To:** Zachary Clarke <[Zachary.Clarke@mbie.govt.nz](mailto:Zachary.Clarke@mbie.govt.nz)>  
**Subject:** brief update 5

Hello Zachary,

I trust you and the team are keeping well.

Please find attached the next update report.

 Cheers,

Nidish

---



Update report 5  
(March 31, 2021)

Hello Zachary,

We are continuing to work closely with our suppliers to address various technical matters and are making very good progress in forging new relationships.

In the previous report we mentioned that <sup>9(2)(b)(ii)</sup> [REDACTED] <sup>9(2)(b)(ii)</sup> [REDACTED], will be certifying our bioreactor after ensuring that it meets NZ's pressure vessel and seismic compliance standards. <sup>9(2)(b)(ii)</sup> [REDACTED] we have now engaged <sup>9(2)(b)(ii)</sup> [REDACTED] for this project.

Not surprisingly, while some suppliers have managed to work through the Covid induced lockdowns, some have struggled to keep up with the schedule due to production constraints caused by maintaining safe working practice and Covid-19 mitigation measures at their manufacturing plants, thereby resulting in some extended lead times. In addition, we have been notified that by US law, for any Covid-19 related items that are being manufactured in the US, their local companies would receive priority over non-US companies and be able to jump the que thereby delaying non-US deliveries. In addition, some changes to the regulatory and quality requirements for certifying high tech pressure and temperature components is becoming more challenging with work-from-home guidelines. These issues have caused the delivery of the 5000L bioreactor from <sup>9(2)(b)(ii)</sup> [REDACTED] and the automatic filling machine to be extended out to the third/fourth quarter of 2021.

<sup>9(2)(b)(ii)</sup> [REDACTED]

The installation of environment monitoring systems supplied <sup>9(2)(b)(ii)</sup> [REDACTED] has now been successfully completed. This means that all process related critical and semi critical areas on site are now monitored continuously using a fully validated cloud-based system.

The bioreactor <sup>9(2)(b)(ii)</sup> [REDACTED] is now in NZ and the installation process has commenced at our facility.

We will continue to keep you posted on our progress.

Cheers,

Nidish





**From:** Zachary Clarke  
**Sent:** Monday, 3 May 2021 10:07 AM  
**To:** Simon Rae; Michael Contaldo  
**Subject:** FYI - BioCell progress report [IN-CONFIDENCE]  
**Attachments:** Update report 6.pdf

See attached

**From:** Nidish Nair <[nidish.nair@biocellcorp.co.nz](mailto:nidish.nair@biocellcorp.co.nz)>  
**Sent:** Friday, 30 April 2021 9:08 PM  
**To:** Zachary Clarke <[Zachary.Clarke@mbie.govt.nz](mailto:Zachary.Clarke@mbie.govt.nz)>  
**Subject:** update report 6

Hello Zachary,

I trust you are keeping well.

Please find attached the next update report.

Have a great weekend.

Cheers,

Nidish

---



Update report <sup>6</sup>

30 April 2021

Hello Zachary,

We have made significant progress this month in our endeavours and the opening of trans-Tasman bubble has helped us tremendously.

<sup>9(2)(b)(ii)</sup> Due to the ease in travel restrictions, <sup>9(2)(b)(ii)</sup> their engineering and installation company are now able to freely visit our facility at Auckland from Australia. <sup>9(2)(b)(ii)</sup> managed the installations at Pfizer, AstraZeneca and CSL plant visited our facility on the 23<sup>rd</sup> of April and brainstormed through various technical issues with the Biocell team. The meeting was very productive and enabled <sup>9(2)(b)(ii)</sup> to understand the Biocell site and location as this is crucial in the design of associated high-pressure pipework and location of various plant components.

Regarding the 5000L bioreactor <sup>9(2)(b)(ii)</sup>, the global quality certification provider has now changed <sup>9(2)(b)(ii)</sup>. It is to be noted that while moving to <sup>9(2)(b)(ii)</sup> would add more time to the certification process, <sup>9(2)(b)(ii)</sup> gives them more confidence in their work. <sup>9(2)(b)(ii)</sup> has now laid out the certification plan as follows:

- <sup>9(2)(b)(ii)</sup> to send drawings and calculations done as per ASME rules to <sup>9(2)(b)(ii)</sup>
- <sup>9(2)(b)(ii)</sup> will share this information to its counterpart in New Zealand that will send <sup>9(2)(b)(ii)</sup> an approval
- The approval will also provide the information required for the filling of an MDR according to ACOP format
- Regarding the bioreactor platform, it is sufficient to provide the technical design according to seismic requirement to <sup>9(2)(b)(ii)</sup> the approval for construction.

The installation process of the smaller 50L bioreactor from <sup>9(2)(b)(ii)</sup> is now speeding up and <sup>9(2)(b)(ii)</sup> is organising their engineer to come from Australia to do the commissioning.

Our automated filling machine is progressing well at <sup>9(2)(b)(ii)</sup> plant in Germany. Biocell's team has been in close discussion with <sup>9(2)(b)(ii)</sup> to advise and comment on machine layout. Biocell is also advising on the types of vials and stoppers used for the factory acceptance test. Biocell team has been liaising with the vial suppliers and have organised delivery of pharmaceutical vials of a range of fill volumes to be shipped from <sup>9(2)(b)(ii)</sup> in Germany.

We will continue to keep you posted on our progress.

Cheers,

Nidish

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

**From:** Zachary Clarke  
**Sent:** Tuesday, 1 June 2021 3:01 PM  
**To:** Simon Rae; Michael Contaldo  
**Subject:** FW: BioCell update report 7 [IN-CONFIDENCE]  
**Attachments:** Update report 7.pdf

FYI

**From:** Nidish Nair <[nidish.nair@biocellcorp.co.nz](mailto:nidish.nair@biocellcorp.co.nz)>  
**Sent:** Monday, 31 May 2021 8:14 PM  
**To:** Zachary Clarke <[Zachary.Clarke@mbie.govt.nz](mailto:Zachary.Clarke@mbie.govt.nz)>  
**Subject:** update report 7

Hello Zachary,

I trust you are keeping well.

Please find attached the next update report.

 Cheers,

Nidish

---



Update report 7

31 May 2021

Hello Zachary,

We continue to make good progress this month and have been able to complete a number of key objectives.

The 9(2)(b)(ii) team in Italy is currently finalising the optimised layout of the WFI plant that they will be installing at Biocell. We have had multiple productive telecons with 9(2)(b)(ii) 9(2)(b)(ii). Based on our most recent conference call last week, we are confident that the technical team in Italy is well equipped to soon finalise the layout for installation.

Regarding the 5000L bioreactor, the supplier, 9(2)(b)(ii) had to change their certification body from 9(2)(b)(ii) to the UK-based firm, 9(2)(b)(ii) 9(2)(b)(ii). Since the move 9(2)(b)(ii) has been able to quickly confirm the seismic load and weight distribution calculations to us. We have since shared these calculations with our structural engineering consulting company, 9(2)(b)(ii) 9(2)(b)(ii), who have confirmed that our site's foundation has the strength to handle the load and pressure exerted by the 5000L bioreactor.

Both 9(2)(b)(ii) have alerted us to the shortage of high-quality stainless steel in Europe and the USA. At this stage, they have both been able to find alternate suppliers and their project planning have not altered significantly.

I am pleased to confirm that 9(2)(b)(ii) has now provided Biocell with the final layout of the automatic filling machine to Biocell and we have promptly signed it off to begin final assembly and qualification.

Another positive development is that the high speed in-line centrifuge 9(2)(b)(ii) 9(2)(b)(ii) has now arrived on site and the local representative will soon be in touch with us to begin the commissioning process on site.

The installation of the 9(2)(b)(ii) bioreactor is also making progress with the validation engineer waiting for a few ancillary items to arrive from Australia to begin the installation and qualification of the equipment at Biocell.

We will continue to keep you posted on our progress.

Cheers,

Nidish





**From:** Zachary Clarke  
**Sent:** Thursday, 1 July 2021 11:54 AM  
**To:** Simon Rae; Michael Contaldo  
**Subject:** FW: BioCell Update report 8 [UNCLASSIFIED]  
**Attachments:** Update report 8\_.pdf

**From:** Nidish Nair <[nidish.nair@biocellcorp.co.nz](mailto:nidish.nair@biocellcorp.co.nz)>  
**Sent:** Wednesday, 30 June 2021 9:04 PM  
**To:** Zachary Clarke <[Zachary.Clarke@mbie.govt.nz](mailto:Zachary.Clarke@mbie.govt.nz)>  
**Subject:** Update report 8

Hello Zachary,

I trust you and the team are keeping well.

Please find attached the next update report.

Have a great week.

Cheers,

Nidish

---



## Update Report 8

30 June 2021

Hello Zachary,

I am pleased to provide you our latest update report with a number of positive developments.

The installation and operational qualification of the 9(2)(b)(ii) bioreactor has been completed at the Biocell site. We had the 9(2)(b)(ii) engineer onsite with Biocell staff for 3 full days, completing the commissioning of this bioreactor.

We have had multiple meetings with the WFI plant supplier, 9(2)(b)(ii), in Europe regarding the design of the WFI plant at Biocell. The technical engineers 9(2)(b)(ii) are working together with Biocell's technical team to optimise the footprint and set up of the WFI plant. The engineering team is ensuring that we have enough plant steam and water supply onsite to ensure that the WFI plant can function efficiently. To maintain uninterrupted supply, the engineering team is currently under discussions to see if an additional water-cooling tower is required to be installed on site.

We are in advanced discussions with three NZ engineering companies who are working to provide us with an estimate for the installation of the water for injection pipework at Biocell.

9(2)(b)(ii)

The steam boiler required to support the operation of the WFI plant and the 5000L bioreactor has also been ordered and is expected to arrive in the third-fourth quarter of this year. We are pleased that the NZ company, 9(2)(b)(ii), was able to manufacture and design the steam boiler in NZ itself, thereby ensuring that we are not overly reliant on the constrained international shipping lines.

Regarding the 5000L bioreactor **9(2)(b)(ii)**, we are currently working with **9(2)(b)(ii)** technical team to fine-tune the software and hardware integration programs. The **9(2)(b)(ii)** team has suggested a few modifications to the agreed system configuration for better compliance and we are continuing our discussions with them to ensure that we shortlist the optimal integration solutions.

We have been notified by FedEx this week that the glass vials that were purchased from **9(2)(b)(ii)** **9(2)(b)(ii)** (for factory acceptance testing and qualification of the automatic **9(2)(b)(ii)** filling machine) has been picked up from the **9(2)(b)(ii)** plant and is currently en route to Germany.

The pharmaceutical grade micronising mill that was purchased from **9(2)(b)(ii)** in UK has also arrived on site and the technical manager from Australia was on site early this month to pass on the qualification documents to the Biocell team, who will begin the commissioning process shortly.

I will continue to keep you posted on our ongoing progress.

Cheers,

Nidish

**From:** Zachary Clarke  
**Sent:** Monday, 2 August 2021 11:48 AM  
**To:** Simon Rae; Michael Contaldo  
**Subject:** Fwd: BioCell Update report 9  
**Attachments:** Update report 9\_.pdf

Get [Outlook for iOS](#)

---

**From:** Nidish Nair <[nidish.nair@biocellcorp.co.nz](mailto:nidish.nair@biocellcorp.co.nz)>  
**Sent:** Saturday, July 31, 2021 4:10:02 PM  
**To:** Zachary Clarke <[Zachary.Clarke@mbie.govt.nz](mailto:Zachary.Clarke@mbie.govt.nz)>  
**Subject:** Update report 9

Hello Zachary,

I trust all is well at your end.

Please find attached the next update report.

Have a great weekend.

Cheers,

---



Update report 9

31 July, 2021

Hello Zachary,

I am pleased to report that we have been making good progress over the last month and that several key objectives are nearing completion.

The final assembly of the automated vaccine vial filling machine has begun in Germany and the factory acceptance testing to ensure it meets the required specifications is set to begin in September. The final software programming/integration and machining tasks were completed prior to the assembly stage.

Glass vials for factory acceptance testing and qualification of the filling machine is on track to arrive at the expected timeframe in Germany from <sup>9(2)(b)(ii)</sup> glass plant in India. Once the vials are received, <sup>9(2)(b)(ii)</sup> will begin factory acceptance tests/trials in September.

<sup>9(2)(b)(ii)</sup>, one of the largest suppliers of rubber stoppers in the world, notified us that there has been an ongoing global shortage amidst huge demand for rubber stoppers, which were also required by <sup>9(2)(b)(ii)</sup> to complete the factory acceptance tests. However, working with <sup>9(2)(b)(ii)</sup>, we were able to purchase the required number of rubber stopper for the vaccine vials from <sup>9(2)(b)(ii)</sup> in Europe without impeding the test schedule.

Of the three NZ engineering companies who have been approached to provide an estimate for the installation of the Water for Injection pipework at Biocell, <sup>9(2)(b)(i)</sup> has provided an estimate on this front and we are still awaiting <sup>9(2)(b)(i)</sup> and <sup>9(2)(b)(i)</sup> to complete the estimation.

The boiler required to support the operation of the WFI plant and the 5000L bioreactor has been manufactured by the NZ company, <sup>9(2)(b)(ii)</sup>. <sup>9(2)(b)(ii)</sup> notified us last week that although the burner required to power the boiler was shipped from Germany in early July, it will not arrive in NZ until September due to shipping delays. However, as the rest of the boiler is ready, the installation at Biocell site is set to begin immediately in October.

Biocell staff are doing trail runs in the <sup>9(2)(b)(ii)</sup> bioreactor that was installed by <sup>9(2)(b)(ii)</sup> at our site last month.

<sup>9(2)(b)(ii)</sup> team are working actively with <sup>9(2)(b)(ii)</sup> and have drawn up the electrical, piping and instrumentation drawing. To ensure that the final Water for Injection system meets all relevant standards, Biocell has now engaged <sup>9(2)(b)(ii)</sup> to provide an independent guidance and certification.



9(2)(b)(i) has indicated that due to the oversight required 9(2)(b)(ii) for a complicated system such as the Bioreactor, there has been some delays in assessment of information at 9(2)(b)(ii). However, the 5000L bioreactor vessel will be delivered to 9(2)(b)(ii) automation team in September from their fabrication vendor in Italy. The automation team will then finish the assembling and cabling of the control system. Factory acceptance testing of the entire vessel and control system to ensure it meets design specifications is due to begin in November.

We will continue to keep you posted on our progress.

Cheers,

Nidish

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT



Nidish

**From:** Zachary Clarke  
**Sent:** Wednesday, 1 September 2021 9:42 AM  
**To:** Simon Rae; Michael Contaldo  
**Subject:** FW: BioCell Update Report 10 [IN-CONFIDENCE]  
**Attachments:** Update report 10.pdf

**From:** Nidish Nair <[nidish.nair@biocellcorp.co.nz](mailto:nidish.nair@biocellcorp.co.nz)>  
**Sent:** Tuesday, 31 August 2021 10:13 PM  
**To:** Zachary Clarke <[Zachary.Clarke@mbie.govt.nz](mailto:Zachary.Clarke@mbie.govt.nz)>  
**Subject:** Update Report 10

Hello Zachary,

I trust you and the team are keeping well amidst the evolving outbreak.

Please find attached the next update report.

Take care.

---



Cheers,

Nidish

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

---



Report 10 .

31 August 2021

Hello Zachary,

We continued to make good progress this month and have been able to work through a number of key objectives.

The glass vials meant for the factory acceptance test have finally reached 9(2)(b)(ii) plant this month. As per the project plan, 9(2)(b)(ii) will continue with the final assembly and then move to undertake the factory acceptance test in September.

Regarding the 5000L bioreactor vessel being manufactured by 9(2)(b)(ii), 9(2)(b)(ii), who were shortlisted as the certification body, has now successfully completed the design appraisal of the vessel. This design approval will allow 9(2)(b)(ii) to immediately begin the construction and welding processes. 9(2)(b)(ii) has reiterated that the compliance times with the regulatory bodies have increased significantly. However, despite the regulatory delays, 9(2)(b)(ii) has indicated that the factory acceptance test for the completed bioreactor vessel will start in November.

The WFI plant is under construction 9(2)(b)(ii) and the complete layout of the 4-core purification equipment that encompasses the WFI plant has been confirmed. A recent meeting with 9(2)(b)(ii), the Australia based installers of the WFI plant, has enabled the approval of the piping and instrumentation drawing, the electrical systems and associated parts list.

We will continue to keep you posted on our progress.

Cheers,

Nidish

