UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K/A

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

Date of Report (Date of earliest event reported): March 14, 2024

Autolus Therapeutics plc
(Exact name of registrant as specified in its Charter)

England and Wales	**001-38547**	**Not applicable**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

The Mediaworks
191 Wood Lane
London W12 7FP
United Kingdom
(Address of principal executive offices)(Zip Code)

(44) 20 3829 6230
(Registrant's telephone number, including area code)

Not Applicable
(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 (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 Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, nominal value $0.000042 per share	AUTL	The Nasdaq Global Select Market
Ordinary shares, nominal value $0.000042 per share*	*	The Nasdaq Stock Market LLC*

* *Not for trading, but only in connection with the listing of the American Depositary Shares on 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. ☐

Explanatory Note

This Amendment No. 1 to the Current Report on Form 8-K amends Item 2.02 of the Current Report on Form 8-K filed by Autolus Therapeutics plc (the "***Company***") on March 14, 2024 (the "***Original Form 8-K***") solely to furnish the transcript of its conference call held on March 14, 2024 for the reason described below in Item 2.02. No other changes have been made to the Original Form 8-K or to the exhibit furnished therewith.

Item 2.02 Results of Operations and Financial Condition.

On March 14, 2024, the Company held a conference call to discuss its financial results for the year ended December 31, 2023. The Company was unable to file the Original Form 8-K that furnished the press release announcing such results with the Securities and Exchange Commission (the "***SEC***") prior to the commencement of the conference call. Accordingly, and in accordance with the rules of the SEC, the Company is furnishing a transcript of its conference call herewith as Exhibit 99.1.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is being furnished pursuant to Item 2.02 of Form 8-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), or otherwise subject to the liabilities of that section, nor will it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Earnings Call Transcript dated March 14, 2024
104	Cover Page Interactive Date File (embedded within the Inline XBRL document)

SIGNATURES

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.

AUTOLUS THERAPEUTICS PLC

Dated: March 15, 2024

By: /s/Christian Itin, Ph.D.

Name: Christian Itin, Ph.D.

Title: Chief Executive Officer

Event ID: 138235356103
Event Name: Q4 2023 Autolus Therapeutics PLC Earnings Call
Event Date: 2024-03-14T12:30:00 UTC

P: Operator;;
C: Olivia Manser;Autolus Therapeutics PLC;Investor Relations
C: Christian Itin;Autolus Therapeutics PLC;Chief Executive Officer, Executive Director
C: Rob Dolski;Autolus Therapeutics PLC;Chief Financial Officer
P: James Shin;Deutsche Bank;Analyst
P: Unidentified Participant;;
P: Gil Blum;Needham & Company Inc.;Analyst
P: Eric Yang;William Blair;Analyst
P: Yanan Zhu;Wells Fargo Securities, LLC;Analyst
P: Jacob Mekhael;KBC Securities N.V.;Analyst

+++ presentation

Operator^ Ladies and gentlemen, and welcome to the Autolus Therapeutics call to discuss the full year 2023 financial results and business time. (Operator Instructions) As a reminder, this conference call is being recorded. I would like to turn the conference over to your host, Olivia Manser. Please go ahead.

Olivia Manser^ Thank you, Suzanne. Good morning or good afternoon, everyone. Thanks for joining us on today's call. With me are Dr. Christian Itin, our Chief Executive Officer; and Rob Dolski, our Chief Financial Officer.

So on slide 2, before we begin, I'd just like to remind you that during today's call, we will make statements related to our business that are forward-looking and the federal securities laws and the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. These may include, but are not limited to statements regarding the status of clinical trials and development and/or regulatory timelines for our product candidates and our expectations regarding our cash runway.

These statements are subject to a variety of risks and uncertainties that could cause actual results to differ materially from expectations and reflect our views only as of today. We assume no obligation to update any such forward-looking statements for a discussion of the material risks and uncertainties that could affect our actual results. Please refer to the risks identified on today's press release and our SEC filings, both available on the Investors section of our website.

On slide 3, you'll see the agenda. As usual, Christian will provide an overview of our operational highlights. Rob will then discuss financial results, before Christian will conclude with upcoming milestones and closing remarks, and we will then take questions. Over to you, Christian.

Christian Itin^ Thanks a lot, Olivia, and welcome, everybody to our full-year update. And obviously, it's been a very successful year for us. And we're going to go through the accomplishments during the course of last year, particularly with our lead program, obe-cel, on the following slide. But what we'd like to start out with is obviously the important transactions that we've been able to complete in February this year, obviously post the reporting period.

Obviously, the two transactions we conducted, one was the strategic collaboration with BioNTech, which I think sets us up in a very interesting and attractive way going forward with a very strong partner. And I think a lot of opportunity to realize synergies between the two companies. The focus of this collaboration has been sort of on three key platforms that we have developed. The first one is providing access to BioNTech to our manufacturing platform, obviously, at the core of that being the Nucleus manufacturing facility, but also, of course, all the systems surrounding the product supply platform.

Secondly, the commercial platform that we've been setting up and obviously are in the midst of preparing the company for a potential launch at the end of this year for obe-cel. Also the systems we set up, the procedures, the presence in the centers we're building up, all obviously can be leveraged beyond to obe-cel. And I think there's significant opportunity there for additional programs to be served through that platform.

And then also, obviously, the access to two of our product candidates, AUTO1/22 and AUTO6NG in a co-development, co-commercialization options that we have granted to do both of those programs. And I think it will allow us to accelerate some of our pipeline programs, and obviously, looking forward to the collaboration here and with our partner. We've also have additional support to launch and to expand obe-cel into additional indications. And so between all of those components, we were looking at an upfront, a contribution of $200 million through an equity investment and $50 million in cash from BioNTech and then an additional $582 million in further option exercise and milestone payments.

So this obviously is a key transaction for us, I think, with a very attractive partner that has a very similar view on how we want to approach oncology, what the challenges are, the opportunities are, and we're really excited to be working with BioNTech on a number of opportunities and products, going forward.

Now what we also did in parallel or right in sequence to executing the agreement with BioNTech is to run a financing transaction, which has yielded gross proceeds of an additional $350 million. So between the two transactions and the year-end cash position of $240 million, we're looking at beginning of the year cash position on a pro forma basis of around$800 million plus, which also sets us up in a very strong position to execute the plans that we have discussed with you leading up to these transactions as well.

Moving to slide number 5, what I'd like to do on this slide is really kind of highlight some of the key activities that we've been engaged in with obe-cel during the course of last year, but also have progressed in the first quarter now as well in 2024. First of all, we've given obviously two key updates during the course of last year on the FELIX data for obe-cel, providing the first data presentation at ASCO, which was focused on the morphological cohort of the FELIX study. This included about 94 patients that we reported on and we presented the overall outcome of the study.

What we then did actually at the ASH time point in December, early December last year is to look at the entire FELIX study, which included two additional cohorts: one cohort with patients that had minimal residual disease, so less than 5% tumor burden at times inclusion; but

also patients that have isolated extramedullary disease, which is a patient group that typically gets excluded from clinical trials due to the challenging nature of the disease. And the very high bar and challenge is to actually get meaningful results in these patients.

So we're provided at ASH, actually, the fatality of the data and we believe that is important because that actually reflects the continuum of tumor burden and risk categories that physicians are facing when dealing with adult ALL patients, and in that regard, reflect a proper cross-section of the patient population. And obviously, as you may remember, and we'll talk about a bit in further detail in upcoming slides. Obviously, we've shown very significant, very meaningful clinical activity with combined with an excellent safety profile across all of these categories of risk in the patients treated in FELIX study.

What we also did is we provided an update on patients where we do actually have longer follow-up. And these come from the ALLCAR19 study as well as the FELIX 1b study. In fact, between the patients that we had actually in that analysis had more than three years of median follow-up. And that gives us a very good understanding of what to expect longer term in terms of outcomes from the study, and then will briefly talk about that as well in the upcoming part of the presentation.

Now, what's absolutely critical in this space is your ability to deliver product, and that's certainly been the most challenging part. And if we think about the path that we've taken with obe-cel with the company is to establish our own capability of delivering product. And obviously, at the core of that is the Nucleus facility, which is located here in the UK in Stevenage. And what managed to do during the course of last year is really get that facility, not just get it final -- the build finalized, but also taking the facility into operation, qualified, fully validate the facility. And all of that data obviously is key data that actually did flow into the BLA filing.

Just as a reminder, from the time point, when we actually broke ground for this facility, which is a four-story industrial build and greenfield build, we took exactly 24 months to actually get the facility fully validated, everything written up, and into the BLA to the BLA filing. Overall, in terms of generating all the reports and the data set, it was 22 months. So that's an exceptionally short period of time and it required us to, frankly, take very different approaches from the build the design, the build, but then also the operational model to be able to achieve this.

So what we also have, obviously, since reported is that we just went through the full inspection cycle with the MHRA. One of the prerequisites that you have if you operate with manufacturing facilities in Europe or in the UK is that you actually do need licensees for those facilities to supply product, not just for clinical trials or for supply within the country, but also to be able to export product.

So if we think about US patients, obviously, we're also exporting back to the US the final produced product here in the UK and that actually required a specific license. So we have obtained this license and they're now actually in a position that we have fulfilled, the first major step here to get the facility in a position where it can actually support [80] patients from the UK.

Now the second, obviously, a key step is obviously the regulatory review coming that we're in the midst of the process of. We filed the BLA at the end of last year and during the course of November. We got by mid-January the filing accepted for review by the FDA with a PDUFA date of November 16, this year.

Meanwhile, we also actually have filed with the European Medicines Agency an MAA, and with that, obviously have now filings in the two major jurisdictions from a commercial perspective for this product. We're also going to be in conversation with the MHRA on the approach here to a registration path. And that's going to be the third jurisdiction we're looking to actually get the product approved as well.

When we look in terms of the commercial readiness, obviously one of the key activities that you have to be involved in involve in is not only in creating awareness for the product, which is mostly the medical affairs team's job to drive that, but also to make sure that we're in a position to deliver the product. And for that, obviously, that centers need to be accredited. We're in the midst of the process of getting centers ready for commercial use of the product and those activities are all on track with an expectation that we will have 30 centers ready at the time of launch for ready-to-use obe-cel, once an approval is in.

So those are kind of the key updates that we ran through from obe-cel perspective during the course of last year. Obviously, a very heavy lift to get to a place where we have both the clinical data as well as the manufacturing capability. And now the focus this year is obviously to drive through the regulatory process and prepare the organization for launch.

Moving to slide number 6, when we look beyond the obe-cel opportunity within ALL, as we are indicated we also are going to be moving into the autoimmune segment. In fact, the first study is open for enrollment. And it's called the CARLYSLE study. What is important about where we are with the program is obviously that we're setting up and setting spacing our program on the very strong foundation that we have built for obe-cel in the adult ALL setting, which gives us a lot of safety data. It gives us obviously the regulatory packages, which are absolutely relevant. It gives us the commercial supply capability and presence in the centers.

These points, we believe, are very critical to be able to deliver effectively in the autoimmune settings. And obviously, what we have shown over the last several years is that we have an exceptional profile from both an activity and a safety perspective with obe-cel.

Looking at programs beyond obe-cel, we did update on two programs. We updated on AUTO8 at an oral presentation of the MCARTY study at ASH where we could show very high levels of clinical activity, and we believe, very nice cellular dynamics that we were seeing beyond just the clinical activity, but also cellular dynamics of the product looked very interesting and seem to benefit from the dual-targeting approach that we're choosing and we've chosen for AUTO8, targeting both BCMA and CD19.

And then the AUTO6NG study in neuroblastoma, the MAGNETO study, also is open for enrollment as of the end of last year. So that's actually very nice progress on those products. And not on this slide, we also published a pediatric ALL data from AUTO1/22 in the journal Blood also in the September timeframe last year.

Moving to slide number seven and looking at the some of the organizational changes that we ran through, first of all, I'd like to congratulate Chris Williams as well as Alex Driggs to their promotions. Chris, obviously, has been instrumental in the various transactions that we have done over the years and obviously most recently at the BioNTech transaction. And Chris has been promoted to Chief Business Officer. And Alex Driggs has been promoted to Senior Vice President for Legal Affairs and obviously continue as the General Counsel of the company.

We also have a transition within the executive team. Edgar Braendle will step down as Chief Development Officer to pursue other opportunities. Edgar will continue to advise the company through the regulatory process through the BLA and MAA through the completion and approval -- of these getting to approvals in those two processes. And obviously, we'd like to thank Edgar for your fantastic job. Edgar joined in the middle of '21 right at the start of Phase 2 of the pivotal section for FELIX study. And obviously a very challenging starting point, managed with the team to get the study obviously conducted to a very successful outcome as well as obviously then translate in record time this data set as well as the data set coming from [Dave's] team on the manufacturing side into the BLA filing, the MAA filing, which is an enormous achievement in a very, very limited amount of time. So a fantastic outcome, a lot of gratitude there and wish Edgar well with his next endeavor.

And what internally we'll have, Miranda Neville takes over from Edgar. She's running the obe-cel program and has been for quite a while, and she will also continue to run the development team. So we have a nice level of continuity and drive forward. As we go through the course of this year, we will obviously expand also our team in -- more also into the autoimmune segment. And there will be certainly announcements during the course of this year, also with the build-out of the development team in that direction as well.

And finally, we have strengthened our Board of Directors. We have the two recent appointments. Lis Leiderman joined us as well as Bob Azelby. Both of them, obviously, bringing very significant level of experience. Liz obviously with a strong financial and transactions' background and Bob with a very strong background in commercialization both on the oncology side, on the CAR-T side, but also on the rheumatology side. So very relevant backgrounds, very significant opportunity for contributions as we go forward and also excited to have both of them are now part of the Board of Directors.

Now with that, I'd like to move to slide number 9. And just briefly remind you, obviously of the unique mechanism of action at the heart of the features that we see in the clinical properties we see with obe-cel. And this is all about driving a product that can physiologically engage with target cells, which means it can engage rapidly. It can deliver the kill. And it can then disengage rapidly as well so that you do not have overactivation of the CAR-T cell in the process.

And as a consequence, you will maximize on the one hand, the activity because the product and the cells get recycled back into action much more quickly. So you have actually more active agents available at any given point in time. But also you avoid the toxicity that is seen with overactivation of the T cells and obviously is at the core for the reduced cytokine release syndrome and in general as well the

immunological effects and toxicities related to neurological toxicities or usually referred to as ICANS. So in the feature that's at the core is very different way of engaging the target antigen, and obviously, as you remember, has resulted in very different profile for the product.

I'd like to do on the next slide, which is going to be slide 11, is really talk about a few aspects of the FELIX study that we have presented in terms of the pooled analysis at the ASH meeting at the end of last year. I think what's important here is to understand and I have sort of already alluded to that when I was briefly talking about the time point when Edgar actually has joined us, we conducted this study in the midst of the pandemic. And that is important because obviously, we're dealing here with patients that are highly immune-compromised, patients that are very high risk of infection. In fact, many of these patients do pass away as a consequence of sepsis in general as a major cause of death.

And as you can imagine, being in the midst of the pandemic, with travel restrictions and lots of concerns around the safety for patients, this has been a really challenging study to conduct And in essence, what it resulted in is actually a study that is pretty much a real-world study that we conducted here.

Now, what is also important to understand is that as you're operating in this type of an environment, you also have to actually make sure that the way that the physicians can manage their patients, gives them a very significant level of -- or an order degree of freedom to, frankly, make the right choices and deal with the circumstances. And challenges that they may also have experienced at the respective sites during that period.

One of the key aspects there is actually the bridging therapy. Most clinical studies conducted in this space actually do restrict the type of bridging therapy you can use, which is the therapy between collection of the cells and actually dosing of the cells. And by restricting those therapeutic options for the bridging therapy, obviously, it helps you select the patients that can manage with a certain type of bridging therapy. But at the same time, if you imagine this situation in the midst of the pandemic, it also would have been very, very challenging if we had actually basically put that in place.

So different from studies in the past, we actually allowed any type of bridging other than Blincyto. So CD19-targeting T cell engager, but any other therapeutic actually was allowed in the bridging therapy. And we did do that because we needed to make sure that physicians have every possibility to manage the patients, given the unforeseen nature and the challenges that many of these institutions were facing. And with that, actually making sure we can keep the patient safe and properly manage the patients.

So that's a key element. And of course, what that also means is that the data we're seeing is very much a reflection of the real-world setting. The same is true, obviously, in terms of the types of patients included. I mentioned that before, whether you have very low disease burden or you have extremely high disease burden or you have disease in areas outside of the bone marrow where the disease tends to be very challenging to manage, in all of those cases is where the patients present and you need to understand actually what the product comes in those patients.

And one of the strengths of the FELIX study is it actually provides data for all of these risk categories, and with, that gives valuable information to the physicians on what to expect with a particular patient and manifestation of the disease in that patient.

Slide number 12, we did actually look at sort of the change in disease burden in these patients as we're comparing the disease burden at screening versus the disease burden at lymphodepletion. And of course, this is an impact what you see here also of bridging therapy. And what's quite remarkable is that from every level of tumor burden at bridging, you get to every other level of tumor burden at lymphodepletion.

So you can go from very low tumor burden of less than 5% being in minimal residual disease, you can go all the way up to 75% tumor burden. But also the reverse. You can have more than 75% tumor burden at screening, actually you can go below 5% at lymphodepletion. And it shows the variability of the disease and the dynamic nature of this disease and the impact of actually bridging therapy here for these patients.

What was very striking to us and this is what summarized on the next two slides is when we then actually look at the outcome of these patients dependent on the level of tumor burden at lymphodepletion. And what's quite striking when you look on slide number 13, is that going from top line in blue, where you have below 5% tumor burden to the middle line in green, which is between 5% and 75% tumor burden to the red line, which is above 75% tumor burden at lymphodepletion. You see there is a profound impact on the event-free survival as you would expect, because there's obviously very different amounts of tumor cells that have to be removed in these patients and to drive outcome.

Now we see very clear differentiation. But remarkably, patients that are below 75% tumor burden tend to actually reach a plateau on the EFS, which is very encouraging when you think about the potential for long-term outcomes in these patients.

Now if we go to slide number 14, we also see an impact on the tumor burden on the actual adverse event profile, particularly with regards to immunological toxicities. And what you can see on the left hand side is a view on the cytokine release syndrome and ICANS in all patients. And you can see we had a very attractive profile, having high-grade CRS in 2% of the patients and high-grade ICANS in 7% of the patients. This is very low. This is lower even than what was observed in these types of patients with a product like Blincyto.

Now when we look at the CRS by the blasts count, the level of tumor burden at the time of lymphodepletion, you can see that there is clearly quite an interesting behavior here. We see overall as tumor burden increases, we see an increase in the overall adverse events with cytokine release syndrome of any grade going from 47% to 88%.

However, we do see that consistently across the board, the high-grade percentage for cytokine release syndrome is low. It's in the 3% to 4% range between 5% and close to 100% tumor burden. But in patients that have minimal residual disease, we actually have not observed any high-grade cytokine release syndrome in these patients.

Now, very similar when we look at ICANS, first of all, I think it's important to realize that the overall level of ICANS relatively low also

compared to other T-cell engaging or CAR-T approaches. But what we also do see here is the same picture that as tumor burden at lymphodepletion increases, we do see an increase in overall ICANS levels in these patients going from 8% to 43%. But even in the extreme high tumor burden, patients have more than 75% tumor burden, the high-grade ICANS is at 15%, which is comparable to a T cell engager.

Now what's also important, and this goes back to also the view that we had on the CRS. If we look at patients that have less than 5% tumor burden, we do not observe high-grade ICANS in these patients. In fact, the overall ICANS level is very low with 8% overall. So it points to an impact of tumor burden at lymphodepletion, both on the outcome from a clinical activity perspective, both on an ORR perspective as well as on the EFS perspective, but also see very clear differentiation with regards to immunologic toxicity and the risk of these patients experiencing immunologic toxicity as a consequence of the therapy. So this gives you actually an ability to anticipate for the physicians and plan accordingly for these patients.

Moving to the exit of the sentinel, a view based on the ALLCAR19 and FELIX Phase 1b data, and this is going to get us to slide 16. And so what we're looking at here on the left-hand side is event-free survival. And we do see that the event-free survival with or without censoring for stem cell transplant gives us a plateau that's somewhere in the range of 35% to close to 45% here. And that also gives us a very attractive proposition because it suggests that indeed a significant proportion of the patients manage to get into a long-term remission.

In these patients, you can see the longest observations with time we have with these patients is at 60 months or five years. When we look at the median overall survival or just the overall survival curve per se, what you do see the median obviously gets crossed at around 16 months. But the actual story is that the fact that we see a tail building and we have around 40% of the patients that are in that are surviving. And it looks like the curve as we see the EFS is stabilizing, suggesting that, indeed, we have long-term benefit for a proportion of the patients, which is very encouraging and something that unfortunately we have not been able to see with other therapeutic modalities in the past in this indication and at this stage of the disease.

Moving to slide 17, this is just a slightly different look, where you just look at swim plots here and you see the [corollary] as well as we just looked at, obviously, depicted in slightly different way. Now if we look at the commercial launch readiness, which is also the key activity that we're engaged in during the course of this year, while we're working with the agencies through the review process for the product, obviously, we have just updated you on the fact that we had this week that we hope got the MHRA inspection and approval for the Nucleus facility and we filed the MAA in Europe as well.

We expect to file an MAA in the UK with the MHRA as well. Timing still to be defined, but it's going to be as soon as we can. And then obviously, we have the FDA PDUFA date on November 16. So this sets us up for very significant, very tangible, obviously progress through the course of this year for obe-cel and also planned data updates for obe-cel and additional follow-up data on the FELIX study in the media section for the ASCO EHA timeframe and then also at the at the end of the year at ASH.

So when we then think about the possibility and the opportunities for expanding obe-cel into additional indications, there's sort of two fundamental paths we can think about. One is to move more broadly into the oncology arena with different forms of B-cell malignancies. And alternatively, also look at the opportunity in autoimmune disease where we know that the driving factor for those auto autoimmune diseases are autoreactive antibodies, obviously driven by B cells and the corresponding plasma cells.

In this -- from this approach perspective, obviously, when we think about the lifecycle management for obe-cel, it goes into two directions. There's obe-cel itself, and then obviously, AUTO1/22, which is the dual targeting approach that we explored in pediatric patients, which gives us opportunity, particularly in those indications where we have established a loss of CD19 antigen as of right of escape. And that's certainly shown in ALL. It's clearly shown in obe-cel. So there's a very clear kind of directions for that type of product.

And with all the weight, the combination of BCMA targeting with CD19, and obviously, that gives us an option for both moving towards the multi-myeloma segment or related diseases as well as plasma cell and B cell-mediated autoimmune diseases.

Now I did mention on slide -- early on here on slide 22 that we have opened the CARLYSLE study and we're enrolling patients. This is really a dose confirmation study, and as a backdrop, I think it's important to understand that the product that is referenced and really has opened up the opportunity for CD19 CAR T product in autoimmune disease at the University of Erlangen, which was a study that was done by Georg Schett and Andreas Mackensen. Actually, it comes from a product that was initially set up for patients with pediatric ALL. And the product has a lot of similarity in its structure, if you look at the chimeric antigen receptor with Kymriah and PMC as a different manufacturing process compared to both of those commercial products.

The properties of the product actually are quite well known and it has allowed us to actually compare our pediatric data to the pediatric data that was obtained at the University of Erlangen. And we do see a very nice match in terms of the overall data as we had seen with Kymriah, as you may remember for -- in the CARPALL study, so very high levels of molecular CRs, comparable superimposable, very similar levels of long-term outcome, very comparable levels of long-term persistence. So the product in Erlangen is a long-term persisting CAR T product, which in pediatric patients also has persistence with two to three years or longer, very similar to what we've seen with obe-cel.

And of course, as we have seen with Kymriah before, obviously, the safety profile that we have with obe-cel obviously is better because of the different way of engaging the CD19 antigen. All of this is done at the exact same dose level that was used with obe-cel in the pediatric studies, which is 1 million cells per kilogram. So we know that our profile is absolutely overlapping on actual clinical data in pediatric ALL patients with the product that was actually ultimately then used in the autoimmune patients in Erlangen.

Now the additional point, I think, here is because we obviously know what the dose is and we have a lot of safety data, obviously, from our product at that level, what we're doing now is moving the product into a single

dose rather than actually have -- or a fixed dose rather than having a weight-based dosing, which is 1 million cells per kilogram, which you have to do in children because of the wide range of body size that you actually have between one year olds and young adults.

Obviously, here in autoimmune diseases, we're dealing with typically with young adults or adults in general, and so we can actually pick a fixed dose, which simplifies the operation at the clinical center and it reduces any possible dosing errors that could happen as a consequence of the variable dosing regimen. So we're exploring, therefore, and confirming the fixed dose here at 50 million cells in six patients. And with that, we believe we're actually well set to then take the next step and move this product forward and towards a pivotal study.

So this is a quick update on the study and what we're intending to do with it. But also, I think the reference to how it relates to the original data that was generated in field, I think, is important also to understand that we do not have to speculate whether our profile of our product is appropriate for these patients. We know, it's exactly the same profile from an efficacy perspective.

So when we then look into other pipeline programs and technologies, obviously, you'll remember there's a number of programs that are ongoing. And we keep on -- we'll keep updating you on these programs as they progress in their early clinical studies, particularly, obviously also AUTO6NG, AUTO9, which will be transitioning into a clinical study as well during the course of this year.

So with that, I'd like to hand over for the financial results to Rob.

Rob Dolski^ Thanks, Christian. And I'm going to be on slide 26, the financial summary.

Good morning or good afternoon to everyone. It's my pleasure to review our financial results for the full year 2023. Our cash and cash equivalents at December 31, 2023, totaled $239.6 million as compared to $382.4 million at December 31, 2022. Our total operating expenses net for the year ended December 31, 2023, were $179.7 million as compared to $143.4 million for the same period in 2022.

Our research and development expenses increased from $117.4 million to $130.5 million for the year ended December 31, 2023, compared to the same period in 2022. This change was primarily due to increases in operating costs related to the company's new manufacturing facility, contractual milestone payments, and headcount related costs, as well as a decrease in our UK reimbursable R&D tax credits claimed through the UK small and medium-size entities. These were partly offset by decreases in clinical and manufacturing costs associated with the obe-cel clinical program.

Please note in prior years, Autolus reported the R&D tax credit as income tax benefits on the statement of operations. The company has revised its financial presentation, including the prior years and will now present such tax credits as a reduction in R&D and development expense. As a result, income tax benefit has reduced by $19.5 million and $24.6 million for the years ending December 31, 2023, and 2022, respectively, with the corresponding reductions in research and development expenses and total operating expenses.

Moving on to general admin, our expenses increased from $31.9 million to $46.7 million for the year ended December 31, 2023, compared to the same period in 2022. This increase was primarily due to an increase in general administrative headcount supporting the overall growth of the business, primarily related to pre-commercialization activity.

Our net loss attributed to ordinary shareholders was $208.4 million for the year ended December 31, 2023, compared to $148.8 million for the same period in 2022. All those estimates with its current cash and cash equivalents and proceeds received from the strategic alliance with BioNTech and our equity financing, we are well capitalized to drive the full launch and commercialization of obe-cel in relapsed refractory adult ALL as well as advance our pipeline development plans, which includes providing runway to data in our first pivotal study of obe-cel in autoimmune disease.

I'll now hand things back to Christian to wrap up with a brief outlook on expected milestones. Christian?

Christian Itin^ Thanks, Rob. So a quick look on slide 28 on the planned news flow, obviously, clearly a significant focus on obe-cel delivery. First, on data, as I mentioned, we're planning to update at the ASCO, EHA, and ASH this year. This is going to be for the June and December timeframes. And we're planning to submit to the UK MHRA a marketing authorization application in the second half of this year.

We know what to say our PDUFA target action date, November 16, this year, and we plan to show the first data from our SLE Phase 1 study towards the end of this year. In addition, obviously, there will be updates on order rate expected for the end of this year as well as opportunities, certainly, for publications during the course of this year from a number of our programs. So this is kind of a quick update on the planned news flow.

And in terms of summary, going to slide 30, obviously, we're in a very strong position with the company. We've been executing very consistently during the entirety of the last two years. We've continued on this exact same pace into 2024, and we continue to do so. We have a strong cash position in the business, as indicated the pro forma, we started the year with north of $800 million in the bank between the year-end cash of the BioNTech transaction and the equity raise that we conducted at the beginning of February. And obviously, this gives us a very strong base to not only drive our lead program forward onto the market and through the launch, but also expand the opportunity beyond, in addition to also the opportunity to expand from a pipeline perspective also through the options granted to BioNTech.

When we think about the capabilities we've built, we are obviously in a very good position with regards to our commercial manufacturing capabilities. That's been an enormous lift over the course of the last years. It was also very significant investment that we have conducted through in that period. Obviously, those costs obviously are going down because a lot of the capital expense related costs is obviously have some -- are behind us. And with that, we see a shift of expense moving from the setup costs for the facility, completion of the pivotal study in ALL, moving over to launch related -- launch preparation related costs.

So that's sort of the key swing that we'll see as we go through the course of this year. And I think we have significant opportunity with the pipeline and also with obe-cel to expand from an indication perspective and also from an overall product opportunity perspective.

So overall, I think we're in a great spot, I think, great outlook for this year. And we're looking forward to taking your questions. Thank you.

+++ q-and-a

Operator^ (Operator Instructions) James Shin, Deutsche Bank.

James Shin^ Hi, good morning, guys. Can you hear me? I'm on a bus. I apologize, if there's any background noise.

Christian Itin^ No worries. Light and clear. Hi, James.

James Shin^ Hi, Christian. Question on the MHRA approval. Does their inspection have any overlap with the FDA or EMA or any other upcoming inspection? And then I have a follow up obe-cel for lupus and ALL.

Christian Itin^ Right, so the MHRA inspection and license is a prerequisite for us as a company to be able to export, whether this is going to be to the US or to the EU. So it is independent and separate from a US FDA perspective, but it is linked to the European filing. In fact, it is a prerequisite for the European filing.

It is actually the fact that the facility has to actually have a certificate from the MHRA even to file with the European agency. So that's obviously where it's directly linked to the European side and it is a necessity for the US side but independent of the FDA review of the facility.

James Shin^ Is there any like overlapping metrics from the MHRA inspection with FDA inspection, by chance?

Christian Itin^ Well, first of all, obviously, the fundamentals are the same, and this is all around, the GMP manufacture and the guidelines associated with GMP manufacturing. So the basis for the inspection, the basis for review is the same basis. So there's no difference there. But they're two independent bodies that actually do the independent reviews, whereas in Europe, the European agency relies on the MHRA's review.

James Shin^ Understood. And then as you prepare for obe-cel ALL launch, [a lot on call you spoken to] is focused to quality product in a timely manner, given the dire condition of the patient. If you look at some of the peers cell therapy launches, (inaudible) pick up, what is obviously to make sure or what have you learned from the peer launches (inaudible)?

Christian Itin^ Yeah. I mean, I'd say it's absolutely relevant question. And in fact, when we talk to physicians that are at (inaudible), the top question coming back or the top voice coming back is we need access to product. And so the ability to get access to product, to get slots, to get the product in time is absolutely critical. And it's a reflection of some of the challenges that the centers experience with prior launches.

So we spend a lot of time, obviously, optimizing our systems, minimizing the turnaround time will be in terms of delivery time at around 16 days

at time of launch. And we're also going to do obviously full runs from each one of the centers through the entire chain to ensure that from every center actually, the flow and the processes are fully operational before launch -- before we're getting to launch.

So there's going to be -- not only the processing have been adjusted to simplify, but also it's going to be a whole bunch of dummy runs from all of those centers to ensure that indeed all aspects of that (inaudible) actually are fully ready and fully (inaudible) for each individual center.

James Shin^ Appreciate that. And then finally, on CARLYSLE, have you considered any of the -- or the prospect patient? And then what are the gating factors to get a subsequent fit patient?

Christian Itin^ So we haven't guided actually on dosing or not doses. Study is open. It's enrolling. The study itself is not a dose escalation study. So we don't have TLT periods. And we're not limited by the typical Phase 1 dose-finding studies, which you'd have to go through with review process (technical difficulty). So we have an ability to actually enroll out all of these six patients as they become available.

We don't have limitations on the study design that would actually gate or slow down the process.

Operator^ Asthika Goonewardene, Truist.

Unidentified Participant^ Hi, guys. This is Carina for Astika. Thanks for taking the question. So I had a question on the FELIX update of ASCO. Besides the longer follow-up, what new data can we expect in this presentation? And also will it be able to paint a clear picture of what obviously all can do in terms of favorable impact for patients outcomes without the need for transplant?

Christian Itin^ So in terms of the -- thanks, Carina. In terms of the FELIX study and what we're expecting to do, obviously, there is a quite a significant level of information within the FELIX study that we haven't actually really worked through or presented yet. The impact of bridging in more detail, what are the components that matter there. There are other components as well. They follow up as well. And there's other risk factors and risk category, a study actually start to see as you go through the data that I think are very helpful and I think very informative.

So there's going to be additional sub analysis -- longer term view, but also additional sub analysis that we're going to be -- we'll be presenting through the course of this year. So that's the first part.

The second part is actually we also have been looking at the impact of transplantation. That's certainly also an area that we're planning to report on as we go through the course of this year. Obviously, an interesting question there is do we think it is actually -- look back, and it's actually improving the outcomes or do you actually have a different type of outcome here? And those are questions we're evaluating, and we'll certainly our reporting as we go through the course of this year. If not at ASCO, then certainly at ASH.

And the data presentations for EHA and ASH later on, that's just an encore of the ASCO presentation?

The presentations are somewhat related, but there's no data the abstract are not identical between the two. They may share some of the data. But in terms of the focus, it's slightly different.

Operator^ Gil Blum, Needham & Company.

Gil Blum^ Hey, good morning and good afternoon. Thanks for taking our questions. So our first question kind of focusing on the bridging aspect in the study. This is something that has also recently come up in the advisory committee materials for (inaudible). It looked like bridging had a pretty important impact on patient survival even before you got there, no treatment. And in many ways, maybe the fact that you allowed physicians to pick their bridging may have actually assisted you here. And how can you optimize bridging? Is there like a study to be done here?

Christian Itin^ It's a really good question. I think first of all, the situation is obviously a bit different between (inaudible) and adult ALL. In (inaudible) progression of disease is much less ramp and much less significant in terms of the speed of deterioration as you would have in ALL. ALL, obviously, can go -- as you've seen, patients go from minimal residual disease to more than 75% tumor burden. I mean that gives you a sense of the explosiveness of the disease.

So bridging is obviously something that we have to do these patients. Otherwise, the tumor burden actually gets overwhelming and in of itself becomes a limitation in these patients. But as you could see, also the impact can be that you either have no -- see no impact whatsoever and the patients just go straight over, stays above 75%. It certainly (inaudible) refractory in the very functional -- as a very functional determination.

But you also may have patients that actually transiently may actually have a significant decrease in tumor burden between enrollment and the actual dosing. And that does have an impact in the sense that the level of tumor burden at lymphodepletion, so right before you are dosing, obviously, it seems to actually have quite a significant impact on outcome. This is the data that we have shown we just walk through a little earlier. So that is absolutely true. That is what you do see.

And it seems better correlated than actually the tumor burden at the time of screening or inclusion because that obviously is somewhat arbitrary. It just happens to be when you actually see the patient, determine the level of tumor burden, and that's obviously could be at any level in the relapse.

And so at the time of reaching, obviously, that gives you much more relevant information. It's part of the therapy and it's always been part of the therapy in ALL. Even if you look at other therapies, at times, if you have an excessive tumor burden, you would actually first intervene with a short course of chemotherapy to push and tumor (inaudible) before you dose.

So one of the things we have done during get inside to development. It actually was important. So also not only improve or have a chance for outcome in that approach, but also to reduce the risk for very severe adverse events. So it is an integral part. And what we certainly will do

is over time is to probably look at different types of bridging and whether we might actually see differences there. So that's certainly part of the analysis. We're also still running through the trial, and it may actually pose, I think, opportunities for also potentially investigator-sponsored study entry.

Gil Blum^ Okay. Switching to autoimmunity, you mentioned that there are a lot of similarities between obe-cel and the German ISD asset. There are a couple of other companies out there who are also have very similar programs to German ISD. What would you say is a differentiator between your program and other products? What do you think is your key advantage?

Christian Itin^ Well, the first thing I think which is interesting is that it's not -- I think is that we can make a statement to our product as it stands. How that may compare to others? I think is very difficult because for the most part, we don't have data to compare to. But we do have data to compare our product to the product that was used in Erlangen. And that is relevant because that gives us a very clear understanding of the features that product in Erlangen had versus ours. And with that, the predictability for outcome. And I think that is relevant.

And I think what we do see also compared to the Erlangen program is that as we had seen prior in the pediatric ALL patients, if you compare the CARPALL study to the ELIANA study from a safety perspective, there's a very significant difference there where we have -- none of the kids actually experienced high-grade CRS where compared to 47% patients with high-grade CRS is the ELIANA study. Both studies were conducted within a very short period of time, actually overlapping each other as well. So same environment, same way of treating patients and managing safety, et cetera.

So we do know that we have a quite a significant difference there. And that difference also was observed and was observable when comparing to the program that was running in Erlangen on pediatric patients, which obviously prior to the work that we all know about on the -- over the enzyme.

Gil Blum^ Perfect. And maybe a last one on this topic. So most discussions that we had on the use of cell therapy in autoimmune diseases suggest that only a relatively small window of the (inaudible) needed to, quote unquote, reset the immune system. I mean, I guess that's one hypothesis that is out there. I'm sure you have different view on that.

Christian Itin^ Yes, I mean it's interesting. There's obviously a lot of hypotheses and that sort of gets me back to actually what we know works. And so what we know works is a product that is a long persisting product in pediatric ALL when used in autoimmune patients, which has a very active immune system. As a consequence, the persistence, of course, is shorter than in highly in compromised pediatric ALL patient. You do see that, that product with that type of properties gives us the type of outcome we're seeing. To suggest that a product that wouldn't actually be active in pediatric ALL would be able to do the -- get the significant outcome in over the new patients, I think it's a possibility can set up, but it's certainly there's no data that would support that at this point.

So what we know is that a long persisting CAR T program gives you the right outcome that we were looking for. We know, our product has exactly

those properties. And I think everything else, you know, people will have to actually run trials and actually figure that out. But it is not, I think, very easily understandable for why you would make that correlation. If you start with a product that is not -- may not be really active or substantially active in pediatric ALL. And then conclude that it would still work in autoimmune. It may. But I think at this point it's subject to state in the absence of data.

Operator^ Eric Yang, William Blair.

Eric Yang^ Hi, Eric on for Matt Phipps. I was wondering, firstly, with the additional cash on the balance sheet, I was wondering how you're thinking about obe-cel develop in other lymphoma indications and if you plan on enrolling any additional patients within NHL or CLL.

Christian Itin^ Thanks, Eric, for joining. So we are currently looking at the quite a range of indications, and we're sort of looking at where we wanted to actually put our bets at. And we're clear we're going to have at least one pivotal study in autoimmune.

And we're looking whether there would be a second autoimmune pivotal study or whether we're going running an oncology study in one of the non-Hodgkin's indications. And that's currently actually under evaluation. That's not yet decided. But we're probably going to generate some additional data also for the cell in the non-Hodgkin's indications, just to round out the experience that we have made so far.

Eric Yang^ Great. And then just additional question. So I know you've had to do next-generation sequencing on patients for enrollment in AUTO4 and AUTO5. And that paper you guys published in the Blood Journal Cancer on the TRBC1 and 2 staining. I was wondering if you think that paper could be supportive of a potential companion diagnostic for AUTO4 and 5?

Christian Itin^ It's a really good question, and that's obviously the reason why we're still working together with the parties you had on the paper. That, obviously, if you can move away from NGS and go to an antibody that you can actually use and with classical staining, that obviously would simplify the approach and probably also accelerate it. Because obviously, if you go with NGS, you actually -- you need to have the sequences, the right drivers, et cetera, specific hand, and then actually run the analysis. It's not trivial.

This could be easier. And it also would actually allow you to include these staining procedures in a more standard panel of stains that you'd be using to characterize tumors. It may actually lead to already a determination of TRBC status in patients ahead of even having -- basically, include them in a therapeutic approach. But how we'd like to have CD19 and other markers or standard markers to analyze, have them actually move also in that direction. And of course, as you point out, it gives you the opportunity for companion diagnostic based on the staining procedures.

Operator^ Yanan Zhu, Wells Fargo.

Yanan Zhu^ Thanks for taking our questions. First, on SLE, I know you mentioned you're not guiding for dosing or not dosing. I'm curious about the level of interest at your first clinical site? And also, regarding your guidance for data late 2024, I was wondering about the number of

patients at the time of readout and the duration of follow-up. Do you have a minimal and [bioful] duration to follow-up?

Christian Itin^ Thanks, Yanan, and thanks for joining. First of all, the study we're conducting in the UK and in Spain -- in the UK, there are actually no competing studies for these types of patients. So that puts us in a good position and one where we think actually, we have obviously very interesting standout feature around the study and opportunity for patients. In terms of data, in the near, we received -- are expecting that we can involve the six patients and we are able to report on those six patients. How much follow-up will have all of them, I think that's premature to sort of point to. But the goal would be to actually have the cohort enrolled and then report on data from that cohort.

Yanan Zhu^ Great. Thanks for those colors. On FELIX, wondering for the midyear data update, would the data be a pooled analysis or would it be the pivotal cohort? Also, since you commented on your bridging therapy strategy, I was wondering, does that have any implications for FDA review? Thanks.

Christian Itin^ Yeah, really good question. So in terms of the data update, obviously, as I indicated, we're looking in particular at different risk groups within the data set. Sa that's going to be a key focus. And I think we're going to be off to the -- the general uptake will be likely across the entire study because from a physician's perspective, that outlook is actually what's really relevant because that reflects the patients that you would actually see in actual practice. And so we're probably going to report on that as a reference point, referencing back to the ASH data.

The bridging itself, obviously, is relevant in the sense that the analyses that you can run in two different ways and different agencies take different positions on it. Look at the analysis based on the tumor burden that screening, which is basically, frankly, the time point where any physician can look at the patients and you focus on the patients that have more than 5% tumor burden. Those are the morphological patients. That's the intent to treat. That's certainly the position or the primary focus you'll see with the European agency as the primary view, which is to the physicians view, this is when the physician can make a decision, okay, this is the patient that gets included. What is the outcome related to that?

And then there, when you look at the review process for Blincyto as well as (inaudible) the focus the FDA has is more of the patients that actually have 5% tumor burden at the current point of dosing. And so that would be 5% at lymphodepletion. And it would be that category of patient, which is the primary group for assessment.

So that different phase and different views that are taken in terms of analyzing data and it really depends on the agency. But that's the fundamental difference on what we're seeing based on prior review history in space.

Operator^ Kelly Shi, Jefferies.

Unidentified Participant^ Hi, this is Dave on for Kelly. And thank you for taking our questions. I have a couple of questions. One is you did analysis of the cell -- German product, which is similar, can you talk

about what kind of patient baseline you are thinking about enrolling in your study? And for data presentation, are you thinking of presenting it at the medical conference?

Christian Itin^ Yeah. So when we look at the patients that we're enrolling in the study, we're enrolling patients that have, I'll say, our lupus patients that have or do not have kidney involvement. So both manifestations, we do see, we do have patients as that's done in at the year-long study. So we'll have at least one organ involvement in these patients. That very much tracks alongside what you have seen and read about in the publications from the Erlangen team. That's very comparable patient population that we're enrolling in terms of inclusion exclusion criteria.

The plan would be for us to see that we can have our first data at one of the medical conferences at the end of the year. So that would be the plan.

Operator^ Jacob Mekhael, KBC Securities.

Jacob Mekhael^ Hi, there, and thanks for taking my question. I have a few about to take. First, I have a question on the option agreement with BioNTech on AUTO1/22 and AUTO6NG, what do you need to show or reach with the program to trigger an opt-in from BioNTech? That's my first question.

Then perhaps more of a broad question on autoimmunity here. Given the larger patient population we're talking about, from your point of view, what needs to happen in the CAR-T ecosystem to ensure that if approved, the treatments -- or there is enough capacity in the ecosystem to ensure that those patients have access to those treatments? Thank you.

Christian Itin^ Thanks, Jacob. I think two very good questions. So first of all, with regards to the option agreements on AUTO1/22 and AUTO6NG was that the option agreement is structured such that the options have to be exercised before we start our pivotal studies with those programs. So it's actually triggered by progression. It's not defined by a defined outcome or defined certain level of activity. It's the actual decision to move forward into a pivotal study.

So that's the latest time point for the exercise. It can happen before but that's the latest time point. So that's the sort of the option exercise question.

In terms of the breadth with regards to autoimmune indications, I think the first observation is that we expect that the initial application for CAR T will really be in, what often referred to as, the more refractory type of population in those indications. So that's intrinsically a small -- a relatively small part of the overall autoimmune indication that you'd be looking at. So the overall lupus population, you may look at a few hundred thousand patients. But actually, what we expect to go in and to be amenable for a CAR-T approach that may be in the few thousands. So it is a smaller subset. And we expect that to be true also with some of the other indications.

So from that perspective and moving into this disease setting, we would expect that capacity actually have the ability to serve, if it's doable and will be there. One of the questions will be ultimately with some of the other indications is [overall] you will actually be able to go into

these indications and have an adequate value proposition for these patients. And I think that's something we're still need to learn on how far into these earlier stages or less severe stages of disease is it sensible to actually bring in a therapy like a CAR-T therapy. And I think that's something -- we'll be frank and we still need to figure out and we need to generate data in the field to get a better understanding of where the right place and how broad that position can be. The initial positioning we believe is very well served with the current types of infrastructures and technologies.

Operator^ Thank you. That's all the time we have for questions. I'll just turn the call back to Christian Itin for closing remarks.

Christian Itin^ Well, thank you very much for joining today. I would say great to have an opportunity to really review. I think all the progress we've been able to go through the course of last year and into this year, a lot more to come this year. We appreciate the continued support and interest. And wish you all a great upcoming period and looking forward to connecting in person again. Thank you.

Operator^ Thank you for your participation. This does conclude the program. You may now disconnect. Everyone, have a good day.