

Michael Fainshtein, CEO of MIRCOD group
“MIRCOD BIOTECH SOLUTIONS”

MIRCOD group of companies are based out of the United States, Russia, Israel, Europe, and in particular, specializing in automation for biotech equipment. The company focuses on treatment of oncological, onco-hematological, autoimmune, and lysosomal diseases. They are dealing with viral diseases, metabolic, and autoimmune diseases, as well as kidney disease.

[What we provide]

Equipment for CAR-T and CAR – NK, as well custom CGT (custom Cell and Gene Therapies). These are the type of chimeric antigen receptor T-cell therapies related to cell and gene therapies where we reprogram the human stem cells in order to hunt and attack the cancer cells. The equipment consists of special designed, state of the art, close loop electronic systems, telemetric software control system and disposable cartridges. It takes between two to three weeks to generate the particular drug from the patient stem cells, that is ready to be infused in the patient body once activated and transduced with the special created lentivirus. The equipment creates the drug from “A to Z” according to preconfigured treatment in a fully automatic mode.

The point of care provides scientists and healthcare specialists with the ecosystem consists of interconnected modules; including centrifuge magnetic separators, special bioreactors (stirred, hollowfiber, conical, etc.), low volume reservoirs, cooling systems, cell activation and transduction subsystems, virus ultrafiltration, diafiltration and concentration – for activation, transduction and expansion of the human cells. Our hardware ecosystem built from standalone sub-systems that could be used in laboratories by scientists, as well as the doctors completely independently.

For an example, scientists can use MIRCOD bioreactors to develop their proprietary protocols for cell expansion or activation.

The mentioned above ultrafiltration and concentration systems might be used as a standalone automated line for lentivirus products.

We grant our customers the efficient system allowing personalization of cell and gene therapies, too address the worlds’ most challenging diseases.

Among the biggest advantages working with MIRCOD close loop systems is ability to develop CGT without an expensive bio-isolators or renting/certifying/building or investing in a special, multimillion clean rooms.

All processes running with MIRCOD equipment are remotely tracked and controlled from any point across the globe. Together with our partners we provide mobile laboratories that might be deployed in small containers near hospitals, research centers, universities etc... These mobile laboratories are certified by USA and Europe authorities as Biosafety Labs, Levels 1, 2 and 3 needless to say, these mobile labs might be used for vaccine production.

[The Market]

The market for such therapies as well as such treatments is a constantly and almost exponentially growing market. Aside from oncology diseases MIRCOD technology suitable for regenerative medicine, cosmetic industry, as well as rare diseases treatments. All systems designed as OEM or ODM and could benefit from its own branding according to the customer business model.

We will be honored to find partners in Japan for strategic business relationships, as well as a pharma companies interested in process automation or technology innovations.

[Q & A]

Q.

When I'm thinking out loud, if you look to the Japan, let's say approval process and how Japanese products are approved. And the organization MHL was a bit conservative in the past now, there has

been a major shift. And now especially with cell therapies, they are one of the front riders in the world with allowing also patients to be treated with cell therapies. And I think that's really something that could be interesting for you. Understand, you're looking for commercial suppliers, but maybe work with the small biotech Companies on cell therapies in Japan could maybe helping you establishing yourself in Japan, not as a seller of the equipment, but as a collaborator in these kinds of studies.

A.

But as a matter of fact, we do provide this equipment to the small companies as well. Our equipment grants the ability to penetrate complicated CGT industry with relatively small cost. Our clients can save the initial investment necessary to build their own clean labs, in particular, for CAR-T and CAR-NK. So, as you might be aware, the entrance barrier for CGT personalization stands in between 15 to \$20 million - just to start. In our case, it starts from a few millions.

Q.

Does your products need to be approved prior to using them for clinical studies?

A.

Absolutely. Anything related to manipulation with human cells with the final goal to create a cGMP compliant product has to go through a strict verification and validation process.

Depends on a desired results, our systems might be a subject for FDA or similar local regulators.

You basically reprogram the human cells, in order to create "Natural Killers" capable to eliminate certain cancer cells. So, it's completely logical for such a systems to fall under a very strict supervision and to be approved by the dedicated regulators.

Q.

For the automation the AI is another accept people are interested in. To do that, your equipment has to have the certain sensors to monitor the state of the product development, manufacturing process itself. Do you have any plan or you already implemented the some devices to other or AI?

A.

We have more than the 100 different sensors embedded inside of the equipment, including the most complicated biomass sensors, etc.

Obviously, algorithms related to data processing, have to be based on rule based engine or certain AI modules. In many cases we have an agreement with third party providers providing us with the unique BI and BA the big data, while each equipment generates terabytes of information during the work.

Q.

It looks like your product is specified for the mammalian cells, but can you adapt that for the bacteria or yeast?

A.

It's been adapted already, while I presented our ecosystem as an automated equipment for certain cell and gene therapies, the fact, the equipment is ready to answer on the most challenging problem related to all aspects of microbiology, drug formulation and manufacturing. Our big bioreactors you can easily use in order to create wonderful beer, too.

Q.

I have one suggestion is for the use of your system. I can say there are many Japanese academic researchers who wants to make a small size production of either cell therapy or antibodies. And then there is a Japanese public grant, if you coupled between academia and industry, you can propose for, to get the money. So I think it could be a good chance for you to start to begin with academic partner. And if you have a capability to produce antibody, I have not heard of it. And I think that'd be even

greater chance.

A.

As a matter of fact, we already cooperate with the biggest universities in many countries: including UC Davis, California University, universities in UK, Middle East, as well as Europe. So it's definitely in our area of interests.

And, it's funny, now I'm sitting with two "hats". From one point of view, we're always looking for the investors. But from the second point of view, we would be happy to invest ourselves in any research related to cell and gene therapies based on our area of interest.

So we do subsidize or we do provide this type of equipment to universities, in most cases for a small compensation and looking for cooperation with academic houses and people.

Q.

Can you share with us a real world example of your system in supporting the CAR-T process?

A.

Should I send the link for the video? Practically we already working in Korea and middle-east. We are working in the United States and China as well. By saying all mentioned above, we just received the permit for development of custom personalized treatments (as a PK) on 20 human subjects in Russia.