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LETTER from the Chair and CEO

Since our inception in 2007, the Melanoma Research Alliance (MRA) has been laser-focused on advancing cutting-edge research needed to achieve our mission. With our singular vision, MRA stands as the largest private nonprofit funder of melanoma research in the world.

Today, MRA has proudly invested more than $143 million through 415 grant awards. We support the world’s best, most promising science and research and are guided by the expertise of our world-renowned Grant Review Committee. We support research from bench to bedside and beyond while helping patients and families navigate the ever-evolving treatment landscape.

MRA-funded investigators have been behind every major breakthrough in melanoma research since our founding. That’s 15 new FDA-approved treatments that have transformed what it means to be diagnosed, treated for, and live with melanoma. Patients are living longer and fuller lives than ever before, and there is so much to be grateful for.

Melanoma research has energized the entire field of oncology and created a new paradigm for how cancer is viewed. Therapies conceived, tested, and approved first in melanoma are now used to successfully treat patients with twelve other types of cancer and are being tested in dozens more.

And, as you’ll see throughout this report, we are not resting on our laurels. That’s because for as much progress as we’ve made, we still haven’t achieved our mission of ending suffering and death due to melanoma. To be direct: too many lives are still being tragically cut short and too many families are being forced to say goodbye, too soon.

Featured in this report are some of our key achievements over the past year. These examples highlight our capacity to partner with stakeholders and fund scientific studies that are continuing to change the way we think about melanoma in the lab, in the clinic, and around the world.

We are deeply grateful for the patients who participate in research and the support of our advocates, donors, volunteers, partner organizations, government leaders, and corporate allies who help us lead the charge in melanoma prevention, detection, and treatment. We anticipate another year of impactful, new findings in our mission to eradicate melanoma and look forward to working with all our partners and supporters.

With gratitude,

Debra Black
Chair and Co-Founder

Marc Hurlbert, PhD
Chief Executive Officer
MRA By the Numbers

$143 million in grants
500+ funded investigators
415 research awards granted

$415+ million in leveraged and follow-on funding
19,537+ donors
18,000+ people have used MRA’s clinical trial navigator to find personalized clinical trial results in their community

MRA supported research... at 159 institutions and in 19 countries

211 different agents for treatment of melanoma studied
722 corporate partners who’ve raised $64 million to support melanoma research

100%
of all donations go directly to research—no admin, development, or other fees
Timeline of FDA Approvals for Melanoma

2007

**NOV 15** The Melanoma Research Alliance (MRA), founded by Debra & Leon Black, held launch meeting of global experts to identify scientific and clinical questions that need to be addressed in order to transform the field of melanoma detection and treatment.

2011

**MAR 25** FDA approved Yervoy — the first anti-CTLA-4 checkpoint immunotherapy — for patients with advanced melanoma. *This represents the first checkpoint immunotherapy to ever earn FDA approval, for any cancer. It also represents the first new melanoma therapy to earn FDA approval in over a decade.*

**MAR 29** FDA approved Sylatron — a type of immunotherapy called an interferon — for the adjuvant treatment of patients with melanoma following surgery.

**AUG 17** FDA approved Zelboraf — the first BRAF inhibitor therapy — for patients with advanced melanoma with a BRAF mutation.

2013

**MAY 29** FDA approved Tafinlar — a BRAF inhibitor therapy — for patients with advanced melanoma with a BRAF mutation.

**MAY 29** FDA approved Mekinist — a MEK inhibitor therapy — for patients with advanced melanoma with a BRAF mutation.

2014

**JAN 10** FDA approved the combination of Mekinist + Tafinlar for patients with advanced melanoma with a BRAF mutation.

**SEPT 4** FDA approved Keytruda — the first anti-PD-1 checkpoint immunotherapy — for patients with advanced melanoma. *This represents the first anti-PD-1 checkpoint immunotherapy to ever earn FDA approval, for any cancer.*

**DEC 22** FDA approved Opdivo — an anti-PD-1 checkpoint immunotherapy — for patients with advanced melanoma.

2015

**SEPT 30** FDA approved the combination of Opdivo + Yervoy for patients with advanced melanoma.

**OCT 27** FDA approved Imlygic — an oncolytic virus therapy — for patients with advanced melanoma.

**NOV 10** FDA approved the combination of Cotellix + Zelboraf for patients with advanced melanoma with a BRAF mutation.

2017

**DEC 20** FDA approved Opdivo for the adjuvant treatment of patients with melanoma following surgery.

2018

**APR 30** FDA approved the combination of Tafinlar + Mekinist for the adjuvant treatment of patients with melanoma with a BRAF mutation following surgery.

**JUN 27** FDA approved the combination of Braftovi + Mektovi for patients with advanced melanoma with a BRAF mutation.

2019

**FEB 15** FDA approved Keytruda for the adjuvant treatment of patients with melanoma following surgery.

2020

**JULY 30** FDA approved the combination of Tecentriq + Zelboraf + Cotellix — bringing BRAF/MEK targeted therapy together with PD-L1 checkpoint immunotherapy — for patients with advanced melanoma with a BRAF mutation. *This represents the first ‘triplet’ therapy to earn FDA approval in melanoma.*

2021

**DEC 3** FDA expanded the approval of Keytruda for the adjuvant treatment of patients with stage IIB or IIC melanoma following surgery.

2022

**JAN 25** FDA approved Kimmtrak — a novel immunotherapy called a bispecific fusion protein — for patients with unresectable or metastatic uveal melanoma. *This represents the first bispecific fusion protein immunotherapy to ever earn FDA approval, for any cancer. It also represents the first therapy to be approved specifically for a rare melanoma subtype.*

**MAR 18** FDA approved Opdualag — which combines two distinct checkpoint immunotherapies into one medicine — for patients with advanced melanoma. *This represents the first LAG-3 checkpoint immunotherapy to ever earn FDA approval, for any cancer.*
Leading the Charge
Reflecting on a Decade of Progress and Future Heights

If you told Dr. Jedd Wolchok at the start of his oncology career what melanoma research would look like today, he likely wouldn’t believe you. Wolchok, now a world-renowned medical oncologist and Meyer Director of the Sandra and Edward Meyer Cancer Center at Weill Cornell Medicine, originally faced an alternate reality from where we find ourselves today.

When Wolchok began his career in oncology around the year 2000, the treatment options for and enthusiasm about melanoma research were slim:

- There was chemotherapy, which only benefitted a slim minority of people,
- There was high-dose interleukin-2, whose response rate was just 3-5% and included significant toxicities and side effects,
- There was flat-out rejection by many oncologists regarding the use of immunotherapy, and
- Funding opportunities, needed to upend the stalled research landscape, were few and far between.

So why would a promising young doctor want to specialize in such a field? Many shied away from melanoma at pivotal points in their training and careers; Wolchok himself was actively discouraged from specializing in the field. As Wolchok explains: “It was a hard slog uphill because there was not a lot of enthusiasm.”
But Wolchok and a small group of oncologists persevered. “There were some of us who were elbow-deep in the science and had our ear to the ground about where the basic science was leading in terms of new pathways that controlled immune regulation,” says Wolchok. Where others saw failure, Wolchok saw potential. Yet the path forward was anything but clear.

A few years later, an immunologist by the name of James P. Allison, PhD, was recruited to Memorial Sloan Kettering, where Wolchok worked at the time. Allison, now a Nobel laureate, was studying the CTLA-4 immune checkpoint pathway and discovered the medication now known as Yervoy (ipilimumab).

Wolchok volunteered to be a principal investigator in the medication’s early clinical trials—and by 2010, a watershed moment arrived: the ipilimumab phase 3 trial demonstrated the first-ever statistically significant survival benefit for people with metastatic melanoma.

The breakthrough caught the attention of the scientific community, and its excitement was felt far and wide:

- The clinical trial result took center stage at the American Society of Clinical Oncology (ASCO) Conference,
- The *New England Journal of Medicine* published its seminal “Improved Survival with Ipilimumab in Patients with Metastatic Melanoma” article,¹
- Interest in and research investments for melanoma research soared,
- In 2011, the U.S. Food & Drug Administration approved Yervoy (ipilimumab) for patients with advanced melanoma, the first checkpoint immunotherapy to ever earn FDA approval for any type of cancer, and
- Within the next decade other checkpoint immunotherapies, including anti-PD1, LAG-3, and combination medications were developed and approved—creating a drastically different treatment landscape for patients and doctors alike.

It was nothing short of a sea change.

For Wolchok, progress was personal: “The most palpable change for me was my waiting room. It used to be that when you treated a disease that had a 6.5-month median survival, your waiting room wasn’t necessarily full of familiar faces. Now, many of my patients recognize each other and see each other over years. It’s a visible and welcome difference.”

Wolchok adds, “I’m sending people who I’ve treated for widely metastatic melanoma to survivorship clinics now. These are people who would have been predicted to have lived for just a few months. I’m so grateful to have seen this in my professional lifetime, and to say that the MRA has been a critical part of this journey.”

Jedd Wolchok, MD, PhD

¹The clinical trial result took center stage at the American Society of Clinical Oncology (ASCO) Conference.
And, indeed, what a journey it has been. Perhaps some of the most surprising breakthroughs include:

- Seeing people with brain metastases living for more than a year,
- Treating people with checkpoint blockade before they have surgery,
- Being able to offer nuanced and individual approaches to patients,
- Offering therapies at different points in the illness trajectory to extend life,
- Development of targeted therapies, like BRAF and MEK inhibitors, enabling patients to take pills at home and experience disease regression, and
- Personalized T-cell adoptive transfer (i.e., isolation and reinfusion of T-cells into patients), which is still experimental, but has tremendous possibilities for the field, particularly for individuals for whom checkpoint blockade hasn’t worked.

“What tops everything is the joy and hope that gains in research have given melanoma patients,” says Wolchok. “All of these moments that people never imagined that they would live to see. Things like, ‘I never thought I would see my kids go to college.’ or ‘I never thought I would see grandchildren.’ This has been an amazing accomplishment.”

The field is light years from where it started. But not all progress has been equal. Better therapies are still needed for rare melanomas, such as acral, mucosal, and uveal. In addition, some melanomas are resistant — or develop resistance — to even the latest therapies. These are what Wolchok calls therapeutic challenges, but he cautions that there are also big-picture issues that require attention as well.

There are many unanswered questions, for example: “We don’t know how long to treat people with checkpoint blockade,” says Wolchok. “Most of these medicines are approved without an end date. From a patient safety and societal healthcare utilization viewpoint, we have a responsibility to tighten that up. If someone has a good response to treatment, maybe we should just stop. Maybe there’s no need to keep pounding away with the possibility of creating a toxicity in someone who’s already cured.” The PET-Stop clinical trial is currently seeking to answer this question by examining the safe discontinuation of anti-PD-1 immunotherapy after one year of a normal PET scan.

Wolchok says another area of ongoing research is adjuvant therapy (i.e., therapy after surgery). Although therapy can help prevent a recurrence, recurrence isn’t a certainty. “That’s one of my biggest fears,” says Wolchok, “that we end up treating someone that’s already cured, creating toxicity, and then unintentionally causing more harm than good. We have an obligation to try and come up with ways to distinguish people who have no evidence of disease from those who may have minimal residual disease. These are important topics…and when it comes to our new therapeutic tools, we need to understand how much is enough.”

Despite remaining obstacles, however, Wolchok believes now is a time of immense hope: Hope for patients, hope for the field, and hope for the future.

It’s a future that has been dramatically changed thanks to the Melanoma Research Alliance (MRA). Wolchok says, “MRA minimizes the burden on the investigator: Short applications, almost immediate funding for meritoriously reviewed applications, not a lot of onerous paperwork—just getting the job done.” Wolchok believes that research can control cancer, meaning that when there is enough funding for research and researcher obstacles are mitigated, the real magic can finally occur. And this is exactly what MRA seeks to do.

Moreover, MRA regularly engages a wide variety of thought leaders from bench to bedside when setting research and funding priorities. “MRA looks to the boots on the ground and from the people in the field and asks: ‘What do you think are the most important areas of focus for this year’s request for proposals?’” says Wolchok. This engagement is a reflection of MRA’s commitment to championing real collaboration and acceleration in the field.

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Hope came on March 18, 2022.

It was the day the U.S. Food & Drug Administration (FDA) approved Opdualag, which brings together PD-1 and LAG-3 checkpoint blockade to energize the immune system against melanoma. Once energized, the immune system is better positioned to attack and destroy melanoma cells.

Opdualag combines nivolumab with relatlimab and are given together as one medicine. Both drugs — called immune checkpoint inhibitors — work by releasing the brakes of the immune system, allowing it to attack cancer cells. Nivolumab (brand name Opdivo), first approved by the FDA in 2014 to treat patients with advanced melanoma, targets the immune checkpoint PD-1 and has since been approved to treat patients with a wide variety of other cancers. Relatlimab is a new drug targeting a different immune checkpoint, LAG-3, and is the first anti-LAG-3 therapy to earn FDA approval.

**Opdualag proved to be a tour de force. In clinical trials:**

- Opdualag effectively activated the immune system triggering a potent and durable immune response against tumors;
- While side effects were common among patients treated with Opdualag, they were overall well tolerated, especially when compared to other combination therapies; and
- Most importantly, patients treated with Opdualag lived more than 2x longer without their melanoma growing, spreading, or getting worse compared to patients who received only Opdivo.¹

The benefits also extend to the field at large, where research into Opdualag significantly advanced researcher’s understanding of two different checkpoint pathways and the ways in which they intersect. Not only this, Opdualag opens the door for significantly more patients to benefit from combination immunotherapy.

The journey to FDA approval was a culmination of efforts and discoveries over several decades. In the 1990s, lymphocyte-activation gene 3 (known as LAG-3) was discovered. However, it wasn’t until 2004 that Dr. Drew Pardoll and colleagues at Johns Hopkins University and St. Jude Hospital discovered that it was a new immune checkpoint. But it was not until 2009 that LAG-3’s relevance to cancer immunotherapy began to be elucidated with the support of an MRA Team Science Award.

“Findings from research supported by the MRA grant demonstrated that, while blocking LAG-3 by itself had very little anti-cancer activity, when you combined it with anti-PD-1 [checkpoint immunotherapy], that duo was significantly more effective than either alone,” says Pardoll.

“It’s a situation where 1 plus 1 equals 5—where you get something more than just adding the effect of the two drugs together.”

Findings from this research were published in 2012. “It was a very successful outcome,” says Pardoll. “It’s a perfect example of the outsized impact of MRA funding, which is strategically targeted to push the field further. The full impact of advancements are often not fully understood until an FDA approval years — or even decades — later.”

Like other lab-based discoveries, research into the therapy that would later be named Opdualag was advanced into clinical trials. This is a critical step in the research process as many therapies show success in model systems only to fail when administered to patients. That’s where Dr. Evan J. Lipson, a medical oncologist also at Johns Hopkins, picked up the mantle. “The basic science researchers passed the baton to me and my team of translational researchers. We began testing LAG-3 checkpoint blockade by itself and in combination with PD-1 blockade to understand whether the benefits seen in the laboratory could be translated safely and effectively into patients with cancer,” says Lipson.

The answer was a resounding yes.

Lipson recalls seeing a patient with melanoma who, despite having received nivolumab (Opdivo), had several tumors, each about the size of a quarter. Within just weeks of starting Opdualag therapy, the tumors had shrunk substantially. “It was remarkable,” Lipson says. “The LAG-3 lightbulb came on. The dramatic improvements we were seeing in patients mirrored what Dr. Pardoll had demonstrated in the lab: we can activate T cells against cancer by targeting LAG-3 in ways we can’t by targeting PD-1 on its own.” Almost 3 years later, this patient is off therapy with no evidence of melanoma. Indeed, in many patients, Opdualag’s impact appears to be durable, meaning that after the drugs activate the immune system against cancer, a patient’s immune cells can keep cancer in remission for years.

Although the scientific breakthroughs are remarkable, the real heroes of clinical trials are the patients. “Without patients, there could be no clinical trials,” says Lipson. “I’m grateful to them for saying, ‘I want to partner with you in pushing the cutting edge forward.’ They’re putting their
faith in us that we’re going to provide them with excellent care and learn something along the way.”

Both Pardoll and Lipson agree that these breakthroughs wouldn’t have been possible without MRA—an organization they credit for always prioritizing science, for being real partners in this process, for connecting collaborators, and who they praise for the scientific rigor of its grant proposal evaluation process. Said Pardoll: “The MRA grant was our very first funding to use mouse models to determine how LAG-3 blocking antibodies might be used most effectively in cancer therapy. That helped guide the decade-long translational work by our clinical research colleagues and the rest is history.”

Opdualag is now a standard-of-care therapy for patients with advanced melanoma. It, and other drugs like it, are being studied—and showing promise—in patients with a wide variety of other tumor types, including cancers of the head and neck, colon, stomach, liver, and lung. The successful development of Opdualag from the basic science lab to the clinic is yet another example of how MRA is leading the way in advancing treatment for patients with melanoma and leaving a lasting impact on cancer research at large.

“Without patients, there could be no clinical trials. They’re putting their faith in us.”

Evan Lipson, MD

Evan Lipson, MD speaking at the 2022 MRA Scientific Retreat
Adjuvant Therapy: Is More Better or is Less More?

When Dr. Jason Luke was a medical student at Memorial Sloan Kettering Cancer Center, he had the benefit of a clinical immunology rotation. “I had a front-row seat for really field-defining work,” says Luke. “I was exposed to translational immunology in clinic, which at the time was mostly vaccine-based, but I managed to grow up at the right time when all these novel [checkpoint] immunotherapies that now inform our field were in clinical development.”

Luke, now the Director of the Immunotherapy and Drug Development Center at UPMC Hillman Cancer Center and an Associate Professor of Medicine at the University of Pittsburgh, credits these early experiences with impacting the trajectory of his work, including the recently-expanded Food & Drug Administration (FDA) approval of Keytruda (pembrolizumab) in earlier stages of disease (Stage IIB and IIC) to reduce the likelihood of melanoma returning following surgery (known as adjuvant therapy).

Keytruda, the first PD-1 checkpoint immunotherapy to be FDA approved in any cancer, was approved in 2014 for the treatment of surgically inoperable (unresectable) or metastatic melanoma. This was followed by the approval of Opdivo (nivolumab), another PD-1 immunotherapy, a few months later for the same indication.

Later, Opdivo and Keytruda, in 2017 and 2019 respectively, were approved for use as adjuvant therapies, to reduce the likelihood of melanoma returning after surgery for patients with Stage III disease. This was important, because studies
have shown that adjuvant therapy for melanoma can reduce the risk of your melanoma returning by up to 50%.\textsuperscript{1,2}

However, according to Luke, even this expanded approval still excluded too many patients who might benefit from adjuvant therapy. “Patients who have surgery to remove very deep primary melanomas on their skin, but have no lymph node involvement (Stage IIB and IIC), are at equal if not higher risk of recurrence than some Stage III patients who were eligible to receive adjuvant therapy.”

The misnomer, Luke felt, was that the determination of who was eligible to receive adjuvant therapy was based on surgical paradigms, not necessarily an individual’s risk of recurrence. With the help of Nageatte Ibrahim, MD at Merck, Luke was able to secure funding to create a global, phase III clinical trial to prove the value of Keytruda adjuvant therapy for patients with Stage IIB and IIC melanoma.

“It was a slam dunk,” says Luke. “The results were exactly as we had predicted and for all the reasons we suspected.” Luke credits his patients for making this clinical trial possible. On December 3, 2021, the FDA expanded approval of Keytruda to include patients with Stage IIB and IIC melanoma—representing an incredible win for the melanoma research community as it expands therapeutic options for a greater number of patients.

Adjuvant therapy, however, is not without its side effects and risks. Mild side effects can include nausea, fever, diarrhea, and fatigue. Although less common but serious, non-reversible side effects can also include diabetes, thyroid conditions, as well as skin, gastrointestinal, and lung reactions. (To learn more about adjuvant therapy, visit: curemelanoma.org/patient-eng/melanoma-treatment/adjuvant-therapy)

The evolution of adjuvant therapy has created tectonic shifts in the field—opening a range of not only treatment options but also discussion points to which the medical, research, and advocacy community are split.

These debates include the following:

- **How much surgery is necessary?** With FDA approval to give immunotherapy after surgery for removing a skin tumor, it raises the question of whether lymph node surgery is necessary. This is an area of substantial disagreement in the field.

- **Should immunotherapy be given after surgery?** Given the potential side effects and risks, should clinicians wait to see if melanoma reoccurs before treating patients, particularly as some patients may be cured through surgery alone? How do we balance the risk of side effects versus the risk of recurrence? Moreover, if patients have already been treated with immunotherapy and their melanoma still comes back, what is the best treatment at that point?

- **What are the implications on the healthcare system?** With twice as many people eligible for treatment with an expensive medication, what does this mean for our healthcare system at large?

\[\text{References:}\]


How do we know who needs treatment in the first place? A big unknown is identifying who is at highest risk for recurrence and who is at risk of getting harmed by treatment. These are, according to Luke, two of the highest priority research questions facing the field today.

Luke adds that most patients have Stage I melanoma and despite some gene expression profile testing and tumor DNA research, it’s all too early to be used at a scale to identify which patients will progress into something more advanced. “We have people with melanomas that involve lymph nodes that never come back. Meanwhile, you’ve got somebody with melanoma the size of a tiny dot on their skin and they develop metastatic disease,” says Luke. “These are all questions that we need to answer as a research community.”

Those questions are at the centerpiece of MRA meetings. “MRA fills a unique role in melanoma research,” says Luke. “They fund very important science that leads to new discoveries, and they bring everyone together at their annual Scientific Retreat. This was where the conversations with Merck around the Keytruda clinical trial first began.”

Thanks, in part, to MRA, “melanoma has been the tip of the spear in cancer, leading the way,” says Luke, “but we have not fixed every problem. How do we make sure that we continue to have these conversations so everybody has access to the best treatments whenever they need them?”

Luke says that in a perfect world, we could determine who is going to have melanoma come back, offer them treatment that will almost certainly cure their melanoma, and provide a perfect therapeutic window to treat patients who really need it, thus avoiding unnecessary side effects among those who don’t. As “pie in the sky” as this may sound, Luke believes this future is not far away.

“MRA fills a unique role in melanoma research... This is where the conversations first began.”

Jason Luke, MD speaking at the 2022 MRA Scientific Retreat
In January 2022, KIMMTRAK (Tebentafusp or “Tebe” for short) became the first-ever Food & Drug Administration (FDA)-approved therapy to treat unresectable or metastatic uveal (ocular) melanoma. In addition to being the first-ever approval specifically for metastatic uveal melanoma, it is also the first-ever T cell receptor therapy to earn FDA approval for any cancer.

Uveal melanoma, though the most common form of eye cancer in adults, is a rare melanoma subtype responsible for only ~5% of all melanoma diagnoses. Uveal melanoma differs from cutaneous (skin) melanoma in its etiology, the mutations that drive it, and in the patterns of metastases. Moreover, it has now been shown that uveal melanoma and cutaneous melanoma are quite different in the ways they engage with the immune system. As a result, therapies, such as immune checkpoint inhibitors, that have transformed treatment options for cutaneous melanoma do not work as well for uveal melanoma. Thanks to a new clinical milestone and the groundbreaking clinical trials of tebentafusp, patients with unresectable or metastatic uveal melanoma now have a treatment option available. The positive pivotal trial and ultimate approval of tebentafusp has also demonstrated that global randomized clinical studies in rare diseases are possible.

Tebentafusp works using a technology called T cell redirection that brings melanoma cells and T cells closer together to facilitate tumor killing. “It acts like a two-sided magnet that drags the immune system over to something called GP-100 expressed by the melanoma cell,” explains Dr. Marlana Orloff, Associate Professor of Medical Oncology at Thomas Jefferson
“The approval of KIMMTRAK represents a new day for patients and families affected by uveal melanoma. It renews hope that patients facing these rare forms of melanoma aren’t being left behind.”

Marc Hurlbert, PhD, MRA CEO

University and principal investigator of the tebentafusp clinical trial. ’For the ‘magnet’ to engage on the melanoma, it needs to be matched to an HLA type. In the case of tebentafusp, it was developed to interact with the most common HLA type, which is HLA-A201. Therefore, determining a uveal melanoma patient’s HLA type early in their diagnosis is important when making treatment decisions. (Additional information about tebentafusp is available at CureMelanoma.org)

Despite the cause for celebration, Orloff cautions that tebentafusp is not without challenges. For starters, patients who do not have the A201 HLA type do not qualify for treatment: representing approximately half of all patients with uveal melanoma. As such, additional treatment options that are effective for this rare melanoma are still urgently needed. Additionally, tebentafusp requires a weekly infusion with at least the first three doses requiring 16+ hour monitoring period following administration—adding an additional layer of complexity for patients and necessitating increased education for providers to ensure safe administration.

Despite its obstacles, however, Orloff is hopeful that what the field has learned through tebentafusp’s development may eventually help other hard-to-treat patient populations, such as patients with cutaneous melanoma who are resistant to standard checkpoint immunotherapy or who haven’t responded well to immunotherapy because, perhaps, under the surface their melanomas have more similarities to uveal melanoma.

“Before this year there were no uveal melanoma treatments... Now, with tebentafusp, the dam has been breached. This is just the beginning.”

Marlana Orloff, MD
In addition to uveal melanoma, MRA is also focused on accelerating research into other rare melanoma subtypes. In 2022, MRA launched the RARE Registry, a new direct-to-patient effort to advance research focused on acral and mucosal melanoma — two rare and difficult-to-treat subtypes of the disease. MRA’s RARE Registry complements existing patient registries focused on uveal melanoma.

Patients with these acral and mucosal melanomas, like those facing uveal melanoma, are often the only—or one of very few—patients at their clinic with this diagnosis. This has made it difficult for patients to connect and share information as well as for researchers to access the clinical information, tissue, and genomic profiles that they urgently need to better understand the causes and possible treatment options for these rare melanoma subtypes.

To address this, MRA began work in 2020 to develop the RARE Registry, a bidirectional and interactive registry for patients facing acral or mucosal melanoma. Through RARE, patients and families affected by rare melanomas will have a platform to build community and researchers will gain critical insight into the risk factors, treatment histories, and unique experiences of patients facing these subtypes to drive research forward.

"I think the time has come where maybe cutaneous melanoma and the cancer field at large can learn a bit now from uveal. I think the investment in research into uveal melanoma, even though it’s a rare melanoma subtype, can hopefully be brought into the other more common melanomas and other cancers," says Orloff.

Orloff credits funders like MRA with helping keep rare melanomas front and center. In fact, about 10% of all MRA grant awards have focused specifically on rare melanoma subtypes. Orloff, an MRA-funded investigator, says, "MRA has been great in having specific funds in every award cycle dedicated to rare melanoma subtypes. At the Scientific Retreat, MRA will often give the stage to me or other melanoma medical oncologists who specialize in treating patients with rare subtypes, so that we can present our work and get the word out. When tebentafusp was approved, MRA reached out to me immediately and did a great job sending that information out broadly.”

In addition to tebentafusp, other interesting research is taking place in the uveal melanoma space, including those designing therapies targeting mutations common in uveal melanoma, called GNAQ and GNA11. At Thomas Jefferson University where Orloff works, the team is exploring several novel approaches to liver-directed therapy, the most common site for uveal melanoma metastasis. "A unique feature of uveal melanoma," says Orloff, "is that the cause of death for close to 90% of patients is liver failure due to extensive hepatic involvement by tumors. By exploring novel approaches to treating liver metastases and conducting clinical trials in this area, we will hopefully broaden our toolbox even further for our uveal melanoma patients.”

Orloff adds, “Before this year there were no uveal melanoma treatments but now, with tebentafusp, the dam has been breached. I’m hopeful that it is the first of many treatment options to come. This is by no means the end. Instead, this is just the beginning.”

LEARN MORE ABOUT THE RARE REGISTRY AT RAREMelanoma.org
“This is bigger than us,” says Patrick O’Neill. “This is a movement, and we want young people to get involved in melanoma prevention and early detection.”

At just 29 years old, Patrick is an unlikely partner in the fight against melanoma. Especially since it is completely off the radar of most people his age. But he’s set out to change that.

Alongside him are his best friends and business colleagues Alex, Dan, Eric, and Reiley. Together they make up Boat Racing LLC and are partial owners of horseracing’s very-own Cinderella story “Hot Rod Charlie.”

Owning a racehorse began as a way for Patrick and his friends to stay in touch and continue the camaraderie they shared in college. What they hadn’t expected was for their horse, Hot Rod Charlie, to run the Triple Crown and now the Breeder’s Cup. Nor could they have predicted the visibility that Hot Rod Charlie would bestow upon their group.

“We’ve been so blessed,” says Patrick, “and we felt as a team that we wanted to do something bigger and beyond ourselves.” That something turned out to be a partnership with MRA in honor of Patrick’s late father and uncle, both of whom passed away from melanoma.

One-sixth of Hot Rod Charlie’s winnings now go to MRA—and as Boat Racing LLC’s stable of other horses grows, they too will contribute winnings towards melanoma research.

The one-sixth donation represents something deeper for the team. The sixth man is a basketball metaphor for the first man
off the bench — the unsung hero — the one you tag in for that extra spark to go from good to great. It represents Patrick’s father and uncle.

Taking advantage of this opportunity as well as their unique networks, Patrick and his partners have tapped into social media, hosted events and pre-race day get togethers, worn MRA-branded masks at the Kentucky Derby, and sought to turn their spotlight onto melanoma awareness. “Melanoma is one of those diseases that if you catch it early, it can drastically reduce the issues you may suffer later in life,” says Patrick. “What we bring to the table is reaching a younger demographic. If we can get through to them now by helping them understand this disease and how to take precautions to protect themselves, then we feel like we’re providing a unique value.”

As Boat Racing LLC’s relationship with MRA has grown, Patrick and his partners have sought to learn more about MRA’s operations, including a visit to Washington, DC where they had the opportunity to meet with and listen to researchers who are impacting the melanoma field. “We could not be prouder to be partnered with MRA and to be associated with what the group represents,” says Patrick. “We are excited for what will transpire in the future.”

It’s a partnership that Patrick says his father would be proud of.

Building a Movement: MRA Partners for Change

MRA’s ability to fund wide-ranging research in melanoma is amplified by unique, multi-faceted collaborations and partnerships. Here are a few additional examples of innovative partnerships that raise awareness of melanoma and sun safety while providing critical funds to support lifesaving research.

- Just six months after Wayne Stinchcomb’s passing, his family founded the Wayne Stinchcomb Big Orange Melanoma Foundation and hosted their first awareness event in his memory. The event, a bull roast, was a big party that included all of Wayne’s favorite songs, an auction, prizes, food, and drink. To date, the Big Orange Foundation has donated over $380,000 to the Melanoma Research Alliance to advance the fight against the disease. Learn more at Big-Orange.org

- In May, for Melanoma Awareness Month, Kathy Mason brought together over 100 people in her North Carolina community to raise awareness of melanoma, the importance of sun safety, and to raise urgently needed funds to support research. In two years, the event has raised over $33,000 for MRA’s life-saving grants program.

- Also in May, more than 2,000 participants and 68 teams came together to raise over $95,000 dollars as part of the second annual Step Up for Melanoma challenge. Step Up for Melanoma is a virtual community-building, fundraising, and awareness campaign that challenges participants to walk 10,000 steps a day, every day, to benefit MRA’s research program throughout Melanoma Awareness Month.

From L to R: Eric Armagost, Greg Helm (Roadrunner Racing), Patrick O’Neill, Reiley Higgins, Daniel Giovachinni, Alex Quoyeser, and Bill Straus (Straus Brothers Racing)
2022 Awards
TEAM SCIENCE AWARDS

Targeting Oncogenic Gaq in Uveal Melanoma
MRA Team Science Award
Boris Bastian, MD, The University of California, San Francisco

Identification & Validation of Novel Druggable Targets in Mucosal Melanoma
MRA Team Science Award
Genevieve Boland, MD, PhD, Massachusetts General Hospital

Targeting Epigenetics to Enhance Anti-Melanoma Immunity
Leveraged Finance Fights Melanoma — MRA Team Science Award
Marcus Bosenberg, MD, PhD, Yale University

Targeting RNA Processing to Enhance Mucosal Melanoma Immunotherapy
MRA Team Science Award
Rotem Karni, PhD, Hebrew University of Jerusalem

Harnessing B Cell Checkpoints in Melanoma
MRA Team Science Award, collaboratively funded by Brigham and Women’s Hospital and The University of Texas MD Anderson Cancer Center
Vijay Kuchroo, DVM, PhD, Brigham and Women's Hospital, Inc.

Targeting Chromothripsis to Suppress Metastasis and Therapy Resistance
MRA Team Science Award
Roger Lo, MD, PhD, The University of California, Los Angeles

Cellular Barcoding to Define Melanoma Drug Resistance and Cell of Origin
MRA Team Science Award for Women in Melanoma Research
Elizabeth E. Patton, PhD, University of Edinburgh

Identifying Public Neoantigens, their TCRs and their Rules of Engagement
MRA Team Science Award
Yardena Samuels, PhD, Weizmann Institute of Science

Improving Immunological Memory During Anti-PD-1 Immunotherapy
MRA Team Science Award, collaboratively funded by Harvard Medical School and Dana-Farber Cancer Institute
Arlene Sharpe, MD, PhD, Harvard Medical School

Noninvasive Prediction of Severe Toxicity from Immune Checkpoint Blockade
MRA Team Science Award, collaboratively funded by Yale University, Washington University, and Stanford University
Mario Sznol, MD, Yale University

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2022 AWARDS

Melanoma Research Alliance Grant Awards

A searchable database of all MRA grants is available at CureMelanoma.org/Grants
TEAM SCIENCE ACADEMIC-INDUSTRY PARTNERSHIP AWARD

Analytical and Clinical Validation of a Multiplex IF Biomarker for Anti-PD1
MRA Team Science Academic-Industry Partnership Award
Janis Taube, MD, Johns Hopkins University School of Medicine

YOUNG INVESTIGATOR AWARDS

New Genetic Tools to Understand the Role of M6A in Melanomagenesis
MRA Young Investigator Award
Claudio Alarcon, PhD, Yale University, School of Medicine

Decipher the Epigenetic Code Regulating Cellular Dynamics in Acral Melanoma
MRA Young Investigator Award
Junyue Cao, PhD, The Rockefeller University

Targeting Anti-Tumor Immunity in Anatomically Distinct Mucosal Melanomas
MRA Young Investigator Award for Women in Melanoma Research
Kasey Couts, PhD, University of Colorado Denver

Investigating Lipid Kinase Pip4k2c in Regulating Anti-Tumor Immunity
Bristol Myers Squibb — MRA Young Investigator Award
Karen Dixon, PhD, Brigham and Women's Hospital

Mechanisms and Relevance of Treg Expansion after PD-1 Blockade in Melanoma
Bristol Myers Squibb — MRA Young Investigator Award
Francesco Marangoni, PhD, The University of California, Irvine

Interfering with Early Cell State Transitions to Prevent Drug Tolerance
The Wayne Stinchcomb Big Orange Melanoma Foundation — MRA Young Investigator Award
Florian Rambow, PhD, Essen University Hospital

Interrogating Epigenetic Regulation of PD1 in Melanoma-Infiltrating T Cells
Leveraged Finance Fights Melanoma — MRA Young Investigator Award in memory of Michael Konigsberg
Debattama Sen, PhD, Massachusetts General Hospital

Tumor-Stroma Metabolic Crosstalk in Melanoma Brain Metastases
Tara Miller Melanoma Foundation — MRA Young Investigator Award
Inna Smalley, PhD, H. Lee Moffitt Cancer Center & Research Institute

Investigating the role of FGL1/LAG-3 Axis in Melanoma Immunity
Bristol Myers Squibb — MRA Young Investigator Award
Jun Wang, PhD, New York University School of Medicine

mRNA-Based Re-Programming of Terminally Differentiated TILs
MRA Young Investigator Award
Yochai Wolf, PhD, The Sheba Fund for Health Service and Research

PILOT AWARDS

A Strategy to Identify the Basis of Melanoma and Parkinson's Comorbidity
The Michael J. Fox Foundation — MRA Pilot Award
Deanna L. Benson, PhD, Icahn School of Medicine at Mount Sinai
Investigating ARID2 as a Suppressor of Melanoma Metastasis
MRA Pilot Award for Women in Melanoma Research
Emily Bernstein, PhD, Icahn School of Medicine at Mount Sinai

Combined Intrathecal Immunotherapeutic Strategies for Melanoma LMD
MRA Pilot Award
Sherise Ferguson, MD, University of Texas MD Anderson Cancer Center

Novel Mouse Models of Uveal Melanoma
MRA Pilot Award
Florian Karreth, PhD, H. Lee Moffitt Cancer Center & Research Institute, Inc

The Role of APC Mutations in Melanoma Brain Metastasis
Leveraged Finance Fights Melanoma — MRA Pilot Award
James Robinson, PhD, The University of Minnesota, Twin Cities

Alpha-Synuclein’s Role in Melanoma Formation and Metastasis
The Michael J. Fox Foundation — MRA Pilot Award
Vivek Unni, MD, PhD, Oregon Health & Science University

Targeted Advertising to Promote Melanoma Awareness Among Black Americans
MRA Dermatology Fellows Award
Leandra Barnes, MD, Stanford University

Germline Genetic Mutations in Patients with Multiple Primary Melanoma
Polka Dot Mama Melanoma Foundation — MRA Dermatology Fellows Award
Audris Chiang, MD, Stanford University

Targeting Lipids for Melanoma Detection and Prevention
Grace Wenzel MRA Dermatology Fellows Award for Women in Melanoma Research
Marianne Collard, PhD, Boston University School of Medicine

Leveraging Social Media to Augment Education on Melanoma in Hispanics
MRA Dermatology Fellows Award
Collin Costello, MD, Mayo Clinic Arizona

Novel Biomarkers and Treatment Strategies for Acral Lentiginous Melanomas
MRA Dermatology Fellows Award
Dekker Deacon, MD, PhD, The University of Utah

Genomic Instability in Melanomagenesis and Progression
MRA Dermatology Fellows Award
Prashanthi Dharanipragada, PhD, The University of California, Los Angeles

Validation of the Melanoma Risk Evaluation (MRE)
L’Oréal Dermatologic Beauty Brands — MRA Dermatology Fellowship Award
Steven Caleb Freeman, MD, Oregon Health & Science University

Delineating Mutational Consequences of Tanning Bed Use in Human Melanocytes
MRA Dermatology Fellows Award
Bishal Tandukar, PhD, The University of California, San Francisco

Individualized Melanoma Prediction Using Self-Adaptive Machine Learning
MRA Dermatology Fellows Award
Guihong Wan, PhD, Massachusetts General Hospital

Jason Luke, MD — University of Pittsburgh — speaks at the 2022 Scientific Retreat
Alcohol Metabolism in Human Melanocytes
MRA Dermatology Fellows Award
Takeshi Yamauchi, PhD, University of Colorado Anschutz Medical Campus

Distant Metastasis by Early ALM in Patients with Skin of Color
MRA Dermatology Fellows Award
Zhentao Yang, PhD, The University of California, Los Angeles

DERMATOLOGY JUNIOR FACULTY/CLINICAL INSTRUCTOR AWARDS
Mitochondrial Genome Alterations in Primary Melanoma
MRA Dermatology Junior Faculty/Clinical Instructor Award
Amy Vandiver, MD, PhD, The University of California, Los Angeles
Tribute & Memorials

In 2021, gifts were made in tribute to the following individuals.

**MEMORIAL GIFTS**

<table>
<thead>
<tr>
<th>Joel Anderson</th>
<th>Rodney Grubb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donald Lester Andrews</td>
<td>Derek Haehnel</td>
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<td>John Keith Arrington</td>
<td>Heidi Haim</td>
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<td>Leland Otto Baldwin, Jr.</td>
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<td>Deborah Barman</td>
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<td>Angela Knight</td>
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<td>William D. Boden</td>
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<td>Russell Dean Bogue</td>
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<td>Martha Pfershy</td>
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<td>Jennifer J. Phillips</td>
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<td>Jason Pruehs-Kozlowski</td>
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<td>Norma Jean Ramich</td>
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<td>Corinne Derrig Rivera</td>
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<td>Stephen England Rogers</td>
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<td>Joseph Vincent Rohr, Jr.</td>
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David Samot  
John Sanger  
Timothy Schiefelbein  
DJ Scholtes  
Michelle Seidel  
Richard Shafritz  
John J. Skay  
Dean Smith  
Michael R. Smith  
Robert Sneed  
Belle Sokoloff  
Nicholas Somich  
Stacee Sorensen  
David Steiner  
Ann Renee Stem  
Bill Stember  
Catherine Sugarbaker  
Eric Sweet  
Kristin Taccogna  
Jack Taitler  
Phillip Teicher  
Claire Threefoot  
Audrey Tramontana  
Michelle Tucker  
Maureen Urrf  
Timothy Valentine  
Myriamne Coffeen Vandeven  
Cindy Vernon  
Ronnie Walker  
Binski Waters  
Grace Wenzel  
Linda Whistler  
Nancy White  

Florence Whitford  
June Whitlock  
Ariana Wilfley  
Tracy Windrum  
Paul Witmer  
R. William Wood  
Larry Young  
Scott Youngblood  

**TRIBUTE GIFTS**  
Brandon Barniea  
John Beer  
Samantha Berkman  
Debra Ressler Black  
Victoria Black  
Bryce Bludevich  
John Bodnar  
Robin Bull  
Tom Busker  
Darcey Chisholm  
Vickie Clodgio  
Ro and Victoria Cochran  
Aaron Cummins  
Michelle Davis  
Mitch Diamond  
Ashley Doherty  
Kerry Dolan  
Joe Gallagher  
Lee Grinberg  
Sigrid Grossman  
Mary Harris  
Beth Hopkins  
Marc Hurlbert  
Michael Kaplan  
Michael Konigsberg  
Mark Langley  
Suzanne Lawton  
Devin Leslie  
Dan Levine  
Jane Lew  
George Lewis  
Justin Long  
Tommy Love  
Daniel Maher  
Mary Maroney  
Ryan Mason  
Debby McCreary  
Elizabeth McGowan  
Jennie Nallie  
Ralph Norberg  
Joel Poor  
Barbara Premisler  
Derrick Queen  
Jeff Rowbottom  
Nancy Schroeder  
Craig Schuh  
Ian Schuman  
Arka Shanks  
Robert Silva  
Stephanie Teicher  
Chris Torrente  
Richard Tucker  
Marty Twomey  
Anne Vaughan  
John Williamson  
Ed Witterholt  
Ron Woods  
Sophie Yagoda
### Financials

Financial presentation based on MRA’s 2021 externally audited financials. Full audit and IRS 990 are available online at CureMelanoma.org/Financials

### Statement of Financial Position

<table>
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<tr>
<th>ASSETS</th>
<th>TOTAL 2021</th>
<th>TOTAL 2020</th>
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<tr>
<td>Cash and Cash Equivalents</td>
<td>$12,982,423</td>
<td>$12,346,871</td>
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<td>Investments</td>
<td>$11,630,333</td>
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<td>Contributions Receivable (Net)</td>
<td>$7,549,216</td>
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<td>Prepaid Expenses and Other Assets</td>
<td>$105,490</td>
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<td><strong>TOTAL ASSETS</strong></td>
<td><strong>$32,267,462</strong></td>
<td><strong>$37,054,829</strong></td>
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<th>LIABILITIES</th>
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<td>Accounts Payable</td>
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<td>Grants Payable (Net)</td>
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<td>Deferred Revenue</td>
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<td>Due to Affiliate</td>
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<td><strong>TOTAL LIABILITIES</strong></td>
<td><strong>$13,144,075</strong></td>
<td><strong>$13,944,288</strong></td>
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<table>
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<tr>
<th>NET ASSETS</th>
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<tr>
<td>Unrestricted</td>
<td>$16,300,897</td>
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<td>Temporarily Restricted</td>
<td>$2,822,490</td>
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<td><strong>TOTAL NET ASSETS</strong></td>
<td><strong>$19,123,387</strong></td>
<td><strong>$23,110,541</strong></td>
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<td><strong>TOTAL LIABILITIES &amp; NET ASSETS</strong></td>
<td><strong>$32,267,462</strong></td>
<td><strong>$37,054,829</strong></td>
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### Statement of Activities

**REVENUE**

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<tr>
<th>Description</th>
<th>TOTAL 2021</th>
<th>TOTAL 2020</th>
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<tr>
<td>Contributions (Collectible Net)</td>
<td>$4,786,386</td>
<td>$5,989,431</td>
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<td>Special Events (Net)</td>
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<td>Sponsorship</td>
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<td>Interest/Investment</td>
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<td>In Kind Contributions</td>
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<td>Other Income</td>
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<td><strong>TOTAL REVENUES</strong></td>
<td><strong>$7,565,800</strong></td>
<td><strong>$8,421,536</strong></td>
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**EXPENSES**

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<th>Description</th>
<th>TOTAL 2021</th>
<th>TOTAL 2020</th>
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<tr>
<td>Research Grants</td>
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<td>$12,549,005</td>
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<td>Personnel Costs</td>
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<td>Travel &amp; Entertainment</td>
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<td>Other Expenses</td>
<td>$540,770</td>
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<td>Meetings &amp; Conferences</td>
<td>$31,261</td>
<td>$254,294</td>
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<td>Professional Fees</td>
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<td>Occupancy</td>
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<td><strong>TOTAL EXPENSES</strong></td>
<td><strong>$11,552,954</strong></td>
<td><strong>$15,693,481</strong></td>
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<td><strong>NET INCOME/(LOSS)</strong></td>
<td><strong>($3,987,154)</strong></td>
<td><strong>($7,271,945)</strong></td>
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**Total 2021 Program Costs**

- **SCIENTIFIC PROGRAM**
  - Non-Grant Expenses: $1,255,484 (10.87%)
  - RESEARCH GRANTS: $8,761,340 (75.84%)
- **FUNDRAISING**: $585,898 (5%)
- **MANAGEMENT & ADMIN**: $537,547 (4.7%)
- **PATIENT ENGAGEMENT**: $399,811 (3.5%)

100% of all donations go directly to research—no admin, development, or other fees.

DONATE TODAY: CureMelanoma.org/Donate
Donor Recognition

A heartfelt thank you to all of our 2021 donors. Your generosity makes our work possible: curemelanoma.org/donate

$1,000,000+
Debra and Leon Black
Bristol-Myers Squibb Company
Jonathan and Sheryl Sokoloff

$500,000-$999,999
Paul, Weiss, Rifkind, Wharton & Garrison LLP
The Stewart J. Rahr Foundation

$250,000-$499,999
Bank of America Private Bank
Jami Gertz and Tony Ressler
Anna-Maria and Stephen Kellen Foundation
Kirkland & Ellis LLP
L’Oréal Active Cosmetics Division
Merck & Co., Inc.

$100,000-$249,999
Akin Gump Strauss Hauer & Feld LLP
Alkermes, Inc.
Credit Suisse
Deloitte
Caryl Englander
Michael and Jacqueline Ferro Family Foundation
Iron Park Capital, LP
Latham & Watkins LLP
Ronald and Jo Carole Lauder
Nancy and Howard Marks

PricewaterhouseCoopers
Jeffrey and Frances Rowbottom
Ian Schuman
Sidley Austin LLP
Simpson Thacher & Bartlett LLP
The Wayne Stinchcomb Big Orange Foundation
Tara Miller Melanoma Foundation
Veritas Capital Management, Inc.
White & Case LLP

$50,000-$99,999
Allen & Overy
Lee Alpert
The Alta Vista Fund of the Chicago Community Foundation
Amgen, Inc.
Bloomberg Philanthropies
BMO Capital Markets
Brownstein, Hyatt, Farber & Schreck
The Carson Family Charitable Trust
Amanda and Jonathan Eilian
Michael and Jacqueline Ferro
Fitch Ratings
Lisa Fox
Goldman Sachs & Co.
Daisy Helman
HPS Investment Partners, LLC
Iovance Biotherapeutics
Johnson & Johnson

Ellias Kefalidis
Thomas Lee and Ann Tenenbaum
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
Natera
Nektar Therapeutics
Novartis Corporation
O’Melveny & Myers
Mary Jo and Brian Rogers
Shearman & Sterling LLP
UBS Financial Services

$25,000-$49,999
Ben Black
Block Communications, Inc.
Cahill Gordon & Reindel LLP
Davis Polk & Wardwell
General Atlantic Philanthropic Foundation
Golub Capital
Hellman & Friedman LLC
Instil Bio
J.P. Morgan Chase & Co.
Milbank LLP
MJR Foundation
Morgan Stanley
New Mountain Capital
Payden & Rygel
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(At right): Roger Lo, MD, PhD — University of California, Los Angeles — speaks at the 2022 Scientific Retreat

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