

ANNUAL REPORT 2021

Saving +
Transforming
Lives



A MESSAGE FROM PWSA | USA's CEO and Board Chair



Dear Friends,

2021 was a year of change and growth for Prader-Willi Syndrome Association | USA (PWSA | USA). This transformational year was filled with excitement, accomplishment, hope, and most importantly, gratitude for our PWS families, donors, and all those who are a part of this wonderful community.

PWSA | USA was able to serve a record number of families, implement organizational strategies to strengthen our association from a financial and process perspective, collaborate with industry professionals on groundbreaking clinical trials, and so much more.

We know living with PWS can sometimes be a tough journey and can present daily challenges for our families. That is why PWSA | USA is here to offer help, hope and support 24 hours a day, 365 days a year. We are by your side through the most challenging times, as well as to share in your important celebrations, successes, and hard-earned milestones.

PWSA | USA focuses on Family Support, Advocacy and Awareness, and Research. As we begin 2022, we see a year full of new programs, excitement, and engagement for our community! A few of these opportunities include:

- The introduction of our new Volunteer Program
- Continued educational opportunities for both families and providers through webinars, community conversations and special "summit" programs
- Launch of our new peer-to-peer fundraising program
- Creation of the PWS Community's first-ever Advocacy Fly-in on Capitol Hill to unite our voices and increase awareness of PWS
- And many other great programs planned for 2022!

Again, as we reflect on the great accomplishments of 2021 and the amazing roadmap set out for 2022, we move forward with passion, hope, and gratitude to our PWS community. We have a wonderful staff, Board of Directors, industry professionals and the best volunteers! Together, we will be united in **HOPE** for the future of our loved ones.

With gratitude,



Paige Rivard

Paige Rivard, MBA
CEO, Mom to Jake (11)



Marguerite Rupnow

Marguerite Rupnow, MBA
Chair, Board of Directors

As we reflect on the successes of 2021 and look ahead to more exciting events and initiatives, we want to take a moment to recognize your dedication to our mission. With your support, PWSA | USA continues to make groundbreaking strides to enhance the quality of life and empower those affected by Prader-Willi syndrome (PWS).

Over the past two years, PWSA | USA went through many changes that have allowed us to provide more help and hope to those we serve. We welcomed a new CEO, Paige Rivard, who has brought a wealth of knowledge and amazing leadership to our team and community. We updated our branding with a new logo and website. We welcomed new staff members to help drive the professionalism and expertise we strive to achieve. We also added several new initiatives and programs that will continue to grow in 2022, including a PWS Parent Retreat, powerful expanded advocacy efforts and a D.C. Fly-In for our advocates to meet with legislators to address critical

needs, and the continuation of our much utilized 24-Hour Support Line.

In 2021, PWSA | USA experienced a few milestones and memorable moments, including a record number of individuals registered for our 2021 Virtual National Convention; but one of the proudest moments for our PWS community was the amount of FDA exposure to possible treatments for PWS. For the first time ever, a drug to help combat hyperphagia was reviewed by an FDA Advisory Board. While the drug was not approved, we know that this was a step closer than we've ever been, and look forward to what's to come in the years ahead!

TOGETHER IN
GROWTH

*PWSA | USA is a soft
place to land, a light
shining in the darkness,
and a community that
cheers us on this grand
adventure.*



TOGETHER IN ADVOCACY

Raising awareness and effective advocacy are essential to ensuring health, safety, and enhanced quality of life for those affected by Prader-Willi syndrome.

2021 has been spent outlining our advocacy three-year plan and securing funding to ensure we can meet our goals. With the creation of PWSA | USA's ONE Voice Initiative, we have created an outline of our goals and demonstrated our plan to achieve them.

PWSA | USA's new ONE Voice Initiative is our re-branded, comprehensive, year-round advocacy program designed to increase national awareness of PWS and to enhance the effectiveness and coordination of PWS-related advocacy to improve outcomes for patients.

Establishing the PWS Awareness Campaign and ONE Voice Initiative will help PWSA | USA to act on the broad range of priority issues facing our community and constituents, including:

- Advancing PWS Research
- Accelerating Treatment Options
- Ensuring Patient Access and Coverage
- Furthering Education, Awareness, and Training

PWSA | USA's ONE Voice Initiative involves an ongoing education and awareness campaign that will prepare our advocates to share their personal stories with policymakers. By sharing their stories and promoting rare disease policy, we aim to improve the prognosis for people with PWS.



As Prader-Willi syndrome is considered a "rare disease," extra effort is needed to bring attention to the needs of the PWS community. Through Phone 2 Action (P2A), our community has the opportunity to connect with lawmakers to ensure passage of legislation and regulations that help our community and to defeat those that do not. In 2021, we are excited to say that there was a record number of emails sent to lawmakers throughout our various P2A campaigns. Thank you to our community for using your voice!



P2A Campaign	Number of Advocates	Legislator Connections
DCCR	145	1,111
Orphan Drug Tax Credit	318	975
STAT Act	53	167
BENEFIT Act	45	135
Better Care Better Jobs	12	38

At PWSA | USA, we work to integrate what we have learned about the needs of our families through our support programs with research that we think will make an important and practical difference in the lives of those affected by PWS.

PWSA | USA offers grant assistance for scientific researchers with an interest in improving the lives of those with PWS. Over the past year, we have received several Letters of Intent (LOIs) that we are in the process of reviewing.

In 2022, we will select to fund LOIs that are centered on showing high promise for translating basic biomedical knowledge to clinical application. The goal is to fast-track better treatment for PWS.

Research: 2022 and Beyond

While all Prader-Willi syndrome research is important, PWSA | USA is particularly interested in facilitating research that can more immediately enhance quality of life of individuals affected by PWS.

The desire to find more and better treatment options to manage and diminish challenges inherent to Prader-Willi syndrome will guide PWSA | USA's research initiatives now and into the future. PWSA | USA's research committee and advisory boards aim to:

- Devote more resources to support development of new therapeutic interventions
- Increase efforts to collaborate with external research partners, such as pharmaceutical companies and the Foundation for Prader-Willi Research
- Evaluate the current grant-making process to ensure a treatment-based research focus
- Encourage innovative research models
- Create new opportunities for researchers and scientists to promote collaboration and information sharing

Supporting
Research to
Help Make
Each Today
a Better
Tomorrow

TOGETHER IN

RESEARCH



TOGETHER IN RESEARCH



MARCH 3, 2021

Sent first letter to FDA sharing recent findings regarding the impact of COVID-19 on PWS individuals and their families.

APRIL 7, 2021

Sent second letter to the FDA asking them to reconsider their decision again. This letter, which was over 100+ pages long, included the names of everyone who signed on and each quote submitted. We received an immediate response from the FDA stating they would be reviewing our letter.

APRIL 14, 2021

First Community Town Hall held.

JUNE 17, 2021

Patient Listening Session granted with the FDA.

MARCH 10, 2021

Sent out a community sign-on survey asking the community to "sign on" to a joint letter to the FDA asking them to reconsider reviewing the results of Soleno's Phase 3 trial. We received more than 26,000 responses.

APRIL 7, 2021

Held a joint advocacy webinar to discuss drug development, the FDA process and the role of the PWS community.

MAY 20, 2021

Second Community Town Hall held.

What is an Advisory Committee?

The FDA may choose to hold an Advisory Committee meeting when reviewing a new drug application.

Not all drug reviews have an advisory committee meeting!

This meeting is taking place because the FDA has questions regarding the application.



JULY 6, 2021

FDA Grants Priority Review for Levo Therapeutics' New Drug Application for LV-101 (Intranasal Carbetocin) for the Treatment of Prader-Willi Syndrome

SEPTEMBER 10, 2021

FDA Advisory Committee announces that it will review LEVO's Carbetocin as a treatment for PWS on November 4, 2021

OCTOBER 21, 2021

Deadline for comments to be submitted by the public for November 4th FDA Advisory Committee Meeting

NOVEMBER 4, 2021

PWSA I USA CEO Paige Rivard and Levo Therapeutics CEO Sara Cotter each release statements regarding FDA's decision to deny Carbetocin drug

JULY 23, 2021

PWSA I USA and FPWR Share Combined FDA Patient Listening Session Summary

OCTOBER 8, 2021

PWSA I USA and FPWR host webinar to educate community on how they can use their voice in November 4th FDA Advisory Committee Meeting

NOVEMBER 4, 2021

FDA holds Advisory Committee Meeting to hear from public on LV-101 Carbetocin and ultimately votes not to approve the drug based on insufficient evidence of its effectiveness to treat hyperphagia in PWS

PWSA | USA's Family Support team members are your partners in hope. They provide guidance and support to individuals diagnosed with Prader-Willi syndrome, their families, and care providers. The team provides education and training to medical providers, educators, and professional caregivers about the syndrome, and advocates for the comprehensive needs of the entire PWS community.

PWSA | USA Family Support Impact



2021

289

NEW DIAGNOSIS PACKAGES
OF HOPE SENT OUT

207

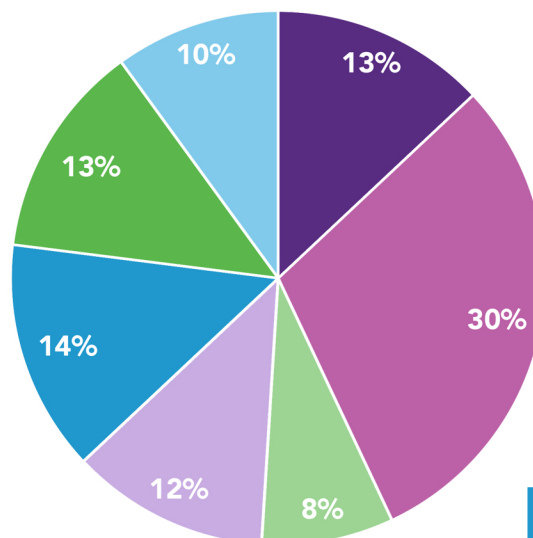
NEW DIAGNOSES

1,851

TOTAL FAMILY SUPPORT
INQUIRIES

1,346

NON-MEDICAL INQUIRIES



- Residential placement/day program concerns and needs
- General PWS questions and emotional support
- Behavior-related concerns
- School-related concerns
- Medical
- Birth-One Support
- Advocacy

**TOGETHER IN
SUPPORT**

2021 Family Support Campaign

Thanks to the generosity of our community, PWSA | USA raised more than \$70,000 to provide funding for our Family Support Program. We received support from 570 donors, 26% more than last year, and 15% of these individuals raised money through peer-led Facebook fundraisers. Our five-person Family Support Team provides help and hope to the PWS community on a national scale.

Through personal stories and pictures shared by our PWS families, we were able to showcase the incredible work our team does daily. Whether it is a compassionate call of support after your child's diagnosis, or a resource-filled consultation when your loved one is entering a new phase of development, PWSA | USA is here for you and your family 24 hours a day, 7 days a week, 365 days a year.

Family Support Campaign Funds:

- Parent Mentor Program
- 24-Hour Support Line
- Grief Support Counseling
- Volunteer Program
- School Success Toolkits
- Intensive Supports and Services

"PWSA | USA has provided our family with ongoing support, and brings us so much hope for Michael to live an independent and full life"

- Rachel, Adoptive Mom to Michael



"It is because of PWSA | USA that we thrive as a family."

- Jennifer, Mom to Josephine



"Family support from PWSA | USA is such a critical part of our lives and for so many others who have a loved one with Prader-Willi syndrome."

- John, Dad to Hunter



24-Hour Support Line: (941) 312-0400

2021 FUNDRAISING EVENTS



7th Annual Clint Hurdle Hot Stove Dinner

On March 20, 2021, surrounded by palm trees, the sandy beaches of Anna Maria Island and our PWSA family, the 7th Annual Hot Stove Dinner was truly something to celebrate. Thank you to Clint and Karla Hurdle for hosting this amazing event and for being incredible

supporters of PWSA I USA. We also want to thank our event partner Leaving Legacies Foundation and all other sponsors for making this year's Hot Stove Dinner a huge success.



12th Annual Hunter Lens Golf Tournament

On October 2, 2021, PWSA I USA Board Member John Lens hosted the 12th Annual Hunter Lens Golf Tournament in honor of his son Hunter who is living with PWS. The event was held at The Back Nine Club in Lakeville, MA. This great event benefits PWSA I USA's

Family Support, Research, and Advocacy efforts in 2022.



Answers for Audrey

On October 22, 2021, Michelle Spring and her family hosted a Trivia Night in honor of her daughter Audrey who is living with PWS. There was something for everyone at this fantastic event - fun trivia games, a silent auction, and great photo-op spots for those who attended! The event was sponsored

by Schallert Engineering, Bi-State Insulation, Winschel Carpet Service, Gateway Paintball, and Thomas J. O'Donnell at Edward Jones. All of the funds raised directly benefited PWSA I USA. Thank you to Michelle, Answers for Audrey sponsors, and those who attended for supporting our programs.



Mattyofit's Miami Endurance Run

On September 25, 2021, Matheus Oliveira ran in the Miami Ultra 100 Marathon for his sister, Ana Beatriz (16) who is living with PWS and in support of PWSA I USA.

"My sister's life-long struggles have inspired me each step of the way."

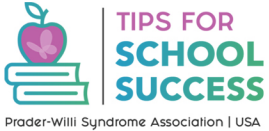
TOGETHER IN HOPE

By hosting a fundraiser, you connect directly to engage supporters, increase visibility of PWS, and raise funds that support our mission to save and transform lives. With PWSA I USA, you can start your own fundraising campaign, and we'll provide you with support all along the way.

If you're interested in hosting a fundraiser in 2022, please contact Development Director Melanie McDonald at mmcdonald@pwsausa.org.

GRANTS

2021 saw the completion of several new initiatives and the promise of more in 2022, thanks to the success in securing **\$115,000** in grants from private foundations and corporate impact programs. We are excited to share some highlights of grant-funded projects that came to fruition this past year, as well as spotlight the generous funders who recognized the potential of these programs and awarded financial support.



While PWSA | USA has provided support in this realm on a number of levels, our new comprehensive **School Success Toolkits** have brought new resources and much-needed support for our families. Many

students living with PWS have IEP's, require in-school therapies (Speech, Physical, Occupational), and can have emotional and/or behavioral difficulties that are common with the syndrome. This year, with the help of funds granted by **RBC Wealth Management** and the **Susan A. & Donald P. Babson Charitable Foundation**, we were able to distribute our School Success Toolkits to families nationwide. Additionally, a grant from the **Veteran's United Foundation** provided funds to support our general Family Support needs.



In response to an increased interest in and need for robust advocacy for our loved ones with PWS, we sought out resources to roll out our newly-redesigned **Advocacy** efforts. Thanks to generous grants from **Harmony Biosciences**, **Saniona**, and the **Everylife Foundation**, we have launched our project ONE Voice initiative and are planning PWSA |

USA's first-ever Washington, D.C. Fly-in to Capitol Hill. Additionally, a grant from the Everylife Foundation now supports the Phone 2 Action platform that provides effective "one-click" advocacy campaigns to ensure busy PWS families can have their voices heard.



In response to ongoing difficulties PWS families have in obtaining timely and accurate diagnosis of sleep issues, PWSA | USA is launching a program for parents, caregivers and practitioners in 2022.

Thanks to a generous grant from **Harmony**

Biosciences "Patients at the Heart" program, we will be providing relevant, responsive, and easy-to-access tools and trainings. Research on sleep in the rare disease community is limited, and this makes identifying and diagnosing sleep disorders complex for our PWS community. We are excited to launch this initiative this year and to create these new opportunities and resources to help demystify and diagnose disordered sleep in PWS.



Caregiver burnout is real, and the additional layer of pandemic stress makes for the "perfect storm." As we connect with our families across the country, we've heard more requests for caregiver training, valuable

respite, and a strong need for a focus on caregiver wellness. We are developing a special **Parent Retreat** to offer parents and caregivers, as well as our volunteer parent mentors, some respite, resources, and meaningful peer connections in 2022. Thanks to generous support from the **James Hervey Johnson Charitable Educational Trust**, we'll have additional resources to help make it happen.

FINANCIALS

(Unaudited)

Operating Support and Revenue

Contributions and Grants.....\$694,294
Fundraising and Special Events.....\$1,033,428
Other Revenue.....\$31,223

Total Operating Revenue.....\$1,758,945

Operating Expenses

Program Services

Family Support.....\$926,688
Advocacy & Awareness.....\$61,165
Research.....\$57,377

Total Program Services.....\$1,045,229

Supporting Services

Management & Administration.....\$84,769
Fundraising.....\$168,292

Total Support Services.....\$253,061

Total Operating Expenses.....\$1,298,290

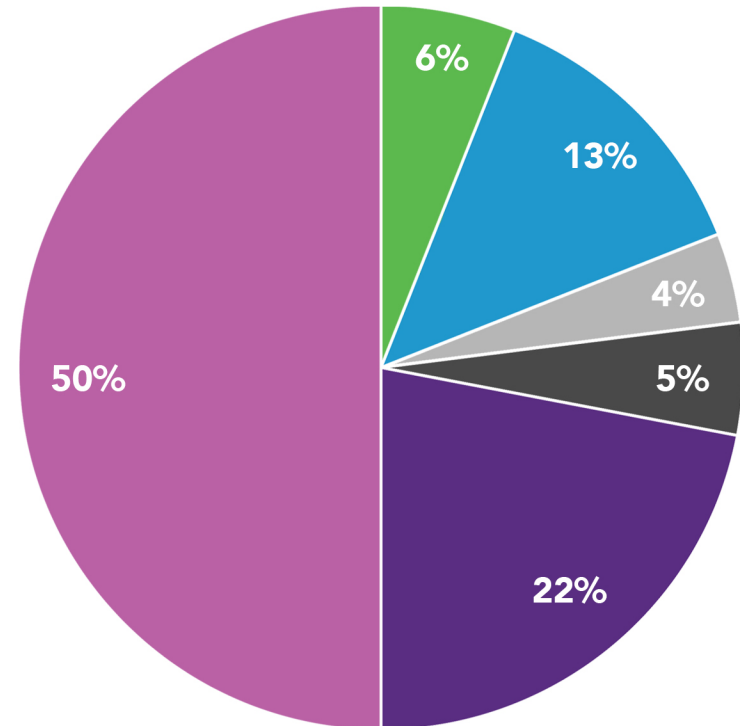
Change in Net Assets from Operations | \$460,655
Net increase in fair value of investments | \$92,778
Change in Net Assets | \$553,433

Net Assets (beginning of the year).....\$1,812,405

Net Assets (end of year).....\$2,365,838



2021 EXPENSES



Administrative

Advocacy Program

Fundraising

Convention Program

Research Program

Family Support Program



TOGETHER IN PURPOSE

Who We Are

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WE ARE STRONGER TOGETHER

PWSA | USA is serving more individuals and families than ever before. Because we do not charge for the services we provide, we're counting on **YOU** to help us save and transform lives!

Regardless of size, your gift is important and will make a real and meaningful difference in the lives of those affected by Prader-Willi syndrome.

Visit www.pwsausa.org, or mail your donation to the address below.

Thank you for your support!

Prader-Willi Syndrome Association | USA
8588 Potter Park Drive, Suite 500
Sarasota, FL 34238

For questions, please email info@pwsausa.org



Click on the image above to hear from those who are directly impacted by your support.