

TSC Alliance

Joint EC/Finance Committee Meeting, Second Quarter Review

Wednesday, August 31, 2022

DRAFT

In attendance:

Voting Officers: Peter Crino (Chair), Bill Joseph, Jessica Krefting, Paul Waxlax

Voting Members of the Finance Committee: Paul Waxlax (Chair), David Coit, Bill Joseph, Brittany Smith

Non-voting Member of the Executive Committee: Matt Bolger, Tanjala Gipson, Dana Holinka, Darcy Krueger, Laura Marks, Chip Burkhalter

Staff Members: Cynthia Arcuri, Steve Roberds, Kari Rosbeck

Opening Remarks:

Pete Crino called the meeting to order at 6:02 p.m. A quorum of voting officers and Finance Committee members were present. To prepare for the October 21 Board meeting, Dr. Crino pointed to the 2023 DRAFT Organizational Goals. These goals by board committee are what we aspire for as an organization for 2023. Dr. Crino requested each committee review their draft goals, fill in missing data (inclusive of ED&I) and approve prior to the Board meeting on October 21. Kari Rosbeck shared it would be great if committee chairs and staff liaisons for the committees could meet prior to October 3 and finalize the draft as we will be putting the board manual together at that time. Dr. Crino then requested that each committee review the 2022 goals and their progress on those goals to ensure success at year end.

Approval of the Minutes from the May 6, 2022 Joint Executive-Finance Committee Meeting

Jessica Krefting presented the minutes from the May 6, 2022 Joint Executive-Finance Committee meeting. *Waxlax* moved to approve the Joint Executive/Finance Committee Meeting minutes from May 6, 2022. *Crino* seconded the motion. *The minutes passed without dissent.*

Brief CSO and CEO Reports:

CSO Report:

Steve Roberds provided the CSO report, giving a brief update and setting the stage for the financials for the remainder of the year and for 2023. For background, Dr. Roberds reminded the committee the third FDA approved drug for TSC, HYFTOR® by Nobelpharma, was approved in April and is now available through specialty pharmacies. Of the three FDA-approved drugs for TSC, the TSC Alliance has contributed indirectly to the development of each of these. We have been working with Nobelpharma for the last four or so years because they were focused on community needs and priorities. It was meaningful to see them follow through on that and to have them represented at the World TSC Conference. Dr. Roberds then gave highlights of our research business plan and programs. The Biorepository now stands at 2200 samples. There are over 767 blood samples linked to data in the Natural History Database including 61 that were collected at the World TSC Conference last month. The community response followed the Saturday morning session presented by our Scientific team, highlighting the research programs and including the ability to donate blood to the program. Additionally, 1821 samples have been distributed to 40 distinct researcher on 46 research projects. On the translational research side, Dr. Roberds shared we are projecting to exceed our budget for contracted revenue by over \$350,000. There are currently 10 active industry partners in the Preclinical Consortium. On the clinical side of translational research, we are moving towards clinical trials of the MEK inhibitor, discussed previously. The TSC Alliance has been contracted to serve as the sponsor or organizer of the study. Springworks is paying for everything including staff time and indirect costs involved and we are working with contract research organizations to write and file the IND. The next steps will be to contract with clinical sites next year for the implementation of

the study. For this year, we are projecting \$389,889 which was un-budgeted contract revenue, and the expense which was also un-budgeted is \$215,998. This is a net income of \$173,891.

On grants and conferences, the TSC Alliance received 18 letters of intent and invited 11 to submit full proposals, 3 from postdoctoral fellowships, 8 from early-stage investigators. We did have ED&I goals on those submitting letters of intent. The first goal was to receive 45% of LOIs from female applicants and we actually received 50%. The second goal was to receive 15% of LOIs from unrepresented groups and we received 11%, a little under our goal. This represents 2 of 18 applicants and had it been 3 out of 11 then we would have been at 16.5%. The 2023 International TSC Research Conference is set for Sept 7-9, 2023, at the Omni Shoreham in Washington DC. Contract is signed and we have recruited two co-chairs. Dr. Rebecca Ihrle, who co-chaired our virtual conference in 2021, suggested that we rotate co-chairs so they can learn over time. Dr. Ihrle agreed to chair her second conference along with Dr. Shafali Jeste also agreed to co-chair the 2023 and 2025 conferences.

Dr. Roberds then highlighted the \$2.5 million grant from the Ramesh and Kalpana Bhatia Family Foundation to establish Anya's Accelerator. The project focuses on these three major goals over three years, 2023-2025:

- **Develop quantifiable patient-reported outcomes (PROs)** for the most impactful aspects of TAND utilizing the combined expertise of individuals and families living with TSC and clinical researchers
- **Identify biomarkers and predictors** of specific aspects of TAND through collaborative and inclusive analysis of existing samples and data
- **Improve the translatability** of and test candidate drugs in TAND animal models by incorporating biomarkers or predictors relevant to those identified in humans

He also shared the path that the TSC Alliance will take over the next three years, which includes hiring 2 new people to assist. The project is different than the TAND checklist. We aim to do things differently, complimentary and innovatively and to learn from the community on what would be relevant quality of life measures. We also want to look ahead at potential biomarkers by getting researchers together with community input. We already have a lot of resources at hand, including tissue and blood samples along with a lot of data from a variety of the clinical trials that have been conducted by our Clinical Research Consortium. TSC researchers along with those from related fields will come together to create a plan for data analysis, and then the TSC Alliance will provide directed funding for this effort. On the preclinical research side, we do have an animal model that is relevant to TAND that is being tested right now and we need to test some compounds in that over the next year to make sure we are seeing robust and reproducible effects. Much of the preclinical work for Anya's Accelerator takes place in years 2-3. There are parts of the project that we shared with the Bhatia Family Foundation that we could do for \$5 million vs \$2.5 million, in which we could start to think about clinical studies and validation of patient reported outcomes. The TSC Alliance has received \$200,000 cash in August which will allow us to hire the new employees over the next four months. The remaining \$2.3 million will be received in January 2023. In 2023, we will decide best path forward, execute experiments in 2023 and 2024, and do the bulk of analysis in 2025.

CEO Report:

Kari Rosbeck then shared the CEO report. The research campaign has raised \$3,363,295 in FY22 as of July 31 of an annual goal of \$4,788,500. Overall, the campaign has raised \$11,652,306 cumulatively or 29% of the overall campaign goal with 50% coming from Foundations and 38% from individual major donors. With the Bhatia Family Foundation gift, we have successfully cultivated 2 of 3 anticipated donors at the \$2.5 million range but still need to obtain our \$5 million lead gift. Ideally, we would like to get to a point in our 50th anniversary year in 2024 where we launch the public part of our campaign. We would need to get to 60-65% of our goal to get to that point. As far as donor

cultivations through July, the staff held 94 meetings, including 66 ongoing conversations and submitted 10 requests totaling between \$ 6.7-9.2 million. The reason for the range is our request to the Bhatia Family Foundation included two levels, \$2.5 or \$5 million, per their request. We have received 6 pledges this year totaling \$3,315,000.

For the 2022 World TSC Conference, Kari presented preliminary numbers. We raised \$710,500 in sponsorships or 96% of our goal from 54 sponsors. Overall, we had 998 conference participants including 458 conference registrants, 34 dinner only, 126 speakers/exhibitors, 28 TSC Alliance Staff (also includes Conference Chair, events team from BDI, and VRI staff member helping with blood draws), 147 virtual attendees, 181 day camp (121 day campers, 60 Corporate Kids Events staff). We achieved higher attendance than 2018 by adding the hybrid component. There were 1351 room nights booked compared to 1,419 that we booked in 2018. This will give us a way to look at room guarantees four years from now. Rosbeck gave an overview of sponsors including Title Sponsor Jazz Pharmaceuticals, Presenting Sponsor Nobelpharma, and Visionary Technology Sponsor Drs. Bonnie and Jonathan Rothberg and Family. Also, the Ken Johnson Memorial Scholarship Funds raised from the TSC Alliance Endowment Fund and Foglia Family Foundation provided the opportunity for families who may not have otherwise been able to attend the conference to participate. We are also thankful for the additional conference sponsors in addition to the 20 TSC Clinics that sponsored our conference bags. Dr. Crino stated it was a great conference, well organized, with very few glitches and those were not major glitches.

Treasurer's Report on the July 31, 2022 Financial Statements (Attachments C through K)

Paul Waxlax gave the Treasurer's report. The Statement of Financial Position as of July 31, 2022 remained strong with a healthy cash balance (keeping where we were last year with \$2.3 million and \$1 million over projections to budget). Pledges receivable were at \$5.7 million vs the \$2 million last year. Total net assets with donor restrictions were at \$6.39 million and \$999,644 unrestricted. Total liabilities and net assets at \$9.68 million vs \$5.95 million last year. The TSC Alliance Dashboard highlights include total revenue as of July 31, 2022 actual \$7.2 vs. \$4.5 million that was budgeted which is 59% above budget. It really shows the growth over last year, 84% over year to date from last year. The drivers are the research business plan and special events which are \$2.9M and \$171,000 over budget, respectively. Grants and research (expense) are under budget YTD and the full year is projected to be \$400,000 to positive net as also mentioned in early part of the meeting. Change in net assets YTD \$2.5 million to the positive vs. budget as of July 31 \$1 million to negative. We are \$3.5 million to the positive, for the full year it will most likely be closer to \$700,000 to the positive. Results are strong and above budget even with double budgeting error that we have discussed in the last couple of meetings.

Functional expenses as of 6/30/22 include program expenses 76.03% YTD vs. 78.5%-year end budgeted, 14.19% support (fundraising) services vs. year-end budget of 11.07%, and administrative costs were at 9.79% vs. year-end budget of 10.43%. Functional expenses are evaluated every quarter and will be calculated next at 9/30/22. Dr. Roberds commented that the 2022 goal is for year end and that grants typically are paid out in the later part of the year so he feels that it will be made up some in programs.

Cynthia Arcuri presented on milestones and staged spending for 2022. Because we were originally planning for a negative budget YTD we put in place gate posts that outlined cuts to get the financials back in alignment. Cynthia shared results and projected results for July 15th and the Sept 15th checkpoint. July 15 in which we used the 6/30/22 balance numbers, cash balance was over by \$823,484 and for total revenue we were over by \$2.5 million. The next checkpoint is using the 8/31/2022 numbers (with numbers still coming in) for the cash balance we are over by \$761,911 however it appears that we are just shy total revenue. We are under by \$273,319 if we take into account the budget for the double counting which was \$317,000 the net difference is about \$43,681

to the positive. From this perspective, Waxlax and Arcuri agreed with the overall strength of the financials they would recommend that we not pull back on our expenses. Paul did recommend if we continue with this milestone and staging next year we look at our targets more closely because we might have been too aggressive with our targets.

Waxlax moved on to cash flow as of July 31, 2022, Q3 seems to be an outflow cycle and Q4 inflow cycle. From his perspective Q4 looks quite conservative we probably aren't projecting some of the unknown cash flows that come in during Q4 and there might be an opportunity for the cash flow to be even stronger than we are currently projecting. In January we see the real inflow of the \$2.3 million from the Bhatia Family Foundation, which is a significant impact on the cash flow. The Finance Committee will review the reserve in 2023 and likely need to increase it.

Arcuri gave an update on the World TSC Conference. As the numbers start to finalize and as of the end of July, we project a net income of \$35,000. TSC Alliance is still finalizing numbers and received the final invoice from the Hilton Anatole (though there are adjustments to be made that are ongoing). There are also a few final expenses coming in over this next month. With less people attending, Cynthia shared we were able to reduce food and beverage costs. She asked if there were any questions about the World TSC Conference about expenses. Brittany Smith stated she again wants to thank everyone for a wonderful conference. Matt Bolger inquired about room night minimum and Rosbeck stated it was exceeded.

Rosbeck shared that we also needed approval by the Finance Committee of the meeting minutes for the Joint Executive-Finance Committee from the May 6. Waxlax asked for a motion to approve the minutes, *Coit* moved and *Smith* seconded the motion to approve the Joint Executive-Finance Committee meeting minutes from May 6, 2022. *The minutes approved without dissent.*

Endowment Fund:

Arcuri shared the TSC Alliance Endowment Fund report on behalf of Marion Adams. The Endowment Fund started the year with \$6,691,013 in investments and are currently at \$6,011,430. June was not a good month but it came back some in July so we are down about 10%. The Endowment Fund Dashboard recap included general contributions of \$3,000 compared to a budget of \$66,000 and at end of July. Arcuri did acknowledge that staff was more focused on the earlier fundraisers and the World TSC Conference and now have shifted to the Endowment Fund. She added that we did receive a \$10,000 check earlier in the week. Expenses slightly under budget and from last year due to lowering expenses for fundraising consultants. Overall, the deficit is primarily due to market conditions at (\$726,000). The largest expenses included transfers to operating including \$70,000 for scholarships for the World TSC Conference which included an additional \$20,000 approved in March.

Next Meetings:

- Finance Committee – October 20, 2022, 4-5:30 p.m. ET
- Joint Executive and Finance Planning Committee Meeting, November 11, Noon to 3 p.m., held via Zoom

Other Business:

Crino opened the floor to Rosbeck to explain the additional business of extended signing authority for CSO to match staff back-up plan. Rosbeck shared that the staff works annually to update the staff back up plan and the long term back up plan. If Rosbeck is out longer than two weeks Roberds assumes the responsibilities of the CEO. Currently, Roberds signing authority is \$100,000. We also have several contracts with the MEK trial or amendments to current Preclinical contracts that are a more expensive than his signing authority. Roberds reviews and authorizes these changes but Rosbeck must sign because of the threshold. For both of these reasons, Rosbeck is asking that

Roberds have similar signing authority as the CEO which also places the organization in a better a long-term situation if something happened to Rosbeck. Rosbeck asked Bolger to step in regarding any bylaws concerns. Rosbeck also stated that any check more than \$25,000 requires two signatures in our software so there is a check and balance. Smith stated she is comfortable with allowing Roberds to sign as there are check and balances and it is justified by the business needs. Crino asked who the other signing person currently and Rosbeck stated it is Arcuri. Bolger stated that it is Article 8 section 1 by resolution, the Executive Committee can authorize CSO with signing authority to match backup plan.

Waxlax moved to approve CSO to have signing authority to match back-up plan (and matching CEO signing authority). *Krefting* seconded the motion. *Motion approved without dissent.*

As there was no further business, *Joseph* moved to adjourn the meeting and *Waxlax* seconded. The meeting was adjourned at 6:47 p.m.

Respectfully submitted,
Jessica Krefting, Secretary