# Ryan Mathis, M.D.

Clinical Executive | Commercial Executive | Physician | Entrepreneur

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## SUMMARY

Forward-thinking physician, executive and entrepreneur who left clinical medicine to join a start-up in its first year to translate a novel technology and reach patients on a broader scale. Assumed various leadership roles across the company to support growth, resulting in a rare blend of scientific, clinical, regulatory and commercial experience. Proven record applying experience to develop translational approaches that improve patient outcomes, build a reimbursement foundation and are strategically positioned to maximize asset value.

- Translated a novel autologous product from animal trials to commercialization.
- Filed Biologic Investigational New Drug (IND) application to transition an autologous product from Human Cell and Tissue Based Product 361 (HCT/P 361) FDA pathway to biologic pathway.
- Authored Regenerative Medicine Advanced Therapy (RMAT) Application and received approval by FDA for two indications.
- Led commercial team (marketing, market access, sales, sales operations) through a strategic change in positioning, rebranding and repricing to achieve revenue and KPI records for 5 consecutive quarters prior to FDA pathway transition.
- Utilized health economic outcome research (HEOR) to strategically price and a build value story accelerating sale cycle and leading to access to more than 1/3 of US hospitals.

## CORE COMPETENCIES

### Clinical

Clinical translation

FDA interactions (CDER/CBER)

IND planning, writing & submission

Regulatory strategy, including accelerated FDA pathways (RMAT)

Clinical trial design & launch

Collecting & applying Real-World Evidence (RWE)

### Commercial

Product launch, positioning & marketing strategy

Strategically leveraging Health Economic Outcomes Research

Pricing & reimbursement planning

US Sales & MSL team development & leadership

KOL & advisory board cultivation

### Corporate

Start-up/early-stage infrastructure building & corporate strategy

Investor relations & public company financing

Pipeline prioritization & optimization

Eliminating internal inefficiencies through cross-departmental teamwork

Developing talent & driving a patient-first culture

## EXPERIENCE

**PolarityTE Inc.** | *Salt Lake City, Utah* 12/2017 – present
Publicly traded clinical stage biotechnology company focused on autologous tissue regeneration

**Chief Medical Officer** 8/2021 – present

- Led transition of an autologous product from FDA HCT/P 361 to biologics pathway, with IND accepted June 2022.
  - Pre-IND FDA interaction
  - IND planning and writing
  - Utilized RWE in IND filing to support safety and enter directly into phase III.
  - GTP to GMP transition including release assay development
  - IND submission and acceptance
- Developed FDA accelerated pathway strategy and authored Regenerative Medicine Advanced Therapy (RMAT) application which was accepted early by the FDA for two indications.
- Provided clinical strategy and interfaced with FDA for a type B (CDER/CBER) meeting granted following RMAT acceptance.

- Utilized RWE and Collaborated with clinical research team on development of Phase III pivotal trial protocol design, site recruitment & onboarding, site training and clinical support.
- Serve on the Data Safety Monitoring Board as the sponsor contact for Phase III clinical trial.
- Led MSL team providing clinical support to trial sites and drove site engagement through continuing education.
- Strategic lead for indication prioritization and utilization of real-world evidence to support healthcare economic story and indication expansion.
- Interface with national patient and provider organizations and committees and serve as a member of the research committee for a national provider organization.

**Vice President of Commercial Strategy – Head of Commercial** 1/2020 – 8/2021

- Led commercial team responsible for marketing, sales, market access and sales operations departments following a largely unsuccessful launch.
- Achieved the companies first cash-flow break even quarter for the department in the first full quarter with the team.
    - Resized sales force and MSLs based on hospital system access.
    - Tackled internal inefficiencies and delays by engaging cross-departmentally and developing new SOPs.
- Achieved 333% revenue growth over five quarters and achieved company records in re-users and revenue every subsequent quarter.
    - Repositioned the product to target an unmet inpatient need to drive adoption by getting entrenched in provider treatment algorithms
    - Redefined key strategic metrics, prioritizing re-users and deeper penetration in hospital systems
    - Developed internal programs to encourage collaboration across clinical, sales, sales ops and marketing.
- Quarterly individual revenue per rep went from ~17K to 216K.
    - Developed and employed a new incentive compensation plan aligned with new strategic initiatives and internal CRM which better defined market opportunity while aligning with KPI goals and cutting cost.
- Implemented online speaker programs to leverage KOLs during COVID19 at a reduced cost.
- In anticipation of FDA pathway change, led the team responsible for transitioning coding strategy from a Q code to J code

**Vice President of Clinical Marketing** 5/2019 – 1/2020

- Managed internal marketing team, consulting marketing teams and a 3M dollar budget.
- Led KOL mapping and implementation of a speaker's bureau program with 17 KOLs from 5 therapeutic disciplines across major US markets.
    - Led strategy including presentation content and market opportunity-based speaker selection.
    - Established a speaker's portal with outside vendor to streamline scheduling for sales partners and ensure compliance.
    - Developed and led KOL onboarding and continued education.
- Cross-departmentally worked to build promotional review committee and managed implementation of a third-party portal and process (compliance, legal).
- Collaborated with sales, market access, compliance and public relations in the development and Implementation of a product brand plan.
    - Orchestrated market research leading to defined messaging, refined value proposition and development of an attributes and benefits model for top-down forecasting, product development and overlayed competitive landscape.
    - Developed and implemented publication strategy and plan.
    - Penetrated new business segments through strategic tactics for sales, clinical support and patient support and refined provider targeting.
    - Strategically led a rebranding in conjunction with repackaging of the product leading to reduction in COGs

- Created a new coding guide in conjunction with market access, compliance and legal.
- Partnered with commercial team to execute a National Sales Meeting roll out of new commercial strategic initiatives and rebrand.
- Clinical and commercial team representative for website redesign.

**Vice President of Clinical Operations** | reported to CEO 6/2018 – 5/2019

- Built and managed US Medical Science Liaison (MSL) team.
- Developed operational framework and processes to provide improved clinical support for commercial users, streamline hospital access, and optimize results for patients.
    - Shortened sale cycle with creation of a standard Value Analysis data packet and presentation highlighting both clinical and health economic outcomes data.
    - Standardized product use with internal clinical training (sales, clinical) program and external training program for medical practitioners and staff.
- Created the inaugural clinical research team and launched a 100-patient randomized controlled trial to support evidence and payer coverage.
- Developed strategic publication plan to expand patient population and continue to build evidence.
- Presented nationally and internationally at conferences, journal clubs and grand rounds, and served as company liaison for professional societies.

**Director of Clinical Operations & Business Development** | reported to COO 12/2017 – 6/2018

- Clinically translated autologous product from animal trial for first in human use.
- Co-authored FDA HCT/P 361 filing.
- Clinical member of original team which developed GTP manufacturing facility and SOPs.
- Identified, recruited and liaised with multi-disciplinary Clinical Advisory Board.
- Created process and logistics for shipment of autologous tissue to AATB standards.
- Established safety reporting process with regulatory and compliance.
- Clinically Supported first in human use of HCT/P product.
- Led a product development driven soft-launch to refine clinical protocol and product logistics in the clinical setting.

## EDUCATION/TRAINING

Medstar Georgetown University Hospital, **Residency in Plastic Surgery** 2014 – 2017

Pennsylvania State University College of Medicine, **Doctor of Medicine (M.D.)** 2010 – 2014

Pennsylvania State University, **BS – Science** 2005 – 2009

## LICENSES/CERTIFICATIONS

Professional License: Medical Physician and Surgeon, Pennsylvania, Active License

## SPECIAL ACHIEVEMENTS

Georgetown University School Masters in Biotechnology, Guest Lecturer 2020
Clinical Performance Award for Junior Residents 2017
Excellence in Resident Teaching “String of Pearls Award” (2015/2016/2017)

## PUBLICATIONS/CHAPTERS

Burgueno-Vega, D., Shahani, S., Mathis, R., Blakely, M. Treatment of stage 4 pressure injuries with autologous heterogenous skin construct: A single-center retrospective study. EPlasty. 2023 May 23;23:e26.

DeFazio MV, Economides JM, Anghel EL, Mathis RK, Barbour JR, Attinger CE. Traction-assisted Internal Negative Pressure Wound Therapy With Bridging Retention Sutures to Facilitate Staged Closure of High-risk Wounds Under Tension. Wounds. 2017 Oct;29(10):289-296. doi: 10.25270/wnds/2017.10.289296. Epub 2017 Jul 26. PMID: 28873059.

Spear, S.L., Mathis, R., Albino, F.P., Pittman, T.A. (2017). The Inframammary Approach to Nipple-Sparing Mastectomy: The Georgetown University Hospital Experience. In: Harness, J., Willey, S. (eds) Operative Approaches to Nipple-Sparing Mastectomy. Springer, Cham. https://doi.org/10.1007/978-3-319-43259-5_4

Tousimis, E., Tambar, S., Kanuri, A., Mathis, R., Willey, S., Seevaratnam, S., Pittman, T. Single-blinded, randomized assessment of post-mastectomy analgesia using exparel (liposomal bupivacaine) versus standard bupivacaine or placebo (saline). 2017 April *ANNALS OF SURGICAL ONCOLOGY* (Vol. 24, pp. 196-197).

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Schwitzer JA, Albino FP, Mathis RK, Scott AM, Gamble L, Baker SB. Assessing Patient-Reported Outcomes Following Orthognathic Surgery and Osseous Genioplasty. J Craniofac Surg. 2015 Nov;26(8):2293-8. doi: 10.1097/SCS.0000000000001983. PMID: 26501967.

Schwitzer JA, Albino FP, Mathis RK, Scott AM, Gamble L, Baker SB. Assessing Demographic Differences in Patient-Perceived Improvement in Facial Appearance and Quality of Life Following Rhinoplasty. Aesthet Surg J. 2015 Sep;35(7):784-93. doi: 10.1093/asj/sjv066. Epub 2015 Jun 10. PMID: 26063837; PMCID: PMC5006218.

Michelotti B, Mathis RK, Roberts J, Wilkinson MJ. Periorbital Mohs Reconstruction: Characterization of Tumor Histology, Anatomic Location and Factors Influencing Post-Operative Complications. Dermatol Surg. 2014 Oct;40(10):1084-93

Mathis RK, Lin J, Dogal NM, Qiu F, Kunselman A, Wang S, Ündar A. Evaluation of four pediatric cardiopulmonary bypass circuits in terms of perfusion quality and capturing gaseous microemboli. Perfusion. 2012 Nov;27(6):470-9. doi: 10.1177/0267659112453078. Epub 2012 Jun 29. PMID: 22751383.

Lin J, Dogal NM, Mathis RK, Qiu F, Kunselman A, Ündar A. Evaluation of Quadrox-i and Capiox FX neonatal oxygenators with integrated arterial filters in eliminating gaseous microemboli and retaining hemodynamic properties during simulated cardiopulmonary bypass. Perfusion. 2012 May;27(3):235-43. doi: 10.1177/0267659112438932. Epub 2012 Feb 15. PMID: 22337759.

Dogal NM, Mathis RK, Lin J, Qiu F, Kunselman A, Undar A. Evaluation of three hollow-fiber membrane oxygenators without integrated arterial filters for neonatal cardiopulmonary bypass. Perfusion. 2012 Mar;27(2):132-40. doi: 10.1177/0267659111430560. Epub 2011 Nov 24. PMID: 22115879.