

# Regenerative Medicine Reimagined

June 2022

# **Forward-Looking Statements**

This presentation of Aziyo Biologics, Inc. ("Aziyo," "we," "us," "our" or the "Company") (together with any other statements or information that we may make or discuss in connection herewith) contains forward-looking statements. All statements other than statements of historical facts, including but not limited to statements regarding future financial condition, results of operations, including, without limitation, cash flow improvement, business strategies, development plans, industry trends, regulatory activities, market opportunity, competitive position, our pipeline, potential growth opportunities, our products, their targeted effects and expected commercial availabilities, our pipeline and investments in new products and technologies, approvals of future products or product uses, expectations regarding continued acquisitions, ability to close and execute on strategic transactions and the potential results of such transactions are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements are based on our management's current expectations, beliefs and assumptions and on information currently available to us. The future events and trends discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements in this presentation are only predictions. These statements involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements due to various factors, including, but not limited to our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings; the impact on our business of the recall of a single lot of our FiberCel product and the discontinuation of its sales by our distribution partner; our dependence on our commercial partners and independent sales agents to generate a substantial portion of our net sales; our ability to maintain our relationships with our existing contract manufacturing customers and enter into agreements with new contract manufacturing customers reduce purchases of our products; our ability to successfully expand, manage and maintain our direct sales force; our ability to achieve or sustain profitability; the adverse impacts of the novel strain of coronavirus disease, COVID-19 or any other future pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide; adverse changes in general domestic and global economic conditions and instability and disruption of credit markets, including as a result of the current COVID-19 pandemic or any other outbreak of an infectious disease; physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products; the continued and future acceptance of our products by the medical community; our ability to obtain regulatory approval or other marketing authorizations by the FDA and comparable foreign authorities for our products and product candidates; and our ability to obtain, maintain and adequately protect our intellectual property rights and other importan

This presentation includes a discussion of certain non-GAAP financial measures, including non-GAAP gross profit and non-GAAP gross margins. We use the non-GAAP financial measures to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that non-GAAP financial measures are helpful to investors for supplemental informational purposes. We recommend that you do not rely on any single financial measure to evaluate our business. The Appendix to this presentation includes reconciliations of these non-GAAP financial measures to the most comparable GAAP financial measure.

This presentation may also contain statistical data, estimates and/or other information or data made by independent parties and/or by us relating to market size and growth, as well about our industry and business. Any such data or information that is based on estimates, forecasts, projections, market research, or similar methodologies, involve a number of assumptions and limitations and are inherently subject to uncertainties, and we have not independently verified the accuracy or completeness of these data. Neither we nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation. In addition, projections, assumptions and estimates of our future performance and the future performance of our industry or the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.



# **Investment Summary**



Highly differentiated regenerative medicine products targeting large markets



Flagship product CanGaroo, nextgen version with antibiotics (CanGaroo RM) 510(k) submitted to FDA April 2022



CanGaroo direct sales force augmented through sales collaboration partnerships with Boston Scientific and Biotronik



Viable bone matrices and acellular dermis product lines provide additional growth drivers and cash generation



4Q21 PIPE financing strengthens balance sheet and validates investment opportunity



Attractive valuation



## **Recent Updates**

- Appointed Co-founder Randy Mills, Ph.D. as Interim President & CEO
  - Co-founded Aziyo in 2015 with Kevin Rakin (Aziyo Executive Chairman)
  - Previous President/CEO of Sanford Burnham Prebys Institute, California Institute for Regenerative Medicine, Osiris Therapeutics
- Financial Highlights
  - FY 2021 net sales of \$47.4M, 11% growth over 2020, 19% growth excluding FiberCel (discontinued)
  - Q1 2022 revenue of \$11.5M, 14% growth (on continuing operations)
  - 2022 revenue guidance of \$47-50M, 11%-18% growth (on continuing operations)
  - 03/31/2022 cash balance of \$22.2M
- Submitted 510(k) and subsequently received acceptance for review by the FDA for CanGaroo RM, next-gen version loaded with antibiotics
- Private placement of \$14M closed on December 8, 2021
  - Primary investors: Birchview Capital, Deerfield Management Company and HighCape Capital
  - Supports near term launch of CanGaroo RM





## CanGaroo: Only Biomaterial Envelope for Implantable Electronic Devices

#### THE ANNUAL MARKET OPPORTUNITY:

• \$600M based on ~600K procedures

#### THE PROBLEM:

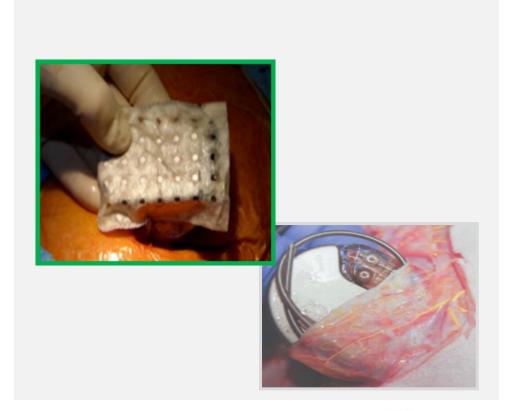
 Fibrotic capsule formation, device migration or erosion, infection, discomfort



### THE AZIYO SOLUTION: CanGaroo

- Only biomaterial envelope that creates a natural, systemically vascularized pocket
- Remodels into native tissue for long term protection

# Indication: To securely hold an IED to create a stable environment





# CanGaroo Helps Create a Healthy Pocket



Fibrotic Scar, Embedded Leads
No Envelope Patient



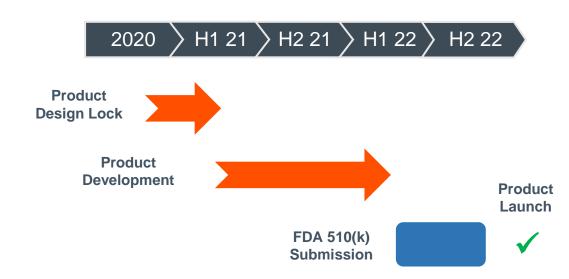
Healthy Tissue, Accessible Leads
CanGaroo Patient

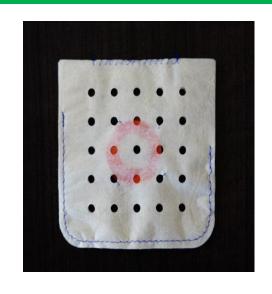


# CanGaroo® RM

CanGaroo biomaterial envelope loaded with rifampin and minocycline in a dissolvable polymer ring

#### **510(k) Development Timeline**







#### <u>Biomaterial + Antibiotics = Favorable Profile</u>

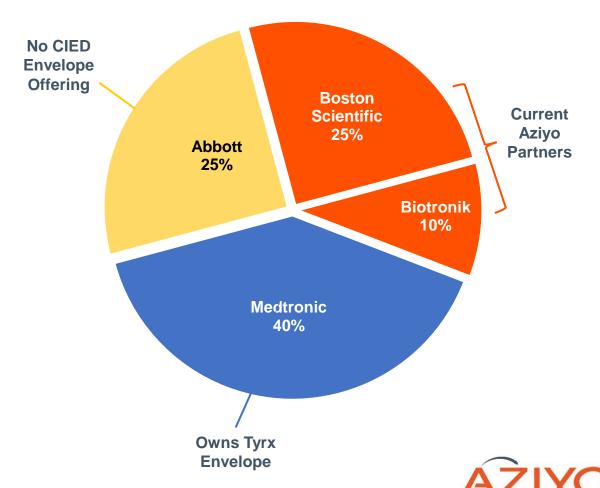
Market Research: In a study among U.S. electrophysiologists currently using envelopes, more than 80% indicated they would consider using a biomaterial envelope that also contains antibiotics<sup>1</sup>



# CanGaroo Go-to-Market Strategy

- Ship product directly to hospitals
- Sold through direct sales force (~30 territories)
- Leverage Boston Scientific & Biotronik commercial agreements to pull through product in U.S.; Biotronik distributes in Europe
- Premier designation as a
   Breakthrough Technology expands
   reach to 4K+ U.S. hospitals

# U.S. Cardiac Implantable Electronic Device (CIED) Market Share<sup>1</sup>



## CanGaroo Future Growth Drivers

- CanGaroo RM clearance and launch
- Investing in US commercial footprint
  - Expanding to 40+ US territories following RM launch
- International sales with recently expanded label
  - Biotronik partnership in Europe
- Clinical studies to further showcase biological remodeling benefits
  - HEAL study compares CanGaroo vs synthetic envelope vs no-envelope at time of CIED change-out
  - CanGaroo Registry follows de novo CanGaroo and no-envelope patients for up to five years
- CanGaroo use in new applications
  - Already approved for use with neurostimulation devices
  - Potential use for other implantable electronic devices



# Highly Leverageable Portfolio to Fuel Growth in CV









**Core Products** 

**Non-Core Products** 

# CV / IMPLANTABLE ELECTRONIC DEVICES

SOFT TISSUE RECONSTRUCTION

ORTHOPEDIC / SPINAL REPAIR

CONTRACT
MANUFACTURING

- Human tissue products
- Profits redeployed into higher-growth / higher-gross margin CV product lines



# Soft Tissue Reconstruction: SumpliD∈rm



#### \$500M MARKET OPPORTUNITY

~100K procedures using biologic products for plastic and reconstructive surgery in the U.S. in 2019

#### THE PROBLEM:

 Native tissue inadequate for defect repair; for procedures requiring larger sizes of biologic materials, increased implanted material volume means increasing inflammatory response risk

# THE AZIYO SOLUTION: SimpliDerm

- Patented acellular dermal process results in matrix structure closely resembling that which occurs naturally
- Low immunogenicity to reduce inflammatory and foreign body response
- Promotes healthy tissue remodeling

### **Growth Strategies**

- Build clinical evidence
- Expand market access with payers and healthcare systems
- Drive product awareness and adoption through national distributor network



## Orthopedic / Spinal Repair: Platform Overview

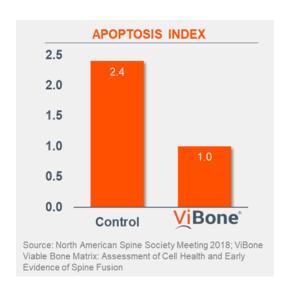
#### \$2B ANNUAL MARKET OPPORTUNITY<sup>1</sup>

~1.5M ortho/spinal repair procedures in the U.S. in 2019

#### THE PROBLEM:

 Standard processing techniques for allografts accelerate cell apoptosis, which may result in non-union or non-fusion

#### **AZIYO SOLUTIONS: Viable Bone Matrix Products**



#### OsteGro°V Fiber VBM ViBone°



Proprietary process optimized to protect the native bone cells and reduce cell apoptosis, with advanced donor screening and product testing methods

### **Growth Strategies**

- Generate product differentiation evidence
- Assist commercial partners to drive share
- Sign new partners
- Develop and launch new products



# **Investment Summary**



Highly differentiated regenerative medicine products targeting large markets



Flagship product CanGaroo, nextgen version with antibiotics (CanGaroo RM) 510(k) submitted to FDA April 2022



CanGaroo direct sales force augmented through sales collaboration partnerships with Boston Scientific and Biotronik



Viable bone matrices and acellular dermis product lines provide additional growth drivers and cash generation



4Q21 PIPE financing strengthens balance sheet and validates investment opportunity



Attractive valuation





# **Appendix**



## **Experienced Leadership Team**



Randy Mills, Ph.D.
Co-founder, Interim President & CEO

- 20+ years experience leading organizations, developing innovative products and building shareholder value
- Internationally recognized expert in regenerative medicine











**Tom Englese Chief Commercial Officer** 

- 15+ years leading commercial organizations through periods of significant growth
- Former GM of a multi-product hospital division







Jerome Riebman, M.D. Chief Medical Officer

- 20+ years leading the development of novel medical products
- Clinical experience in cardiovascular and thoracic surgery







**Courtney Guyer** VP, Marketing

- 15+ years leading marketing functions
- Numerous product launches in med tech and regenerative medicine



Johnson Johnson



**Peter Edwards General Counsel** 

- 20+ years leading legal departments at multibillion-dollar companies
- Expertise in corporate governance, litigation and M&A transactions







**Matthew Ferguson Chief Financial Officer** 

- 20+ years leading finance and administrative functions at public and private healthcare and technology companies
- Experience scaling multiple commercial-stage med tech businesses







Darryl Roberts, Ph.D.
EVP, Operations & Product Development

- 20+ years leading product development efforts and operations
- Experience in regenerative medicine solutions



Johnson Johnson



Jeffrey Hamet VP. Finance

- 20+ years leading finance departments in public and private companies
- 8+ years public accounting experience







# **Statement of Operations**

|   | Quarter Ended<br>March 31, |           |
|---|----------------------------|-----------|
| (\$ in thousands)                               | 2021                       | 2022      |
| Core Products                                   | 10,664                     | 8,140     |
| Non-Core Products                               | 2,220                      | 3,355     |
| Net Sales                                       | \$12,884                   | \$11,495  |
| Total Net Sales Growth                          |                            | -11%      |
| Net Sales Growth Excluding Discontinued Product |                            | 14%       |
| COGS (excluding amortization)                   | 5,706                      | 6,365     |
| COGS  | 6,555                      | 7,214     |
| Gross Profit (excluding amortization)           | \$7,178                    | \$5,130   |
| Gross Profit                                    | \$6,329                    | \$4,281   |
| Gross Margin (excluding amortization)           | 56%                        | 45%       |
| Gross Margin                                    | 49%                        | 37%       |
| Operating Expenses:                             |                            |           |
| Sales and Marketing                             | 4,703                      | 4,818     |
| % of Net Sales                                  | 37%                        | 42%       |
| General and Administrative                      | 3,605                      | 4,113     |
| % of Net Sales                                  | 28%                        | 36%       |
| Research and Development                        | 1,720                      | 2,272     |
| % of Net Sales                                  | 13%                        | 20%       |
| Total Operating Expenses                        | \$10,028                   | \$11,203  |
| Loss from Operations                            | (\$3,699)                  | (\$6,922) |





## **Non-GAAP** Reconciliation

|  | Quarter Ended |          |
|--|---------------|----------|
|  | March 31,     |          |
| (\$ in thousands)                                      | 2021          | 2022     |
| Net Sales  | \$12,884      | \$11,495 |
| GAAP Gross Profit                                      | \$6,329       | \$4,281  |
| Intangible asset amortization expense                  | \$849         | \$849    |
| Non-GAAP Gross Profit (excluding amortization expense) | \$7,178       | \$5,130  |
| GAAP Gross Margin                                      | 49%           | 37%      |
| Non-GAAP Gross Margin (excluding amortization expense) | 56%           | 45%      |



## Generating Clinical Data to Support Product Differentiation

#### **HEAL:** Retrospective Remodeling Benefit Study

#### **Study Details**

- Multi-center comparative study
- 3 cohorts: CanGaroo, Tyrx, No Envelope
- Up to 100 participants (30-35 per cohort)
- Comparing healing & clinical outcomes/complications through
  - Biopsies, pre-op & intra-op photos, POSAS scar scale
  - Classification of lead adhesions & amount of fibrotic tissue in the pocket
- No study-related follow-up visits

#### Status: 11 sites recruiting patients<sup>1</sup>

Additional sites in process

# **DeNovo Registry: Outcomes & Complication Comparison Between CanGaroo and No Envelope**

#### **Study Details**

- Overall enrollment up to 500 patients in a 2:1 ratio (CanGaroo : No Envelope)
- Standard follow-up: 1 week, 4-6 weeks, 3 months, any unscheduled visits, any reoperations
- Optional extended follow-up (≤65 yrs.): 1 week, 4-6 weeks, 3 months, 6 months, every 6 months going forward for up to 5 years, any unscheduled visits, any reoperations

#### Status: 21 sites recruiting patients<sup>1</sup>

Additional sites in process



