Aytu BioPharma Announces Business and Pipeline Progress and Reports Second Quarter 2022 Financial Results

Quarterly Net Revenue Increased 53% Year-over-year to $23.1 Million

PREVEnt Pivotal Study for AR101 in Vascular Ehlers-Danlos Syndrome On-track to Begin in Mid-2022

Initiation of Randomized, Sham-controlled Study of Healight in Patients with SARS-CoV-2 to Begin Shortly

ENGLEWOOD, CO / February 14, 2022 / Aytu BioPharma, Inc. (NASDAQ:AYTU), a pharmaceutical company focused on developing and commercializing novel therapeutics, today announced business and pipeline progress and reported financial results for its fiscal second quarter 2022 ended December 31, 2021.

“The last several months have been a time of significant progress across our commercial business, exemplified by the consistent growth in our commercial prescription and consumer health product revenues, with multiple products hitting all-time highs in prescription performance, leading to the second highest revenue quarter in Aytu’s history,” said Josh Disbrow, chief executive officer of Aytu BioPharma.

“In parallel, we’ve continued to execute our longer-term corporate strategy focused on developing novel treatments, including AR101, for pediatric-onset diseases. AR101 has received orphan drug designation, and we are underway with efforts to initiate our PREVEnt registrational study by mid-2022, evaluating AR101 as a first-in-class treatment for VEDS, a devastating and life-threatening pediatric-onset disease for which there are no approved treatments. The combination of our team’s incredible work advancing our pipeline and commercial business with our strengthened balance sheet, sets us up for a meaningful 2022 and our potential to provide benefit to patients and caregivers, while creating value for our stakeholders.”

Fiscal Second Quarter 2022 Financial Results:

- Net revenue for the second quarter of fiscal year 2022 was $23.1 million, compared to $15.1 million for the same quarter in fiscal year 2021, a 53% increase year-over-year
    - Net revenue from prescription sales was $14.6 million, compared to $7.2 million in the same quarter last year, growth of over 103% year-over-year
        - ADHD brands Adzenys XR-ODT and Cotempla XR-ODT experienced 8.7% growth in prescriptions compared to the quarter ended September 30, 2021, reaching all-time high weekly prescription levels for Adzenys XR-ODT
        - Prescription pediatric portfolio comprised of Poly-Vi-Flor, Tri-Vi-Flor, and Karbinal ER experienced 5.7% growth compared to the quarter ended

September 30, 2021
    - Net revenue from the consumer health division was $8.5 million, compared to $7.9 million in the same quarter last year, growth of over 7% year-over-year
- Gross profit increased to $12.3 million in the second quarter of fiscal 2022, compared to $8.9 million in the same quarter in fiscal year 2021
- Net loss for the second quarter of fiscal year 2022 was $11.5 million, or $0.44 per share, compared to $9.5 million, or $0.72 per share for the same quarter last year
- Adjusted EBITDA[1], (EBITDA excluding Research & Development (R&D) expenses related to our AR101 and Healight programs), for the second quarter of fiscal year 2022 was $(3.5) million.
    - R&D expenses included a $2.5 million milestone payment upon achieving Orphan Drug Designation for AR101
- Cash and cash equivalents totaled $35.3 million as of December 31, 2021

Pipeline Progress:

- **IND Clearance and Orphan Drug Designation Granted for AR101 for the Treatment of Vascular Ehlers-Danlos Syndrome:** The U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug (IND) application for AR101 (enzastaurin), a PKCβ inhibitor, enabling Aytu to proceed with initiating a pivotal clinical trial for AR101 for the treatment of vascular Ehlers-Danlos Syndrome (VEDS), a life-threatening inherited connective tissue disorder for which there are no approved treatments. Aytu plans to initiate the PREVEnt Trial to assess the safety and efficacy of AR101 in patients with COL3A1-confirmed VEDS by mid-2022.

  Additionally, in December 2021, the FDA granted Orphan Drug designation (ODD) to AR101 for the treatment of VEDS. The FDA grants ODD status to drugs and biologics that are intended for the safe and effective treatment, diagnosis or prevention of rare diseases, or conditions that affect fewer than 200,000 people in the U.S. ODD affords Aytu certain financial incentives to support clinical development and the potential for up to seven years of market exclusivity in the U.S. upon regulatory approval.

- **First U.S. Patent Issued Supporting Healight UV-A Light Catheter:** The United States Patent and Trademark Office (USPTO) issued a U.S. patent for the Healight™ ultraviolet-A light-based respiratory catheter. U.S. Patent Number 11,179,575, titled “Internal Ultraviolet Therapy,” is the first issued patent protecting the Healight investigational device and covers methods of treating a patient for an infectious condition inside the patient’s body through the insertion of a UV-light-emitting delivery tube inside a respiratory cavity of the patient at specific UV-A light wavelengths. The term of this patent extends to August 2040.

  Aytu is preparing to initiate a sham-controlled study of Healight for use in patients with

SARS-CoV-2 imminently.

Business Progress:

- **Strengthened Financial Position with $15 Million Debt Refinancing with Avenue Capital**: Aytu entered into an agreement with the Avenue Venture Opportunities Fund, L.P., an affiliate of Avenue Capital Group, to refinance the company's existing senior secured loan facility. Under the new financing agreement, Aytu is borrowing $15 million at an interest rate of the greater of prime and 3.25%, plus 7.4% and is using the proceeds to refinance its previous credit facility with Deerfield Private Design Fund III, L.P. and Deerfield Partners, L.P. The new facility with Avenue Capital provides a three-year term, consisting of 18 monthly payments of interest only followed by equal monthly payments of principal and accrued interest. The interest-only period may be extended to up to 36 months contingent upon Aytu achieving certain milestones. There are no minimum revenue or cash balance financial covenants in connection with the agreement. In addition, under the terms, Aytu issued the Avenue Venture Opportunities Fund warrants to purchase shares of its common stock equating to 7.00% of the principal amount.
- **Expanded Leadership with the Appointment of Mark Oki as Chief Financial Officer:** Mark Oki joined Aytu as the company's chief financial officer, bringing over twenty years of financial leadership experience in the biotechnology and pharmaceutical industries across numerous development- and commercial-stage companies.
- **Manufacturing Transfer of Adzenys XR-ODT and Cotempla XR-ODT On-Track for Completion in the First Half of 2023:** Aytu continued to progress the technology transfer of heritage Neos brands, Adzenys XR-ODT and Cotempla XR-ODT, out of its Grand Prairie, Texas manufacturing facility to a global contract manufacturer. This tech transfer is expected to drive a significant improvement in the gross profit margin across the company's ADHD product portfolio and reduce working capital requirements associated with inventory purchases. The company remains on-track to complete this transition by the middle of calendar year 2023.

Aytu will not host a conference call to discuss its second quarter fiscal year 2022 financial results. Moving forward, the company may host conference calls in conjunction with key product and pipeline updates or other corporate developments, as appropriate.

[1] Aytu uses the term EBITDA or Earnings Before Interest, Income Taxes, Depreciation and Amortization, which is a term not defined under United States Generally Accepted Accounting Principles. The Company uses this term because it is a widely accepted financial indicator utilized to analyze and compare companies on the basis of operating performance. The Company believes that presenting EBITDA adjusted to exclude expenses related to development of its AR101 and Healight development programs and non-cash adjustments

(Adjusted EBITDA) provides information to the reader to evaluate the Company's commercial activities. See reconciliation of Adjusted EBITDA to net income in table set forth below. The Company's method of computation of EBITDA may or may not be comparable to other similarly titled measures used by other companies.

About Aytu BioPharma, Inc.

Aytu BioPharma is a pharmaceutical company with a portfolio of commercial prescription therapeutics and consumer health products, and a growing therapeutics pipeline focused on treating rare, pediatric-onset disorders. The company's prescription products include Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING) and Cotempla XR-ODT® (methylphenidate) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING) for the treatment of attention deficit hyperactivity disorder (ADHD), as well as Karbinal® ER (carbinoxamine maleate), an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary fluoride-based prescription vitamin product lines containing combinations of fluoride and vitamins in various formulations for infants and children with fluoride deficiency. Aytu is also building a therapeutic pipeline, which includes AR101 (enzastaurin), a PKCβ inhibitor in development for the treatment of vascular Ehlers-Danlos Syndrome (VEDS). VEDS is a rare genetic disease typically diagnosed in childhood resulting in high morbidity and a significantly shortened lifespan, and for which there are no currently approved treatments. AR101 has received Orphan Drug designation from the U.S. Food and Drug Administration. To learn more, please visit aytubio.com.

Forward Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this press release, are forward-looking statements. Forward-looking statements are generally written in the future tense and/or are preceded by words such as 'may,' 'will,' 'should,' 'forecast,' 'could,' 'expect,' 'suggest,' 'believe,' 'estimate,' 'continue,' 'anticipate,' 'intend,' 'plan,' or similar words, or the negatives of such terms or other variations on such terms or comparable terminology. Forward-looking statements, including but not limited to any statements regarding the financial results and statements presented in this press release. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: the ability to attract and retain key management team members, the future growth potential of our commercial portfolio, the anticipated start dates, durations and completion dates and the potential safety and efficacy of our product candidates AR101 and Healight. We also refer you to the risks described in 'Risk Factors' in Aytu's Annual and

Quarterly Reports on Form 10-K and 10-Q and in the other reports and documents it files with the Securities and Exchange Commission.

AYTU BIOPHARMA, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per-share)
(Unaudited)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2021	2020	2021	2020
Product revenue, net	$ 23,125	$ 15,147	$ 45,022	$ 28,667
Cost of sales	10,826	6,251	20,267	10,314
Gross profit	12,299	8,896	24,755	18,353
Operating expenses				
Research and development	4,920	286	7,016	469
Selling and marketing	9,660	5,705	18,957	11,531
General and administrative	7,953	5,584	16,169	11,004
Acquisition related costs	–	1,312	–	1,312
Impairment of goodwill	–	–	19,453	–
Amortization of intangible assets	1,060	1,584	2,153	3,169
Total operating expenses	23,593	14,471	63,748	27,485
Loss from operations	(11,294)	(5,575)	(38,993)	(9,132)
Other income (expense)				
Other income/(expense), net	20	(379)	(20)	(1,130)
Loss from contingent consideration	(277)	(3,313)	(496)	(3,311)
Loss on extinguishment of debt	–	(258)	–	(258)
Total other expense	(257)	(3,950)	(516)	(4,699)
Loss before income tax	(11,551)	(9,525)	(39,509)	(13,831)
Income tax benefit	(3)	–	(110)	–
Net loss	$ (11,548)	$ (9,525)	$ (39,399)	$ (13,831)
Weighted average number of common shares outstanding	26,412,473	13,281,904	26,003,026	12,717,180
Basic and diluted net loss per common share	$ (0.44)	$ (0.72)	$ (1.52)	$ (1.09)

AYTU BIOPHARMA, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per-share)

	(Unaudited) December 31, 2021	June 30, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 35,277	$ 49,649
Restricted cash	–	252
Accounts receivable, net	22,989	28,176
Inventory, net	16,558	16,339
Prepaid expenses	11,298	9,780
Other current assets	1,418	1,038
Total current assets	87,540	105,234
Property and equipment, net	4,294	5,140
Operating lease right-of-use asset	3,845	3,563
Intangible assets, net	81,339	85,464
Goodwill	46,349	65,802
Other non-current assets	457	465
Total non-current assets	136,284	160,434
Total assets	$ 223,824	$ 265,668
Liabilities		
Current liabilities		
Accounts payable and other	$ 15,604	$ 19,255
Accrued liabilities	50,685	51,295
Accrued compensation	5,041	5,939
Short-term line of credit	7,209	7,934
Current portion of debt	16,343	16,668
Current portion of operating lease liabilities	1,173	940
Current portion of fixed payment arrangements	3,310	3,134
Current portion of CVR liabilities	–	218
Current portion of contingent consideration	1,206	4,055
Total current liabilities	100,571	109,438
Debt, net of current portion	129	180
Operating lease liabilities, net of current portion	2,716	2,624
Fixed payment arrangements, net of current portion	4,623	6,324
CVR liabilities, net of current portion	1,392	1,177
Contingent consideration, net of current portion	8,297	8,002
Other non-current liabilities	560	355

Total liabilities	118,288	128,100
Commitments and contingencies		
Stockholders' equity		
Preferred Stock, par value $.0001; 50,000,000 shares authorized; no shares issued or outstanding as of December 31, 2021 and June 30, 2021	–	–
Common Stock, par value $.0001; 200,000,000 shares authorized; shares issued and outstanding 30,010,468 and 27,490,412, respectively, as of December 31, 2021 and June 30, 2021	3	3
Additional paid-in capital	323,231	315,864
Accumulated deficit	(217,698)	(178,299)
Total stockholders' equity	105,536	137,568
Total liabilities and stockholders' equity	$ 223,824	$ 265,668

AYTU BIOPHARMA, INC.
Reconciliation of GAAP to Non-GAAP Financial Information
(In thousands)

	Three Months Ended December 31, 2021
Reconciliation of net loss to Adjusted EBITDA:	
Net loss	$ (11,548)
Addback:	
Research and development – AR101 & Healight	4,204
Depreciation and Amortization	2,461
Stock based compensation	1,161
Interest expense	755
Other income	(775)
Loss on change in fair value of contingent considerations	277
Income tax benefit	(3)
Adjusted EBITDA	$ (3,468)

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