

August 12, 2024



# Atara Biotherapeutics Announces Second Quarter 2024 Financial Results, Operational Progress and Leadership Update

*Tab-cel<sup>®</sup> U.S. BLA Accepted Under Priority Review With PDUFA Action Date of January 15, 2025*

*ATA3219 Lupus Nephritis and Severe Systemic Lupus Erythematosus Study Initiation Expected Q4 2024; Initial Clinical Data Expected Mid-2025*

*Enrolling ATA3219 Non-Hodgkin's Lymphoma Study; Initial Clinical Data Expected Q1 2025*

*Effective September 9, 2024, Pascal Touchon To Assume Role of Chairman of the Board of Directors of Atara; Cokey Nguyen, Ph.D., Currently Chief Scientific and Technical Officer, To Be Appointed President and CEO*

*Cash Runway Into 2027 Enables Key Pipeline Readouts*

THOUSAND OAKS, Calif.--(BUSINESS WIRE)-- [Atara Biotherapeutics, Inc.](#) (Nasdaq: ATRA), a leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune diseases, today reported financial results for the second quarter 2024, recent business highlights, and key upcoming milestones for 2024.

“Building on the recent BLA acceptance with Priority Review for tab-cel, we are making significant progress with the agency towards the target action date of January 15, 2025, while supporting our partner Pierre Fabre with their U.S. launch preparation,” said Pascal Touchon, President and Chief Executive Officer of Atara. “During the quarter we continued to advance the clinical development of our lead CAR T program, ATA3219, and remain on track to deliver key value creating milestones within the next 12 months. This is highlighted by initial data from our non-Hodgkin’s lymphoma study anticipated in the first quarter of 2025, which we believe will provide a read-through for ATA3219’s potential in autoimmune disease. On that front, we plan to initiate our ATA3219 Systemic Lupus Erythematosus trial in the fourth quarter, including the cohort without lymphodepletion, with initial data expected in mid-2025.”

Dr. Touchon continued, “Following the landmark milestone of the world’s first-ever approval of an allogeneic T-cell therapy and with the potential first U.S. approval approaching, we are advancing our differentiated allogeneic CAR-T programs into the clinic. With the Company in a strong position, I have decided to move into the role of Chairman for personal reasons to dedicate more time to my family. I look forward to having a very active and strategic advisory role as board chair and continuing to help Atara create value with the potential tab-cel U.S.

approval and initial clinical data with ATA3219. I believe the future of Atara is bright under the leadership of Cokey Nguyen, Ph.D. who will be promoted to the role of President and CEO. Cokey is a visionary leader in the cell therapy field, and our Board of Directors values his deep commitment to our staff and to patients as well as his expertise across the breadth of our business.”

“I admire the strong foundation we built under Pascal’s leadership. I am honored to serve as Atara’s CEO at this pivotal time to continue our journey to get tab-cel approved in the U.S. and to unlock the disruptive potential of our allogeneic CAR-T platform,” said Cokey Nguyen, Ph.D. “I look forward to working alongside our world-class and innovative teams to rapidly innovate and strive to develop better cell therapy treatment options for patients.”

### ***Tabelecleucel (tab-cel<sup>®</sup> or Ebvallo<sup>™</sup>) for Post-Transplant Lymphoproliferative Disease (PTLD)***

- U.S. Food and Drug Administration (FDA) accepted the filing of Atara’s Biologics License Application (BLA) for tabelecleucel (tab-cel<sup>®</sup>) indicated as monotherapy for treatment of adult and pediatric patients two years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate
- The BLA has been granted Priority Review with a Prescription Drug User Fee Act (PDUFA) target action date of January 15, 2025
- The data package for the filing includes pivotal and supportive data covering more than 430 patients treated with tab-cel across multiple life-threatening diseases
- The BLA submission is supported by the latest pivotal ALLELE study data-cut that demonstrated a statistically significant 48.8% Objective Response Rate (ORR) ( $p < 0.0001$ ) and favorable safety profile consistent with previous analyses
- Atara received a \$20 million milestone payment from Pierre Fabre Laboratories in August 2024, following the acceptance of the tab-cel BLA, with the potential to receive a \$60 million milestone payment from Pierre Fabre contingent upon FDA approval of the tab-cel BLA

### ***ATA3219: CD19 Program in Lupus Nephritis (LN)***

- Atara expects to initiate a Phase 1 study of ATA3219 as a monotherapy for the treatment of systemic lupus erythematosus (SLE) with kidney involvement (lupus nephritis [LN]) in Q4 2024 with initial clinical data anticipated in mid-2025
  - The Phase 1 open-label, dose-escalation study is designed to evaluate safety, preliminary efficacy, pharmacokinetics, and biomarkers of a single dose of ATA3219 administered to LN subjects refractory to one or more lines of treatment. Subjects will receive lymphodepletion treatment followed by ATA3219 at a dose of 40, 80, or 160 x 10<sup>6</sup> CAR+ T cells. Each dose level is designed to enroll 3-6 subjects
- Atara is positioned to potentially expand ATA3219 Phase 1 study into additional autoimmune indications via the same Investigational New Drug (IND) application previously cleared for the LN study
- Preclinical data supporting the potential of ATA3219 in SLE was presented in poster presentation at the International Society for Cell & Gene Therapy meeting. The data

demonstrated that ATA3219 CAR T cells led to complete CD19-specific B-cell depletion against SLE or multiple sclerosis patient peripheral blood mononuclear cells

- Additional preclinical data presented in the poster showed that ATA3219 CAR T cells, which incorporate the next-generation 1XX costimulatory domain, released lower levels of pro-inflammatory cytokines while maintaining cytotoxic function and potency in response to stimulation with CD19+ target cells when compared to autologous CAR T controls. Mitigating inflammatory cytokine release that is typically seen with standard CD19 CAR T signaling may lead to reduced toxicity and better tolerability if confirmed in clinical trials

### ***ATA3219: CD19 Program in Severe Systemic Lupus Erythematosus (SLE) Without Lymphodepletion***

- Atara plans to expand the Phase 1 LN study of ATA3219 and add a new cohort in severe SLE without lymphodepletion (LD) in Q4 2024 with initial clinical data anticipated in mid-2025
  - Eligible subjects with severe SLE will receive ATA3219 at a dose of 40, 80, or  $240 \times 10^6$  CAR+ T cells
- The elimination of LD is designed to further simplify the treatment regimen and to potentially provide a differentiated safety profile to patients without comprising efficacy which may improve patient access
- There is compelling clinical and scientific rationale supporting the potential to eliminate the need for LD based on the EBV T-cell backbone and unique features of ATA3219, including: 1) low alloreactivity risk and favorable safety in over 600 patients treated without LD, due to T-cell receptor EBV specificity and partial human leukocyte antigen matching; 2) expansion and persistence data without LD correlating to efficacy in patients treated with tab-cel; and 3) the inclusion of clinically validated features into ATA3219 such as the 1XX costimulatory domain and memory phenotype that increase potency and persistence

### ***ATA3219: CD19 Program in Non-Hodgkin's Lymphoma (NHL)***

- Atara continues opening sites and initiating enrollment of a multi-center, Phase 1 open-label, dose-escalation clinical trial of ATA3219 in NHL, including large B-cell lymphomas, follicular lymphoma, and mantle cell lymphoma, with initial clinical data anticipated in Q1 2025
- Study designed to evaluate safety, preliminary efficacy, pharmacokinetics, and biomarkers. Subjects will receive LD treatment followed by ATA3219 at a dose of 40, 80, 240, or  $480 \times 10^6$  CAR+ T cells. Each dose level is designed to enroll 3-6 patients
- Previously presented preclinical data demonstrated superior *in vivo* persistence and CD19-specific anti-tumor efficacy compared to an autologous CD19 CAR T benchmark with no observed toxicity or alloreactivity

### ***ATA3431: CD19/CD20 Program for B-Cell Malignancies***

- Preclinical data presented at ASH 2023 demonstrated early evidence of potent antitumor activity, long-term persistence, and superior tumor growth inhibition compared to an autologous CD19/CD20 CAR T benchmark
- Dual CD19 and CD20 targeting designed to address CD19 escape and tumor

variability and may provide additional efficacy in lymphoma

- Atara is progressing toward an IND submission in H2 2025

### ***Leadership Updates***

- Effective September 9, 2024:
  - Cokey Nguyen, Ph.D., the Company's current Chief Scientific and Technical Officer, will be promoted to the role of President and CEO and Pascal Touchon, the Company's current President and CEO, will transition to the role of Chairman of the Board of Directors
  - Cokey Nguyen, Ph.D., will be appointed to the Company's Board of Directors
  - Carol Gallagher, Pharm.D., current Chair of the Board, will transition to become Independent Lead Director

### ***Second Quarter 2024 Financial Results***

- Cash, cash equivalents and short-term investments as of June 30, 2024 totaled \$35.3 million, as compared to \$46.2 million as of March 31, 2024
- Q2 2024 accounts receivable totaled \$2.4 million; however, this amount does not include the \$20 million milestone payment owed by Pierre Fabre related to the tab-cel BLA acceptance, which was received in August 2024
- On August 9, 2024, Pierre Fabre and Atara entered into an agreement for Pierre Fabre to purchase certain existing tab-cel intermediate inventory from Atara for \$15.5 million, which is expected to be received from Pierre Fabre in September 2024
- Together, cash, cash equivalents, short-term investments, accounts receivable as of June 30, 2024, the \$20 million tab-cel BLA acceptance milestone payment, and the \$15.5 million tab-cel intermediate inventory purchase amount total \$73.2 million
- Net cash used in operating activities was \$10.6 million for the second quarter 2024, as compared to \$52.8 million in the same period in 2023
  - Q2 2024 net cash used in operating activities included a \$20 million cash payment received from Pierre Fabre for a milestone payment achieved in March 2024, whereas Q2 2023 had no such cash receipts
- Total revenues were \$28.6 million for the second quarter 2024, as compared to \$1.0 million for the same period in 2023. Total revenues increased by \$27.6 million year over year, primarily due to revenue recognized as a result of additional obligations for the expanded partnership with Pierre Fabre and accelerated recognition of existing deferred revenue due to the planned transition of substantially all activities relating to tab-cel at the time of BLA approval and transfer to Pierre Fabre
- Total costs and operating expenses include non-cash stock-based compensation, depreciation and amortization expenses of \$7.7 million for the second quarter 2024, as compared to \$13.8 million for the same period in 2023
- Research and development expenses were \$33.3 million for the second quarter 2024, as compared to \$56.1 million for the same period in 2023
  - Research and development expenses include \$3.3 million of non-cash stock-based compensation expenses for the second quarter 2024, as compared to \$7.2 million for the same period in 2023
- General and administrative expenses were \$8.9 million for the second quarter 2024, as compared to \$13.3 million for the same period in 2023
  - General and administrative expenses include \$3.0 million of non-cash stock-

based compensation expenses for the second quarter 2024, as compared to \$5.4 million for the same period in 2023

- Atara reported net losses of \$19.0 million, or \$3.10 per share, for the second quarter 2024, as compared to \$71.1 million, or \$16.91 per share, for the same period in 2023

### **2024 Outlook and Cash Runway**

- Atara expects full year 2024 operating expenses to decrease by approximately 35% from 2023
- The large majority of the year-over-year operating expense reduction began in Q2 2024 and is expected to continue for the remainder of the year
- Atara expects that cash, cash equivalents, short-term investments, and accounts receivable as of June 30, 2024, plus the items noted below, in total will enable funding of planned operations into 2027:
  - \$20 million milestone payment for the acceptance of the tab-cel BLA received from Pierre Fabre in August 2024 and \$60 million contingent upon the approval of the tab-cel BLA;
  - \$15.5 million purchase by Pierre Fabre of tab-cel intermediate inventory to be received in September 2024 and additional anticipated purchases of tab-cel inventory through the manufacturing transfer date by Pierre Fabre;
  - anticipated reimbursement for tab-cel global development costs through the BLA transfer by Pierre Fabre;
  - operating efficiencies resulting from completed workforce reductions;
  - the planned transition of substantially all activities relating to tab-cel at the time of the BLA transfer to Pierre Fabre potentially as early as Q1 2025, which will further reduce quarterly operating expenses; and
  - anticipated royalties from sales of tab-cel by Pierre Fabre in the U.S. post BLA approval

### **About ATA3219**

ATA3219 combines the natural biology of unedited T cells with the benefits of an allogeneic therapy. It consists of allogeneic Epstein-Barr virus (EBV)-sensitized T cells that express a CD19 CAR construct for the treatment of CD19+ relapsed or refractory B-cell malignancies, including B-cell non-Hodgkin's lymphoma and B-cell mediated autoimmune diseases including systemic lupus erythematosus. ATA3219 has been optimized to offer a potential best-in-class profile, featuring off-the-shelf availability. It incorporates multiple clinically validated technologies including a modified CD3 $\zeta$  signaling domain (1XX) that optimizes expansion and mitigates exhaustion, enrichment during manufacturing for a less differentiated phenotype for robust expansion and persistence and retains the endogenous T-cell receptor without gene editing as a key survival signal for T cells contributing to persistence.

### **About ATA3431**

ATA3431 is an allogeneic, bispecific CAR directed against CD20 and CD19, built on Atara's EBV T-cell platform. The design consists of a tandem CD20-CD19 design, with binders oriented to optimize potency. Dual targets address the limitations of single antigen loss and tumor variability. ATA3431 features a novel 1XX costimulatory domain, memory phenotype, and retained, unedited T-cell receptor. Preclinical data have demonstrated early evidence of

antitumor activity, long-term persistence, and superior tumor growth inhibition compared to an autologous CD19/CD20 CAR T benchmark.

### **Next-Generation Allogeneic CAR T Approach**

Atara is focused on applying Epstein-Barr virus (EBV) T-cell biology, featuring experience in over 600 patients treated with allogeneic EBV T cells, and novel chimeric antigen receptor (CAR) technologies to meet the current limitations of autologous and allogeneic CAR therapies head-on by advancing a potential best-in-class CAR T pipeline in oncology and autoimmune disease. Unlike gene-edited approaches aimed at inactivating T-cell receptor (TCR) function to reduce the risk for graft-vs-host disease, Atara's allogeneic platform maintains expression of the native EBV TCR that promote in vivo functional persistence while also demonstrating inherently low alloreactivity due to their recognition of defined viral antigens and partial human leukocyte antigen (HLA) matching. A molecular toolkit of clinically-validated technologies—including the 1XX costimulatory domain designed for better cell fitness and less exhaustion while maintaining stemness—offers a differentiated approach to addressing significant unmet need with the next generation CAR T.

### **About Atara Biotherapeutics, Inc.**

Atara is harnessing the natural power of the immune system to develop off-the-shelf cell therapies for difficult-to-treat cancers and autoimmune conditions that can be rapidly delivered to patients from inventory. With cutting-edge science and differentiated approach, Atara is the first company in the world to receive regulatory approval of an allogeneic T-cell immunotherapy. Our advanced and versatile T-cell platform does not require T-cell receptor or HLA gene editing and forms the basis of a diverse portfolio of investigational therapies that target EBV, the root cause of certain diseases, in addition to next-generation AlloCAR-Ts designed for best-in-class opportunities across a broad range of hematological malignancies and B-cell driven autoimmune diseases. Atara is headquartered in Southern California. For more information, visit [atarabio.com](http://atarabio.com) and follow [@Atarabio](https://twitter.com/Atarabio) on [X](https://www.x.com/) and [LinkedIn](https://www.linkedin.com/company/atarabio).

### **Forward-Looking Statements**

This press release contains or may imply "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. For example, forward-looking statements include statements regarding: (1) the development, timing and progress of tab-cel<sup>®</sup>, including the BLA and potential indications, the potential characteristics and benefits of tab-cel<sup>®</sup>, and the progress and results of, and prospects for, the global partnership with Pierre Fabre Laboratories involving tab-cel<sup>®</sup>, and the potential financial benefits to Atara as a result of the global partnership with Pierre Fabre Laboratories, including the receipt, timing and amount of any payments to be received by Atara thereunder; (2) the development, timing and progress of Atara's AlloCAR-T programs (including ATA3219 and ATA3431), including the timing of the start of any clinical trials, the timing of the availability of data from such clinical trials, the timing of submissions of regulatory applications, and the potential benefits, characteristics, safety and efficacy of such product candidates or product candidates emerging from such programs; (3) Atara's cash runway, the timing and receipt of potential milestone and other payments, and operating expenses, including Atara's ability to fund its planned operations into 2027; and (4) Atara's planned transition of substantially all activities relating to tab-cel at the time of the BLA

transfer to Pierre Fabre and the timing thereof. Because such statements deal with future events and are based on Atara's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including, without limitation, risks and uncertainties associated with the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success; the COVID-19 pandemic and the wars in Ukraine and the Middle East, which may significantly impact (i) our business, research, clinical development plans and operations, including our operations in Southern California and Denver and at our clinical trial sites, as well as the business or operations of our third-party manufacturer, contract research organizations or other third parties with whom we conduct business, (ii) our ability to access capital, and (iii) the value of our common stock; the sufficiency of Atara's cash resources and need for additional capital; and other risks and uncertainties affecting Atara's and its development programs, including those discussed in Atara's filings with the Securities and Exchange Commission, including in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings and in the documents incorporated by reference therein. Except as otherwise required by law, Atara disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events or circumstances or otherwise.

## **Financials**

**ATARA BIOTHERAPEUTICS, INC.**  
**Condensed Consolidated Balance Sheets**  
(Unaudited)  
(In thousands)

	June 30, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 31,314	\$ 25,841
Short-term investments	3,978	25,884
Restricted cash	146	146
Accounts receivable	2,422	34,108
Inventories	18,749	9,706
Other current assets	5,801	6,184
Total current assets	62,410	101,869
Property and equipment, net	2,317	3,856
Operating lease assets	48,948	54,935
Other assets	3,609	4,844
Total assets	\$ 117,284	\$ 165,504
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 5,253	\$ 3,684
Accrued compensation	7,269	11,519
Accrued research and development expenses	2,014	17,364
Deferred revenue	107,582	77,833
Other current liabilities	26,149	31,826
Total current liabilities	148,267	142,226
Deferred revenue - long-term	567	37,562
Operating lease liabilities - long-term	38,703	45,693
Liability related to the sale of future revenues - long-term	36,448	34,623
Other long-term liabilities	4,167	4,631
Total liabilities	\$ 228,152	\$ 264,735
Stockholders' (deficit) equity:		
Common stock	—	—
Additional paid-in capital	1,909,097	1,870,123
Accumulated other comprehensive loss	(14)	(204)
Accumulated deficit	(2,019,951)	(1,969,150)
Total stockholders' (deficit) equity	(110,868)	(99,231)
Total liabilities and stockholders' (deficit) equity	\$ 117,284	\$ 165,504



**ATARA BIOTHERAPEUTICS, INC.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
**(Unaudited)**  
**(In thousands, except per share amounts)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Commercialization revenue	\$ 28,640	\$ 793	\$ 55,997	\$ 1,677
License and collaboration revenue	—	164	—	506
Total revenue	28,640	957	55,997	2,183
Costs and operating expenses:				
Cost of commercialization revenue	4,627	2,895	6,612	3,111
Research and development expenses	33,332	56,141	78,838	118,297
General and administrative expenses	8,912	13,335	20,025	27,207
Total costs and operating expenses	46,871	72,371	105,475	148,615
Loss from operations	(18,231)	(71,414)	(49,478)	(146,432)
Interest and other income (expense), net	(818)	307	(1,299)	576
Loss before provision for income taxes	(19,049)	(71,107)	(50,777)	(145,856)
Provision for income taxes	—	1	24	23
Net loss	\$ (19,049)	\$ (71,108)	\$ (50,801)	\$ (145,879)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	41	304	190	1,134
Comprehensive loss	\$ (19,008)	\$ (70,804)	\$ (50,611)	\$ (144,745)
Basic and diluted net loss per common share	\$ (3.10)	\$ (16.91)	\$ (8.64)	\$ (34.89)
Basic and diluted weighted-average shares outstanding	6,143	4,204	5,883	4,181

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20240812401307/en/>

**Investor and Media Relations:**

Jason Awe, Ph.D.

Head of Corporate Communications & Investor Relations

(805) 217-2287

[jawe@atarabio.com](mailto:jawe@atarabio.com)

Source: Atara Biotherapeutics, Inc.