

# Abeona Therapeutics: Scaling an individualized launch after NTAP

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**Information cutoff:** October 3, 2026, end of day

On October 1, a new Medicare hospital payment pathway for ZEVASKYN took effect. Two days later, Abeona Therapeutics had an early launch to assess: Q2 product revenue had risen sequentially, treatment centers were being added, and the company had disclosed a batch that could not be commercially released under its specifications. The company had not yet reported results after the payment change became effective.

For classroom purposes, assume you advise Abeona's leadership on the next increment of launch effort. This is a hypothetical assignment, not a claim that the company disclosed a fixed budget, internal disagreement, manufacturing bottleneck, or planned reallocation. Should the next increment favor QTC activation and patient access, manufacturing yield and lot-release reliability, or a staged plan that funds both against evidence gates? What evidence should determine whether to expand, pause, or redirect effort while the company preserves liquidity and its separate ABO-701 development program?

## A treatment pathway built around each patient

ZEVASKYN is an autologous cell-based gene therapy for wounds in patients with recessive dystrophic epidermolysis bullosa (RDEB). It is made from a patient's own cells and applied to wounds by a qualified treatment center. Abeona describes a process that runs from biopsy collection through individualized manufacturing, quality inspection and lot release, shipment, and surgical application. The product's shelf life is 84 hours. The company says patient biopsy quality and cell growth can vary, and treatment centers must be qualified to enroll and administer treatment. These stages interact, but the public filing does not identify one as the binding limit on launch growth. [C1]

Revenue follows product transfer rather than patient interest or treatment-center activation. Abeona recognizes product revenue when a QTC obtains control, typically after final quality inspection. The center is not required to use the product, and Abeona has no right to payment before that transfer. [C1] Thus referral, biopsy, treatment, batch release, application, and recognized revenue are different events.

Abeona's August 13 update reported five patients treated in the second quarter and recognized revenue for four treatments. One Q2 batch yielded fewer than the sheet threshold required for revenue recognition. The release separately said 12 treatments had been completed since launch, revenue had not been recognized for two patients because of low yield or lot-release specifications, and three treatments had been completed in Q3-to-date. The figures cover different periods and units; they do not produce a reliable conversion or failure rate. [C2]

One specific process signal also appears in the Q2 10-Q. Abeona said a July 2026 batch could not be released as a commercial product because cellular identity was outside specification. FDA allowed release to the site under a single-patient investigational new drug authorization only. At the time of the filing, Abeona was working with FDA on a proposed specification revision and said FDA acceptance was not assured. This is one batch-specific event; the filing does not establish a general rate or the status of the proposal at the October cutoff. [C1]

## **More centers, a new payment pathway**

Abeona reported seven QTCs in its August quarterly update; Columbia and Children's Hospital of Philadelphia had been activated during Q2, while CHOP and UTMB had begun collecting patient biopsies. The company named Cincinnati Children's as its seventh center in July and University of Florida Health as its eighth in September. Activation and biopsy collection show network development, not that each center has treated a patient or generated revenue. [C2, C6]

CMS's April 2026 proposal had proposed disapproving ZEVASKYN's New Technology Add-on Payment (NTAP) application. The FY2027 inpatient prospective payment system final rule reversed that proposal and approved the add-on effective October 1. The rule lists eligible inpatient cases under ICD-10-PCS codes XHR0XGA through XHR7XGA and a maximum of \$2,045,550 per eligible case, subject to the statutory lesser-of formula. This is a supplemental payment to eligible hospitals, not a payment to Abeona or a payment on every QTC treatment. At the cutoff, no post-effective utilization result was available. [C4, C5, C7]

The payment change may affect the economics of eligible hospital cases and the work required to support access. It does not establish whether a patient is eligible, whether a QTC will use the pathway, how many cases will qualify, or what portion of any hospital payment reaches Abeona. The company said NTAP could support access and treatment-center economics; actual utilization and revenue effects remained unknown. [C5]

## **Different routes to care**

ZEVASKYN is not the only approved gene therapy for DEB. FDA-approved VYJUVEK is a topical HSV-1 vector-based treatment applied weekly to wounds. ZEVASKYN instead uses a patient-specific cell product that is manufactured and surgically applied. These routes differ in modality and administration; the sources here do not provide a head-to-head comparison of effectiveness, total cost, or patient preference. [X1]

Krystal Biotech reported global Q2 2026 VYJUVEK net product revenue of \$119.2 million, along with company-reported reimbursement approvals and prescriber counts. These figures provide market context, not a direct benchmark: they are for a different treatment modality, global business, and scale. They cannot establish ZEVASKYN's addressable share, adoption rate, or attainable margin. [X2]

## **Financial capacity and choices**

At June 30, 2026, Abeona reported \$146.826 million in cash and short-term investments, compared with \$191.404 million at December 31, 2025. Second-quarter net loss was \$20.191 million. Management said resources were expected to fund operating expenses and capital expenditures for at least 12 months from the 10-Q's issuance, while noting additional financing might be needed to fully implement its plans. These company-level figures do not give ZEVASKYN's treatment margin, the launch's cash needs, or an exact runway. [C1]

Abeona also has a separate investigational pipeline, including ABO-701, for which the company reported a \$7.0 million one-time upfront license expense in Q1 2026. The public materials do not disclose the program’s future budget or show that spending on ZEVASKYN must displace ABO-701. Treat it as an opportunity-cost question, not a forced choice. [C1, C2]

### Exhibit 1. Launch activity: different denominators and time windows

| Reported measure                                | Value     | Period or basis                                                  |
|-------------------------------------------------|-----------|------------------------------------------------------------------|
| ZEVASKYN net product revenue                    | \$11.380m | Q2 2026; +31% sequentially in issuer release                     |
| Patients treated                                | 5         | Q2 2026                                                          |
| Treatments with recognized revenue              | 4         | Q2 2026                                                          |
| Batch below revenue-recognition sheet threshold | 1         | Q2 2026                                                          |
| Treatments completed                            | 12        | Since launch, as reported Aug. 13                                |
| Patients for whom revenue was not recognized    | 2         | Cumulative since launch; low yield or lot-release specifications |
| Treatments completed                            | 3         | Q3-to-date as of Aug. 13                                         |

*Source: Abeona Q2 results release (C2). The categories are not interchangeable and must not be combined into a rate.*

### Exhibit 2. Qualified treatment-center network

| Network indicator                    | Reported status            |
|--------------------------------------|----------------------------|
| QTC count in Aug. 13 update          | 7                          |
| QTCs added during Q2                 | Columbia and CHOP          |
| Biopsy collection noted in Q2 update | CHOP and UTMB              |
| Cincinnati Children’s                | Named seventh QTC, July 21 |
| University of Florida Health         | Named eighth QTC, Sept. 16 |

*Sources: C2 and C6. Center activation and biopsy collection do not establish a treatment, eligible NTAP case, or recognized revenue.*

### Exhibit 3. What NTAP changes-and does not establish

| Item                       | Rule or evidence at cutoff                                                       |
|----------------------------|----------------------------------------------------------------------------------|
| Final status               | FY2027 IPPS NTAP approved; effective Oct. 1, 2026                                |
| Eligible cases             | Inpatient ICD-10-PCS<br>XHR0XGA-XHR7XGA                                          |
| Maximum add-on             | \$2,045,550 per eligible case; statutory lesser-of formula applies               |
| Payment recipient          | Eligible hospital, not Abeona                                                    |
| Post-effective utilization | Not yet reported by Oct. 3                                                       |
| QTC / company economics    | Eligible-case count, hospital payment, and any share reaching Abeona are unknown |

Sources: CMS final rule (C4); Abeona announcement (C5); April proposal (C7).

### Exhibit 4. Liquidity and reporting context

| Measure                                | Amount / disclosure                                                                                                                              |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Cash and cash equivalents, June 30     | \$56.229m                                                                                                                                        |
| Short-term investments, June 30        | \$90.597m                                                                                                                                        |
| Combined cash resources, June 30       | \$146.826m                                                                                                                                       |
| Combined cash resources, Dec. 31, 2025 | \$191.404m                                                                                                                                       |
| Q2 net loss                            | \$20.191m                                                                                                                                        |
| Management liquidity statement         | Resources expected to cover operating expense and capex at least 12 months from 10-Q issuance; additional financing may be needed for full plans |

Source: C1. Combined resources and change are calculated from reported balance-sheet values. Net loss is not cash burn; the liquidity statement is management's estimate, not a guaranteed runway.

### Exhibit 5. One disclosed release event

| Filing description                                                                                                                                                                                                                                                                                | Limit                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| A July 2026 batch was not releasable as a commercial product because cellular identity was out of specification; FDA permitted release to the site under a single-patient IND only. Abeona was discussing a proposed specification revision with FDA, whose acceptance was not assured at filing. | One batch, not a process failure rate; October status of the proposed revision is not disclosed. |

## Assignment

Recommend how Abeona should sequence its next incremental launch effort. You may recommend a combination, but identify what should be funded first and what evidence would change that choice.

- What is the strongest case for access/QTC activation, and what would show that activation is translating into patient flow?
- What is the strongest case for manufacturing and release reliability, and what batch-level measures would distinguish isolated events from a persistent issue?
- Which staged gates would reveal whether access, release, reimbursement, or another step is limiting progress?
- How should eligible inpatient NTAP cases and hospital payments be tracked without treating them as Abeona revenue?
- What information would you request before changing launch spending or ABO-701 funding?

## Source notes

- **C1:** Abeona Therapeutics Inc., Q2 2026 Form 10-Q, filed Aug. 13, 2026, accession 0001493152-26-037576. [SEC filing](#).
- **C2:** Abeona Q2 2026 results, Aug. 13, 2026, Form 8-K accession 0001493152-26-037575, Exhibit 99.1. [SEC exhibit](#).
- **C4:** CMS FY2027 IPPS final rule, 91 FR 49570, 49731. [Federal Register PDF](#).
- **C5:** Abeona, “CMS Grants New Technology Add-On Payment (NTAP) Status for ZEVASKYN,” Aug. 4, 2026. [Issuer release](#).
- **C6:** Abeona, UF Health QTC activation release, Sept. 16, 2026. [Issuer release](#).
- **C7:** CMS FY2027 IPPS proposed rule, 91 FR 19312, 19428-19430. [Federal Register PDF](#).
- **X1:** FDA, VYJUVEK Prescribing Information. [FDA label](#).
- **X2:** Krystal Biotech Q2 2026 results release, Aug. 3, 2026. [Issuer release](#).