UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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FORM 8-K

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CURRENT REPORT

Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934

September 28, 2023
Date of report (Date of earliest event reported)

_____

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

_____

Delaware	**001-36464**	**23-2936302**
(State or other jurisdiction	(Commission	(IRS Employer
of incorporation)	File Number)	Identification No.)

500 College Road East, Suite 310	
Princeton, New Jersey	**08540**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(609) 683-1880**
(Former name or former address, if changed since last report)

_____

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.0001 per share	AGRX	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01.   Entry into a Material Definitive Agreement.

On September 28, 2023, Agile Therapeutics, Inc. (the "Company") entered into the Seventh Amendment (the "Seventh Amendment") to that certain Project Agreement (Detailing – Field Team), dated April 30, 2020 (as amended, the "Syneos Agreement"), by and between the Company and Syneos Health Commercial Services, LLC ("Syneos"), pursuant to that certain Master Services Agreement, by and between the Company and inVentiv Commercial Services, LLC. As previously disclosed, pursuant to the Syneos Agreement, Syneos provides the Company with a field force of sales representatives to offer certain detailing, sales operation, compliance, and training services ("Services") with respect to Twirla®, in exchange for an up-front implementation fee and a fixed monthly fee. The Syneos Agreement expires on August 23, 2024. At that time, the Syneos Agreement will terminate automatically unless extended upon the mutual written agreement of the parties. The Company may terminate the Syneos Agreement for any reason upon timely written notice without incurring a termination fee.

As part of its dual efforts to reduce operating expenses (i.e., "OPEX") and to optimize its commercial platform and align with its focus on regional promotion, the Company negotiated a restructuring of the Syneos Agreement. Pursuant to the Seventh Amendment, the Company agreed to pay Syneos a fixed weekly fee (the "Weekly Fee") for the performance of Services through August 23, 2024, and to create an incentive to meet certain sales and operational objectives. The Weekly Fees, when taken cumulatively, represent a reduction in the total fees due to Syneos under the remainder of the Syneos Agreement, reflecting, in part, a reduction in the number of field force sales representatives, through elimination of vacancies and underperforming territories, and the streamlining of certain Services available to the Company. The Weekly Fee allows for potential annual merit increases for Syneos field sales representatives and leadership, and is subject to change should the number of field force representatives increase or decrease.

Pursuant to the Seventh Amendment, a portion of the Weekly Fee is designated as an incentive fee, which Syneos is eligible to earn each quarter upon the attainment of certain commercial sales and operations performance objectives. In the event Syneos fails to earn the incentive fee in a given quarter, the amount already paid to Syneos for that quarter as part of the Weekly Fee will be credited against any outstanding amounts the Company may owe to Syneos.

Except as modified by the Seventh Amendment, all terms and conditions of the Syneos Agreement remain in full force and effect.

The foregoing description of the Seventh Amendment does not purport to be complete and is qualified in its entirety by reference to the Seventh Amendment, a copy of which is filed as Exhibit 10.1 to this Form 8-K and is incorporated herein by reference.

Item 9.01.   Financial Statements and Exhibits.

(d)   Exhibits.

Exhibit Number	Description
10.1	Seventh Amendment to Project Agreement, dated September 28, 2023, by and between Agile Therapeutics, Inc., and Syneos Health Commercial Services, LLC.
104	Cover Page Interactive Data File (Embedded within the Inline XBRL Document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Agile Therapeutics, Inc.

Dated: September 28, 2023

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairperson and Chief Executive Officer

Exhibit 10.1

SEVENTH AMENDMENT TO
PROJECT AGREEMENT
(DETAILING – FIELD TEAM)

This Seventh Amendment (the "Amendment") dated April 3, 2023 (the "Effective Date") is made by and between Syneos Health Commercial Services, LLC, with an office at 500 Atrium Drive, Somerset, N.J. 08873 ("Syneos Health") and Agile Therapeutics, Inc. with an office located at 500 College Road East, Suite 310, Princeton, New Jersey 08540 (the "Client"). Syneos Health and Client may each be referred to herein as a "Party" and, collectively, as the "Parties."

W I T N E S S E T H:

WHEREAS, Syneos Health and Client are parties to a Project Agreement (Detailing – Field Team) made as of April 30, 2020, First Amendment to Project Agreement (Detailing – Field Team) dated June 1, 2020, Second Amendment to Project Agreement (Detailing – Field Team) dated January 1, 2021, Third Amendment to Project Agreement (Detailing – Field Team) dated July 1, 2021, Fourth Amendment to Project Agreement (Detailing – Field Team) dated September 1, 2021, Fifth Amendment to Project Agreement (Detailing – Field Team) dated February 1, 2022, and Sixth Amendment to Project Agreement (Detailing – Field Team) dated January 3, 2023 (collectively, the "Agreement"); and

WHEREAS, Syneos Health and Client desire to amend the Agreement as set forth herein.

NOW THEREFORE, in consideration of the premises and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, it is agreed as follows:

1. Except as provided in this Amendment, the terms and conditions set forth in the Agreement shall remain unaffected by execution of this Amendment. To the extent inVentiv any provisions or terms set forth in this Amendment conflict with the terms set forth in the Agreement, the terms set forth in this Amendment shall govern and control. Terms not otherwise defined herein, shall have the meanings set forth in the Agreement.

2. Section 5, "Termination" is hereby amended to include the following new subsection (e):

> "Notwithstanding Section 12(a)(i) of the MSA, pursuant to the payment terms set forth in Attachment F, Client specifically agrees to pay Syneos Health weekly the amount due and in the event such weekly payment is failed to be made, Syneos Health will provide a [***] grace period for Client to provide payment; thereafter if

Exhibit 10.1

> payment is still not secured, Syneos Health reserves the right to terminate the Work Order within [***] notice to Client."

3.   The Amended and Restated Exhibit A, the "Project Team" as defined is hereby amended to [***] engagement center representatives ("EC Reps"), [***] Representatives, [***] Regional Sales Managers ("RSMs") and [***] National Business Director ("NBD"). Also, the table after the 2nd paragraph is hereby deleted in its entirety and replaced with the below table:

Position	Headcount	Allocation
Project Team		
Representatives	[***]	[***]
EC Reps	[***]	[***]
RSM	[***]	[***]
NBD	[***]	[***]

4.   The Amended and Restated Exhibit A-1, "Field Operations Services," is hereby deleted in its entirety and replaced with the Second Amended and Restated Exhibit A-1 attached herein.

5.   Amendment and Restated Exhibit F, "Compensation – Fixed Fees, Variable Fees and Pass-through Costs," is hereby deleted in its entirety and replaced with the Second Amended and Restated Exhibit F attached herein.

6.   This Amendment may be executed simultaneously in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. Execution and delivery of this Amendment by exchange of facsimile copies or via pdf file bearing the facsimile signature of a party hereto shall constitute a valid and binding execution and delivery of this Amendment by such party. Such facsimile copies and/or pdf versions shall constitute enforceable original documents.

7.   The terms of this Amendment are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and may not be contradicted by evidence of any prior or contemporaneous agreement. The Parties further intend that this Amendment constitute the complete and exclusive statement of its terms and shall supersede any prior agreement with respect to the subject matter hereof.

[Signature Page to Follow]

Exhibit 10.1

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10) (iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant customarily and actually treats and private and confidential.

      WHEREFORE, the parties hereto have caused this Amendment to be executed by their duly authorized representatives.

AGILE THERAPEUTICS, INC.	SYNEOS HEALTH COMMERCIAL SERVICES, LLC
By: /s/ Al Altomari	By: /s/ Corey Swinson
Name: Al Altomari	Name: Corey Swinson
Title: Chairman and CEO	Title: Director, Customer Contract Management
Date: 9/22/2023	Date: 9/28/2023

Exhibit 10.1

SECOND AMENDED AND RESTATED
EXHIBIT A-1
FIELD OPERATIONS SERVICES

1.0	Executive Summary

This Exhibit A-1 describes the scope of work, deliverables, and assumptions for field operations initial implementation and ongoing annual support for the Project (as defined in Section 3.1.1(a)). Any changes to the assumptions, deliverables, or scope of work described in this Exhibit A-1, or any new work request(s), will follow Section 3.1.1(d), Change Control Process of this Exhibit A-1.

2.0	Scope of Services

The following service areas are part of field operations initial implementation and ongoing annual support:

- Operations Management

- Customer Relationship Management (CRM)

- Customer Master Source Data & Validation

- Travel and Expense Management

- Transparency Reporting

- Data Management

- Analytics and Reporting

- Targeting, Alignment and Call Plan Administration

- Incentive Compensation Management

- Field Support Services

- Technology Training Services

- LMS System Support

- Quality Management and Assurance

- Field Trigger Email with Veeva Engage

3.0	Scope of Work Definition

3.1 Operations Management

Exhibit 10.1

3.1.1   As part of operations management, Syneos Health will provide the following:

(a)   <u>Project Management</u>. Syneos Health will provide a fully integrated project management approach for the implementation of the operations services (the "Project") including the following:

(1)   Leadership of Project kick-off meeting to include review of scope, timelines, and assumptions for each functional area, Sales Team member introduction, and status reporting formats and meetings.

(2)   Integration of all Project activity, timelines, and deliverables across all functional areas into a consolidated Project schedule.

(3)   Leadership, facilitation, and documentation of all meetings, including meeting notes and action items.

(4)   Management of the Project schedule including task management, escalation of issues, risk identification, and interdependencies through Project documentation including:

(i)   Issue tracker;
(ii)   Milestone tracker; and
(iii)   Action item tracker.

(5)   Project status meetings and Project status reporting, including weekly status reports and plan reviews with the Client.

(6)   Project close-out and lessons learned session to include any information that can be applied to the ongoing operational support of the Client after the initial implementation is complete.

(7)   Project management implementation deliverables including the following:

(i)   Weekly implementation schedule identifying Project activities and target completion dates.
(ii)   Weekly implementation log of risks, actions, issues, and key decisions ("RAID").

(b)   <u>Technical Operations Management</u>. Technical operations Project implementation deliverables include the following:

Syneos Health Project Code: 7007244

Exhibit 10.1

(1)   Ongoing communication plan;

(2)   Technical operations deliverables document identifying standard deliverables and key business rules – delivered within six (6) weeks of the first day in the field;

(3)   Monthly technical operations status report;

(4)   Monthly operation leadership meeting and supporting documents; and

(5)   Quarterly business review meeting and supporting documents.

(c)   <u>Field Administrative Management</u>. Syneos Health will oversee all field administrative tasks, including the following activities:

(1)   <u>Field Administrative Management—Implementation</u>.
(i)   Project set up and roster management using Syneos Health's proprietary master roster system;
(ii)   Onboarding of new hires, including all aspects of administrative systems and processes (e.g., travel, CRM system, business cards, welcome memo, conference call accounts, fleet coordination, credentialing, licensure);
(iii)   Meeting planning logistics for national and POA meetings;
(iv)   Venue sourcing, hotel sourcing/booking, meal and events arrangements, ground transportation set up, flight arrangements, travel letter development, and budget tracking for national and POA meetings;
(v)   One (1) resource for on-site meeting support available, as needed;
(vi)   Training development and coordination;
- Identify and coordinate Syneos Health/Client courses for LMS upload

- Coordinate presenters/training schedules & agendas

- LMS course completion monitoring

- Post launch mastery training plan development

(vii)   Team Expense Travel and Budget Policy development.

Exhibit 10.1

(2)   Field Administrative Management—Ongoing Support.

(i)   Roster management and distribution;

(ii)   Continuation of meeting planning logistics, as described above, either with Client vendor(s) or as a stand-alone offering;

(iii)   Monitoring Project parameters and managing eligibility and payout of incentive compensation and awards within approved Project guidelines;

(iv)   Coordinate, route, track, and report operational initiatives, questions, or directives across all of the internal administrative departments, as well as external vendors and Client home office;

(v)   Review of monthly invoicing and budgets for adherence to Project P&L;

(vi)   Coordination with sample management and fulfillment vendor (if applicable);

(vii)   Coordination with Syneos Health compliance on HCP expense monitoring and reporting;

(viii) Onboarding of backfill new hires to include all aspects of administrative systems and processes;

(ix)   Coordination of communication to the field;

(x)   Ad hoc reporting (e.g., turnover/vacancy reports, budget tracker);

(xi)   Monthly field employee roster audits; and

(xii)   Payroll processing;

(xiii) Review and ensure all field expense reporting is completed, to include HCP reporting;

(xiv)   Field communication to include the following for the team conference call:

- FAQ development with HR and business lead

- Communication script

- Project exit check list and acknowledgement

(xv)   Monitor return of Syneos Health property;

(xvi)   Monitor return of Client property (i.e., samples, marketing materials, etc.);

(xvii) Coordination with fleet department on return of vehicle (if applicable); and

(xviii) Deactivations of all Project specific accounts (i.e., conference call/WebEx, etc.).

Exhibit 10.1

(d) <u>Change Control Process</u>. During the Term of this Project Agreement, the Parties may mutually agree to alter the Field Operations Services outlined in this Exhibit A-1. Such changes will be addressed as follows:

(1) Assess the impact of scope changes on Project schedules, resources and pricing;

(2) Provide a formal vehicle for approval to proceed with any changes to the Project Agreement;

(3) Provide a Project audit record of all material changes to the original Project Agreement; and

(4) If requirements arise that are outside the scope of this Exhibit A-1, a Change of Scope document (or an amendment to the Project Agreement, as applicable) will be submitted for Client approval following the below process:

(i) Client requests additional requirements for new functionality or deliverables outside the scope of work provided herein.

(ii) Syneos Health reviews change, meets with Client and internal team members to understand and scope Client expectations regarding business need, timelines, and other deliverable expectations.

(iii) Syneos Health provides Change of Scope (or Amendment or new Project Agreement, as applicable) document, which outlines work effort, timeline and pricing impacts of the change. Pricing will be determined based on standard rates provided below.

(iv) Client accepts proposal and signs Change of Scope (or Amendment or new Project Agreement, as applicable) document which authorizes work to begin on the change request.

(5) <u>Standard Pricing Table</u>.

Role	Price/HR
Software Development	[***]
CRM Configuration	[***]
Data Management	[***]

Exhibit 10.1

Role	Price/HR
Alignment/Call Planning	[***]
Incentive Comp Modeling/Design	[***]
Analytics & Reporting	[***]
Project Management/Business Analysis/Solution Design	[***]
Testing	[***]
IC Administration	[***]
Training (Content/Delivery)	[***]
Hardware/Help Desk	[***]

3.2 Customer Relationship Management ("CRM")

3.2.1 CRM; Client Configuration and Available Functionality. Syneos Health will provide a CRM application. Additionally, within its CRM application, Syneos Health will set-up a single, Client-specific, dedicated CRM environment configured specifically to the Client's business rules (the "Client Configuration"). The core functionalities within the Client Configuration are as follows, and will be configured by Syneos Health upon selection by Client:

(a) Customer profile management across account types (individuals and organizations);

(b) Call recording, reporting, and loading of Call plans;

(c) Closed-Loop Marketing ("CLM"), loading and presentation of digital media as part of integrated call record;

(d) Sample management and recording of samples and physician signature capture as part of integrated call record, including Prescription Drug Marketing Act (PDMA), CFR Part 11 Validation, if requested by Client;

(e) Medical Inquiry Request Form ("MIRF") including physician signature capture;

(f) Field Coaching Report (FCR) configuration;

Exhibit 10.1

(g) Pre-established reports and dashboards to enable field and field management performance (online only); and

(h) iPad/online platform options including online/home office PC, field tablet PC, and iPad to support mobility needs and improved customer interaction.

3.2.2 <u>CRM; Client Configuration Development and Implementation</u>. CRM implementation will be led using an agile development approach including the following deliverables:

Exhibit 10.1

Project Deliverable	Definition
Initial Requirements	Demonstration of the Client Configuration; and discussion of Client needs and business environment to support the general usage and end-user experience; will include accounts, functions, Call types, products, customer profile maintenance, etc.
Alpha Review	First iteration of the Client configuration based on requirements gathered in the Initial Requirements session. Detailed demonstration of the Client Configuration for more in-depth review of Client requirements.
Configuration Requirements Document ("CRD")	After the Alpha Review, Syneos Health will provide the Client with a draft CRD document which summarizes all end-user system requirements taken from both the Initial Requirements and Alpha Review sessions. The CRD will form a basis for the final Client Configuration specifications, risk assessment, testing, training, and validation (if applicable).
Beta Review	The final phase of the Client requirements will be a Beta Review, which will allow for any changes to the Client Configuration system requirements for final testing and production readiness.
CRD Sign-Off	Any changes or additions to the Client Configuration requirements during the Beta Review will be incorporated into the final CRD and submitted to the Client after the Beta Review session for final approval and signature.

3.2.3   Client Configuration Assumptions. The scope of the Client Configuration CRM delivery and associated timelines for the Project assumes the following:

(a)   Necessary Client members are available for the Initial Requirements, Alpha Review, and Beta Review meetings (each typically 3 hours), based on the weeks assumed in the agreed upon Project plan (Alpha Review/Beta Review may be done via WebEx);

(b)   Sign-off of documentation within 5 days of delivery by necessary Client members;

(c)   No customization of code outside of CRM provided configuration capabilities;

(d)   Use of standard MIRF functionality and data extracts to medical information;

(e)   Client Configuration/CRM does not include Adverse Events/Pharmacovigilance ("AE") reporting or recording. An alert is setup in the CRM system to remind field users of the appropriate number/process to communicate to HCPs;

Exhibit 10.1

(f)   Linking to company or external web-based systems within CRM tab structure;

(g)   Access to Syneos Health Veeva Vault for Client approved content including: CLM presentations and approved email templates. Alternatively, Syneos Health Veeva Vault may be setup to attach directly to Client internal Veeva Vault system in cases where Client is using Veeva Vault for internal Medical, Legal, Review ("MLR"). Syneos Health Veeva Vault is not used for internal Client MLR usage, only for field delivery of approved content;

(h)   Sample management functionality, if required, and data feeds for sample shipments, SLN validation, and sample product information as determined by Client requirements;

(i)   Inclusion of sales data within standard Veeva reporting functionality (online only);

(j)   Field Coaching Report originates from manager, not representative, including data entry only. Form will not be pre-populated with any data from any source;

(k)   Call history within the Sales Force Automation ("SFA") system not to exceed 15 months (5 Quarters) without purchasing additional data storage from Salesforce.com;

(l)   External access for Client home office administrators can be granted with change control processes in place to ensure integrity of Syneos Health production environment, with additional license costs as dictated by home office license pricing in contract; and

(m)   Ongoing support for CRM system including tier 2/technical support for escalated calls from field support desk, and home office support needs;

3.3   Customer Master Source Data and Validation

3.3.1   <u>Veeva Network and Veeva OpenData Validation</u>.

(a)   Syneos Health shall provide a near real-time customer validation process leveraging the integration of Veeva Network and Veeva OpenData. This combination gives direct access to Veeva OpenData for adding and changing of HCP and HCO data, which allows for field users to search, add, and immediately pull-down HCPs/HCOs industry standard identifiers and compliance information, such as SLN and DEA, upon adding the new prescriber, as opposed to waiting the standard 2-3 weeks for weekly data exports and validation.

Exhibit 10.1

(b)   Client and Syneos Health's targeting and alignment team will also have access to Veeva OpenData for sales or marketing research, such as to identify initial target universe, ongoing target adjustments, new product or market evaluations, etc.

(c)   The Veeva Network service includes the following:

(1)   Configuration and support for utilizing Veeva OpenData and the Veeva Network to allow for this Customer Master Data solution to control the universe in the CRM system and to provide for data stewardship services via Veeva OpenData provided controls.

(2)   Data change requests can be submitted by field users to the Veeva OpenData data stewards, which increases efficiency and decreases timelines associated with routine action request processing for universe changes discovered by the field.

(3)   The Veeva Network account search will allow for the field to search the Veeva OpenData Customer Master Data for any HCP or HCO that meets the search criteria, and provides the ability to add that HCP or HCO to their Veeva CRM territory. The information included is pre-validated by Veeva OpenData so an eligible HCP can be sampled immediately. Additionally, all valid address information known for that account will be brought down with the HCP or HCO selected.

(d)   The Veeva OpenData service includes access to the following data set:

(1)   Licensed field and home office users have access to entire customer universe (HCPs, HCOs, addresses, affiliations) in the Veeva OpenData customer universe.

(2)   Usage of compliance data scrub – for industry standard identifiers SLN, NPI, DEA #s for initial and ongoing data validation.

(3)   Usage of data hygiene scrub – for HCP demographic data such as address, specialty etc. for initial data validation.

(4)   Access to email address data is not included in standard offering but may be available on a per record basis for marketing initiatives as needed and is recommended for usage if Client is implementing enhanced approved email functionality (not included in base CRM license).

Exhibit 10.1

3.4 Travel and Expense Management

3.4.1 <u>Travel & Expense Set-Up and Ongoing Services</u>. Syneos Health shall leverage its then current travel and expense ("T&E") management system application (and solution provider) (collectively, the "T&E Management Solution"), currently Concur, for capture and reimbursement of all expenses incurred by Syneos Health employees recruited for the Client's Project, and for HCP data capture necessary for transparency reporting. The T&E Management Solution assumes the following:

(a) Required Client members are identified and available for requirements gathering;

(b) Client's requirements align with the standard baseline Concur configuration, (i.e. able to utilize existing expense types, approval workflow, etc., without customization);

(c) Completion of Configuration Request document for Project set-up based on Client spend limits and business rules;

(d) Acceptance of Syneos Health universe for HCP selection utilizing Medpro Concur Connect;

(e) Ongoing support for Concur T&E management system including tier 2/technical support for escalated calls from field support desk;

(f) Changes to or additional audit rules may be requested post-deployment;

(g) On-going roster management as teams expand or re-align (including territory and manager changes);

(h) Information on areas such as Amex cards, mileage rates, report approvers, etc. are communicated and decided on at onset of implementation based on Client business rules;

(i) T&E management system setup and support is only provided for Syneos Health employees. If any Client employees are supported, Client will be responsible for the deployment of the T&E management system and capture of any HCP meal spend, etc. for the Client employees;

(j) Coordination of Learning Management System ("LMS") Project set-up and communication of system access and viewing of Concur module to new hires/end users;

(k) Inclusion of Expense Management in Technology Training sessions; and

Exhibit 10.1

(l)   Tracking of completed Concur module review in LMS per user.

3.4.2   <u>Travel & Expense Deliverables</u>. The T&E management system application work stream will be managed by the Operations Manager, the Concur system subject matter expert, and the compliance lead, and will include the following deliverables:

Project Deliverable	Definition
T&E Guidelines	General Syneos Health guidelines provided to assist the Client in developing their T&E program; this can be reviewed and modified by Client as required.
Compliance Business Rules Document	Detailed document describing all compliance business rules associated with the Client Project. A draft will be provided with Syneos Health's base business rules and guidance with review and modifications as needed, and approval by Syneos Health and Client.
ERD (Expense Requirements Document)	Detailed document describing standard Concur functionality and Client-specific business rules based on requirements gathering and configuration request. Following internal review, final document will be reviewed and approved by Syneos Health and Client.
Training Documentation	Training documentation provided to field users and management with guidance on T&E management system application and compliance business rules and usage.

3.5   Transparency Reporting

3.5.1   <u>Background</u>.   H.R. 3590, Section 6002: "Transparency Reports and Reporting of Physician Ownership or Investment Interests," also referred to as the "National Physician Payment Transparency Program" a/k/a the "OPEN PAYMENTS" or "Sunshine Act" and H.R. 3590, Section 6004: "Prescription Drug Sample Transparency," requires certain data collection and reporting regarding payments or transfers of value and drug sample distribution to physicians.

3.5.2   <u>Data Management</u>.   Syneos Health will provide the following data management services to Client:

(a)   Regular reports of HCP-related meal expenses in Syneos Health's standard format;

Exhibit 10.1

(b) Regular reports Syneos Health's standard format of items of value non-sample items left with HCPs;

(c) Syneos Health will run full-cycle system testing and support UAT testing; and

(d) All reports will be clearly defined in terms of layout, content and delivery in the Data Requirements Document.

Syneos Health will work with Client in the data requirements process to confirm the file format, data elements, file delivery process and frequency to meet Client specifications for transparency reporting and Client System Integration. Syneos Health's Monitoring and Auditing processes for transparency reporting is detailed in Exhibit C, below.

3.6 Data Management

3.6.1 Generally.

(a) Syneos Health will provide data loads and data integration services for standard data imports and exports. Data management services includes data flowing to and from the Veeva CRM application, including Client data sources, third parties (i.e. sales data), or service partners. The data management team will work with the Veeva CRM, and analytics and reporting tools, to ensure that all Client business rules and data requirements are understood and planned for in the overall implementation plan.

(b) A full description of all data files and formats for data interfaces will be provided in the Data Requirements Document ("DRD"), which will be included as part of the Project Plan with necessary approvals from the Client and Project leads. The DRD will also include a Production Schedule, for ongoing data management services.

3.6.2 Data Loads, Imports and Extracts—Standard. The Project assumes use of standard data loads and file formats for all initial and ongoing data support as provided below:

(a) Standard initial data loads shall use agreed upon Syneos Health/Client formats including:

(1) Territory hierarchy;

(2) Customer universe, alignments, and Targets/Call plans;

(3) Product information; and

(4) Call history (if required).

Exhibit 10.1

(b)   Standard reoccurring data imports shall be conducted at set frequencies and in agreed upon formats within five (5) business days of receipt as needed for the following:

    (1)   Prescriber/account sales data (weekly & monthly);

    (2)   Prescriber payer data (weekly & monthly);

    (3)   Call Plan/Targets (quarterly); and

    (4)   Customer universe updates—validation responses (weekly).

(c)   Standard reoccurring data extracts shall be provided at set frequencies to either home office or third-party vendors as needed for processing to include:

    (1)   Call/activity data (weekly or monthly – Syneos Health to provide within 5 business days from the end of the cycle);

    (2)   Medical inquiries (daily);

    (3)   Sample activity (weekly or monthly – Syneos Health to provide within 5 business days from the end of the cycle);

    (4)   Extracts supporting Transparency Reporting in Section 3.5 (monthly or quarterly);

        (i)   DME Spend data from Concur;

        (ii)   Items of value, open payments reports;

        (iii)   Hand-carry sample reports for ACA 6004 (Knipper clients only); and

    (5)   Customer Universe Validation Requests (weekly – Syneos Health to provide within 5 business days from the end of the cycle).

(d)   Standard data maintenance services will be provided for the ongoing support of the systems and data at fixed frequencies as defined below to include:

    (1)   State license validation process to reduce field impact in sampling (weekly);

    (2)   PDRP flagging on accounts (monthly);

    (3)   Routine merging of accounts (quarterly);

Exhibit 10.1

(4)   Setup of integration between Veeva CRM and data warehouse, which allows roster, Territory hierarchy and Product management to be seamless (daily);

(5)   Processing of action requests (Client data changes) (quarterly);

(6)   Time off Territory and holiday updates (monthly);

(7)   Ongoing maintenance of sales and payer data (weekly or monthly based on sales data provider availability);

(8)   Training database setup and management (quarterly);

(9)   Tier 2/technical support for data issues routed from the Field Support Desk (daily);

(10)   Customer sales data extracts for IC (as defined in Section 3.10) processing (monthly); and

(11)   Customer sales data and Call/activity extracts for A&R processing (monthly).

3.6.3   Assumptions. The scope of the data management delivery and associated timelines for the Project assumes the following:

Project Deliverable	Definition
Initial Requirements	Discussion of client needs regarding data loads, extracts, and imports and finalization of Project plan and scope based on SOW assumptions and change management process
Third Party Agreements (TPA)	Syneos Health will secure, in coordination with Client, any rights and licenses that Syneos Health needs from external vendors such as sales data companies which require TPA for data services to be provided
DRD (Data Requirements Document)	Syneos Health will provide the Client with a DRD document which summarizes all data loads, imports, and extracts, as well as any business rules, frequencies, and formats associated with the data services to be provided as part of implementation and ongoing data management services, the DRD draft will be reviewed, modified as needed, and signed by the Client to confirm Project deliverables
Test Files	The Client or third parties will provide needed test files in specified formats and agreed dates in the Project plan based on the implementation schedule

Exhibit 10.1

Final Production Files	The Client or third parties will provide final production files in specified formats and agreed dates in the Project plan based on the implementation schedule

3.6.4   Non-Standard; Changes.   Any additional data feeds not included in the standards as defined above, or changes to data exchanges or maintenance subsequent to the approved DRD will follow the change control process and rate schedule set forth in Sections 3.1 and 3.1.1(d) respectively.

3.7   Analytics and Reporting

3.7.1   Veeva CRM Dashboard Reporting.

(a)   Reporting Generally; User Types. The Project assumes general field activity reporting will be provided in the Veeva CRM Dashboard Reporting environment utilizing Syneos Health's pre-configured reporting tools to optimize field performance and implementation setup time. Syneos Health reporting will be provided for the following user types aggregated based on the user type's span of control:

(1)   Representative (Territory level);

(2)   Field Management (regional level); and

(3)   Home Office (national level).

3.7.2   Veeva Report Configuration and Templates.

(a)   Syneos Health will configure the reporting tools to include Client specific fields and terminology, where applicable, within Veeva and SalesForce.com guidelines. Veeva requirements, development, and deployment will follow the requirements and format as provided in the Veeva CRD as stated in Section 3.2, and may include the following: field activity, including the following: Call activity, Call plan adherence, sample activity, CLM utilization, synchronization monitoring, manager exceptions, and/or administration.

(b)   Report Templates. The Veeva template field reporting package is designed to drive sales behavior in the following ways:

(1)   Evaluation of prescriber sales for pre-Call planning from account summary report;

(2)   Measure that the most valuable drivers of sales were detailed and sampled in accordance with the recommended Call plan - account/physician –

Exhibit 10.1

(i)   Average Calls per day –reviews Call activity against Target or segmentation;

(ii)   Reach and frequency can be found on analytics tab;

(iii)   Call plan information can be found on the Call plan tab; and

(iv)   Call Plan Analysis Report can be found on the analytics tab.

(3)   Measure the impact of detailing and sampling on sales –

(i)   Effort vs. results report can be found on the analytics tab.

(4)   Examine the landscape for the product to identify top sales accounts and potential –

(i)   Territory sales analysis—reviews trends in Client Product and competitive landscape; can be found on analytics tab;

(ii)   Territory payer analysis –examines payer information; can be found on analytics tab; and

(iii)   Territory comparison report—compares sales performance at the Territory level for all territories within span of control; can be found on analytics tab.

(5)   Report Template Table.

Template Reports	Base Assumptions	Standard Frequency
Account Summary	Prescriber based product level prescription data	At same frequency as sales data (aka prescription data) delivery to Client
Activity/ Administrative	1. Reviews key territory and/or district performance indicators with drill down details for: a. Interactions b. Detailing c. Sampling 2. Review key territory and/or district administrative metrics with drill down details	Real time as of last synchronization and refresh

Exhibit 10.1

Template Reports	Base Assumptions	Standard Frequency
	3. Any information collected within a check box or drop down list into the Veeva systems can be aggregated into a dashboard element	
	4. Text box information can be rolled into a report but not the dashboard	
	5. Dashboards can have up to 20 measurement elements	
	6. All Dashboard elements are pictorials which aggregate data from an underlying report	
	7. All pictorials are flexible but limited to two dimensions	
	8. Color selection is not an option	
	9. Filters can be applied to comparable data	
	10. Reports can be filtered by user level (Field, Management, Home Office)	

	11. Other Reportable Activities
	
	   a. System Utilization
	   b. Pending Interaction (Exception/incomplete information)
	   c. Time off Territory
	   d. Synchronization Reports
	   e. Interaction by Date and Time
	   f. Field Action Requests	

	12. Account Demographics
	   a. Target/Non-Target
	   b. Account Type (practitioner, pharmacy, staff, etc.)
	   c. Specialty
	   d. Segmentation
	   e. Custom Profile Attributes	

	13. Closed Loop Marketing (CLM)
	   a. Slide Utilization as % of Calls
	   b. View Duration
	   c. Ranking of Slides by View count and Average Duration	

Exhibit 10.1

Template Reports	Base Assumptions	Standard Frequency
	d. Viewer Reaction (Positive, Neutral, Negative)	
Reach and Frequency	Adapted to specific activity measurements and goals within set up matrix (calls, targets only, reach, frequency, sample distribution)	Real Time as of last synchronization and refresh
Average Calls Per Day	Average Calls Per Day versus goal	Real Time as of last synchronization and refresh
Territory Sales Analysis	1. Adapted to specific product/market definition 2. Monthly prescriber-based product level prescription data; Up to 3 promoted products	At same frequency as sales data (aka prescription data) delivery to Client
Territory Comparison (Mgmt. supplement)	1. Adapted to specific product/market definition 2. Monthly prescriber-based product level prescription data; Up to 3 promoted products 3. Comparison of sales data amongst the assigned span of control	At same frequency as sales data (aka prescription data) delivery to Client
Territory Payer Analysis	1. Monthly payer-based product level prescription data 2. Analysis of the prescriber payer 3. Top payers 4. Comparison of payer market products	At same frequency as sales data (aka prescription data) delivery to Client
Effort vs. Results aka Impact Report	1. Adapted to specific product/market definition 2. Up to 3 promoted products 3. Monthly prescriber-based product level prescription data	At same frequency as sales data (aka prescription data) delivery to Client

3.7.3 <u>Custom Analysis & Insights</u>.

Additional work-effort will require work estimates and Change of Scope as detailed in Section 3.1.1(d), to be coordinated by the PM.

As a result of some of the changes Syneos Health will be allocating analytics support to Client. This should enhance current reporting Client is receiving as there will be more insights applied, as well as the opportunity to better handle ad hoc reporting needs (the "Analyst Services").

Exhibit 10.1

3.8 Targeting, Alignment and Call Plan Administration

3.8.1 <u>Generally</u>. Syneos Health will provide targeting and sales force alignment services for optimization of key targets. The goal of these services is to:

(a) Optimize geographic coverage on the most valuable Targets while balancing Territory workload;

(b) Target list generation based on business-specific workload parameters including the incorporation of any segmentation, detailing and frequency provided; and

(c) Identification of uncovered white space geography.

3.8.2 <u>Deliverables</u>.

(a) Metropolitan Statistical Area (MSA) overview;

(b) Alignment summary including coverage of top targets;

(c) Uncovered geography summary;

(d) Mapping at territory, district and national levels;

(e) Zip-Terr;

(f) Span of control; and

(g) Target list.

3.8.3 <u>Assumptions</u>.

(a) The scope assumes the following:

(1) Alignment will be created utilizing Syneos Health's preferred alignment software;

(2) Territory workload parameters and Project assumptions are agreed upon before work starts;

(3) All third-party agreements are signed off on before work starts;

(4) If third-party data purchased by Syneos Health will be passed through to Client;

(5) Client will supply physician level universe which will include best address. Any workload specific data points will be mutually agreed upon by the Parties (i.e., Rx, Deciles, etc.);

Exhibit 10.1

(6) One (1) per-deployment interactive alignment session for the field managers for minor geographic tweaks; and

(7) Quarterly Target or Call plan updates will be managed through the Veeva Action Request process, with timing provided for call plan updates that represent [***] changes in territories, geographies or segmentation. This will be done for alignment and Target updates each quarter, with District Manager/Sales Management reviews, per the agreed upon process between Client and Syneos Health.   Additional work-effort will require work estimates and Change of Scope as detailed in Section 3.1.1(d), to be coordinated by the PM.

(b) Items not included in the assumptions:

(1) Major realignments or re-targeting exceeding [***] changes in territories, geography, or segmentation such as new Target strategy, expansions, or down-sizing; and

(2) Additional mapping and data analysis.

3.9 Incentive Compensation Management

3.9.1 <u>Generally</u>. Syneos Health incentive compensation management will design and /or implement an annual incentive compensation ("IC") plan and administer quarterly payouts. Syneos Health IC personnel will facilitate an IC assessment meeting to ascertain scope of work, IC plan parameters, data availability, budget, IC plan goals and incentive compensation culture. Sessions will be led by Syneos Health IC employees experienced in the discipline of IC plan design and field performance measurements.   The assessment sessions are strategically structured to aid in the IC plan design, consisting of metrics aligned to business strategy. After the IC plan design has been approved by the parties, the Syneos Health incentive compensation department will implement, manage and administer IC plan.

3.9.2 Standard IC Services are inclusive of the following:

(a) Post the launch year, which will include at least one full year from the date of launch, a single annual IC plan for each Client team (i.e. Sales and Sales Managers) for the covered field employees, with no more than two (2) Plan Updates (as defined herein) per year. A "Plan Update" is defined as a change, which does not alter the IC plan structure thus resulting in an amendment to the IC plan. Changes to IC plan structure, which require a new set of modeling, design work, and/or plan communication documentation are considered a "New Plan," and may be subject to a separate Statement of Work ("SOW").

Exhibit 10.1

(b)   The components of an IC plan will include the following:

(1)   Plan concept presentation deck;

(2)   Formal plan document with electronic signature;

(i)   Inclusive of:

- Plan design measurements
- Business rules
- Data crediting
- Calculations
- Participation rules
- Terms and Conditions

(ii)   IC Plan document will be reviewed by the following:

- Syneos Health Sales Leadership
- Syneos Health Human Resources
- Syneos Health Corporate Compensation
- Syneos Health Authorized Legal

(3)   Monthly spreadsheet ("IC Grid") of calculated results (dependent on data availability and IC plan design);

(4)   Monthly field scorecards (dependent on data availability and IC plan design);

(5)   Quarterly payout administration in accordance with the Syneos Health payroll calendar;

(6)   A single contest/special performance for field force per year to include:

(i)   Contest Concept Presentation Deck;

(ii)   Formal Plan Document with electronic signature;

(iii)   Single payout administration in accordance with the Syneos Health payroll calendar; and

(iv)   Single contest grid and/or scorecard of contest results.

(7)   A single annual President's Club contest/trip to include:

(i)   Results published in conjunction with the monthly IC reporting process.

Exhibit 10.1

(8)   Additional services and changes will be subject to the Change Control Process and subject to an amendment.

3.9.3   <u>IC Plan Deliverables and Timelines</u>.

(a)   <u>Design Phase</u>.

Category	Description	Duration/Timeline
IC Plan Meeting(s)	Initial Meeting to discuss: ● Corporate Philosophy ● Sales Goals/Objectives ● Sales/Marketing Strategy ● Business Rules ● Data Inputs ● Eligibility Requirements	1 day – initial meeting; subsequent follow-up meetings may be held to discuss pending topics or matters requiring further discussion from initial meeting. Maximum timeline 3 weeks
IC Modeling	Based on inputs derived from initial IC meeting(s), Syneos Health will create/provide IC deck illustrating: ● Recommended IC plan(s) ● Payout Scenarios/Distribution	● 1 week to provide recommendation ● 1 week for feedback/follow-up ● Additional time may be needed if data is required for modeling
Field Communication	IC Plan communication includes: ● PowerPoint deck (Management Team & Sales force) ● Word/PDF document (for IC plan participants/acknowledgement)	3 weeks (maximum) once IC plan has been finalized.

(b)   <u>Implementation Phase</u>.

Category	Description	Duration/Timeline
IC Plan Programming	● Data Process Setup ● SQL Programming	Maximum of 3 weeks after receipt of initial sales data file in final format

Syneos Health Project Code: 7007244

Exhibit 10.1

Category	Description	Duration/Timeline
	- User Interface Setup - Report/Scorecard Programming - KPI/MBO Programming (if applicable) - Acknowledgement Portal Setup - Administration Portal Setup - Programming QC & Testing - Validation & QC of IC plan programming (independent of Programming QC) - Minor changes (cosmetic, etc.)	

(c) <u>Maintenance/Management Phase</u>.

Category	Description	Duration/Timeline
Plan Administration	IC plan processing - Report Generation - Payout Grid/Summary - Scorecard - Management Summary - IC plan QC - Report Distribution - Roster Management - Eligibility; LOA; PIP; New Hire - IC Portal Maintenance - Acknowledgment - Administration	4 weeks after receipt of monthly sales data file

As IC is a passthrough expense to Client, Syneos Health encourages Client input on IC plan design. In instances where Client has given input into the IC plan design or when Syneos Health implements an IC plan design created by Client, Client acknowledges and agrees that it shall use

Exhibit 10.1

best efforts to timely approve such IC plan design. The foregoing notwithstanding, in the event field force goals, dependent data, Client requested input, and/or plan documentation are not approved by Client and/or acknowledged by the field force within forty-five (45) calendar days into the then current IC plan period, Syneos Health reserves the right to implement either the IC plan which was utilized in the prior IC period or an Syneos Health standard best practice IC plan, and Client acknowledges that by engaging Syneos Health to perform incentive compensation management, Client is expressly consenting to the foregoing.

3.10   Field Support Services

3.10.1 <u>Help Desk</u>. The Syneos Health field support service desk supports Syneos Health systems and operational processes for field user readiness and performance.

(a)   Field support service desk hours are Monday through Friday, 8am-10pm, Eastern Standard Time

(b)   Standard Syneos Health metrics and KPIs for call and ticket resolution

(c)   Field Support can be reached via telephone or via email

(d)   Knowledge base will be supplied for field support service desk based on Client business rules and system configuration

(e)   Standard monthly reporting will be provided along with post-rollout daily monitoring reporting for 2 weeks following each field deployment

3.10.2 <u>Asset Management</u>.

(a)   Syneos Health will provide asset management services ranging from hardware procurement, to configuration and deployment, and includes tracking IT assets throughout the life of the Project. Syneos Health maintains a suite of standard Windows images and custom images available as needed. Client hardware is asset tagged, scanned and secured in a locked area with restricted access for designated IT personnel.

(b)   Standard hardware platform includes:
(1)   Field laptop with carrying case

(2)   Apple iPad with cover

(3)   Printer

Exhibit 10.1

(c)   Users are given Syneos Health-hosted email boxes with the option to configure with Client-like domains/addresses to give the look and feel of a Client employee.

(d)   All Client launches include a [***] spare pool of hardware to be used as replacements in the event of breakage or theft/loss. Repairs/replacements are shipped out to the end-users within 48 hours of receipt of broken hardware.

(e)   Passcode-protected iPads are deployed using our mobile device management software with remote-wipe capabilities for added security.   App packaging and deployment capabilities are available.   For clients opting for iPads with data plans, we can activate with one of the major carriers prior to shipment and then maintain that data plan throughout the life of the contract.

3.11   Technology Training Services

3.11.1 <u>Generally</u>. Syneos Health will provide technology training services for the Sales Team. The technology training services format follows Syneos Health's core training content and facilitation approach. Training delivery assumes the following structure:

(a)   Pre-learning home study training (e-modules)

(b)   Face-to-face training (up to 1 day)

(c)   Post-training mastery (up to 2 hours WebEx)

3.11.2 <u>Content</u>. The training content will include key Syneos Health supported field hardware and applications including the following topics: iPad basics, Concur T&E, HCP Spend Capture, Veeva CRM, Veeva Analytics & Dashboards, and Customer Maintenance. New hire training will be delivered using the same content developed for implementation and offered at the frequency of **one class per quarter**, with the preferred Client format of either WebEx or face-to-face delivery. Additional training is offered as needed following the Change of Scope process in Section 3.1.1(d) of this Exhibit A-1.

3.12   Learning Management System (LMS)

Syneos Health will supply Client with our standard LMS system for the delivery and tracking of all online training. Standard LMS reporting will be provided to internal Syneos Health leadership and Client for communication of training completion and verification of required compliance training.   The LMS can contain a combination of Syneos Health and Client-created content to enable its

Exhibit 10.1

use across all product, selling skills, soft skills, and compliance training and service as a central repository for all training records.

Standard LMS Service Levels are indicated in the below table:

Standard SLA - Content Load*	
Task/Request	**Timeline**
Simple PDF Load	1-2 days
Simple SCORM Load	2-4 days
Simple Assessment	2-3 days
Registrations/Assignments for existing activities and users	24 hours
Add Additional users (upon notice)	End of next business day
Transcripts	24 hours
Complex Assessment	3-5 days
Complex Course with Assessment	5-7 days
High Stakes/Large Assessment	5-7 days

3.13 Quality Management and Assurance

3.13.1 <u>Quality Management System (QMS)</u>. All Client implementations are managed via an approved set of Standard Operating Procedures (SOPs) which are part of Syneos Health's Quality Management System (QMS) under the Head of Quality Assurance. Key processes such as project governance, document control, CRM implementation and training are required for assigned operations personnel. Other SOPs such as Change Control, security and access control, asset provisioning, and CRM end-user training are additional required training for implementation teams, which are also delivered and tracked within Syneos Health's Learning Management System (LMS).

3.13.2 <u>System Validation (Sampling Only)</u>. When required by sampling, formal Computer System Validation (CSV) is conducted by professional validation resources following Syneos Health's System Validation SOP. The work is driven by the approved Configuration Requirements Document (CRD), and includes a Validation Plan, Operational Qualification, Performance Qualification, Test Evidence (typically screen shots), Deviation Reports, Traceability Matrix and a Validation Summary Report.

3.14 Field Trigger Email with Veeva Engage

3.14.1 Field Trigger Email with Veeva Engage. Syneos Health will provide field-trigger email follow-up to HCPs to reinforce key messages in the Call and distribute the Prescribing Information. Syneos Health leverages Veeva's approved email capabilities to ensure compliance and a controlled environment to protect the integrity of the HCP communication. Approved content for email templates may be stored in the Syneos Health Veeva Vault or the Client's internal Veeva Vault (if applicable) and linked with the CRM

Exhibit 10.1

Client Configuration. The solution will also include Veeva Engage to deliver built in virtual voice and video capabilities in a single solution for the field teams.

4.0	**Operations Services Termination and Data/System Conversion**

Syneos Health will retain all documented business requirements, system configurations, and data collected during the term of the Project Agreement. If the Client wishes to convert the field team pursuant to the Project Agreement, Client may have the option to continue on with Syneos Health-provided operations services to limit the disruption of field operations and leverage custom built systems, business rules and data integration. In such a case, a separate agreement will be established to confirm the scope and fees for any stand-alone operations services required. Alternatively, the parties may agree to convert the pre-built CRM configuration utilized for Client, for a fee mutually agreed to by the parties, to cover the migration of data, requirements documentation, and transfer of CRM configuration ownership, training on Client configuration settings and administration, as well as the Project management of the operations conversion, all to ensure a successful migration. Additionally, if the Client does not want to migrate the Syneos Health CRM configuration, the option may be made for Syneos Health to transfer Client data, business rules documentation, current data production schedules, and custom reporting formats for a fee mutually agreed to by the parties. If Syneos Health provides any migration or materials, Client is solely responsible for the system knowledge and performance post-conversion. Syneos Health may provide additional services based on the standard rates provided in the Change Control 3.1.1(d) of this Exhibit A-1.

Exhibit 10.1

**SECOND AMENDED AND RESTATED EXHIBIT F
COMPENSATION - FIXED FEES, VARIABLE FEES AND PASS-THROUGH COSTS**

I.   FIXED FEES

Client shall pay Syneos Health a weekly fee in accordance with the below table ("Weekly
Fee") for the performance of the Services which shall be paid by close of business every
Friday. For the avoidance of doubt, the Weekly Fee includes $[***] to provide for the
continuation of Agile's patient support program, which is the subject of a Work Order
between the Parties dated June 28, 2022 for Syneos Health Project #7041456.

Period	Weekly Fee Amount
April 1, 2023 through September 30, 2023	$[***]
October 1, 2023 through August 23, 2024	$[***]

a. Scale Up

Client may increase the number of Representatives or EC Reps above the number
outlined in Exhibit A (a "Scale Up") upon written notification to Syneos Health. In
the event of a Scale Up, Client shall pay a per Representative or per EC Rep an
implementation fee of $[***] and increase the Weekly Fee as follows:

Position	Per position additional Weekly Fee for the period of April 1, 2023 through September 30, 2023	Per position additional Weekly Fee for the period of October 1, 2023 through August 23, 2024
Per Representative	$[***]	$[***]
Per EC Rep	$[***]	$[***]

b. Scale Down

Exhibit 10.1

Client may decrease the number of Representatives or EC Reps below the number outlined in Exhibit A (a "Scale Down") upon sixty (60) days written notification and as mutually agreed to between the Parties. In the event of a Scale Down, Syneos Health shall decrease the Weekly Fee as follows:

Position	Per position additional Weekly Fee for the period of April 1, 2023 through September 30, 2023	Per position additional Weekly Fee for the period of October 1, 2023 through August 23, 2024
Per Representative	$[***]	$[***]
Per EC Rep	$[***]	$[***]

II.   VARIABLE FEES

There are no variable fees associated with the Services.

III.   PASS-THROUGH COSTS

There are no pass-through costs associated with the Services.

IV.   INCENTIVE FEES

(a)   Included in the Weekly Fees, starting on July 1, 2023, (set forth in Section I, above) is Syneos Health's management fee, a portion of which in the amount of $[***] (the "Incentive Fee") is subject to Syneos Health's achievement of certain performance objectives (the "Performance Objectives") as set forth below:

Quarterly Metrics			
Split	Type	Metric	Target / Payout
50%	Sales	TRx Cycles	[***]
50%	Ops	Calls per rep / Day	[***]

Exhibit 10.1

In the event that Syneos does not achieve the Performance Objectives for a given Quarter, the amount of the Incentive Fee already paid for that Quarter shall be credited against any outstanding amounts Client owes to Syneos Health.

(b) In the event of a Scale Up or Scale Down of Representatives, the weekly Incentive Fee shall be adjusted by $[***] per Representative.

(c) In the event of termination of this Project Agreement by the Client, effective as of the date of notification of such termination from the Client, the Performance Objectives shall no longer be applicable and the outstanding Incentive Fees will be earned at [***]; unless Project Agreement is terminated due to material breach by Syneos Health in accordance with Section 12(ii) of the MSA.

V. INVOICES; BILLING TERMS

Invoices shall be billed to Client on a weekly basis and payment due by close of business every Friday. All invoices shall include the following:

- A/P Email
- A/P Telephone
- A/P Mailing Address
- A/P E-invoice System
- Other Contacts to be Included on Submission of Invoice
- Accountant

Payment to Syneos Health may be made by the following method:

ACH Payment (Preferred Method)
[***]
ACH # [***]
Account # [***]

Advice transmittals should be directed to [***].

In the event Client will be issuing purchase orders for payment of Syneos Health invoices, Client shall issue such purchase orders within [***] following the execution of this Project Agreement. A purchase order shall include the following:

- PO Number
- PO Contact Name
- PO Contact E-mail
- PO Contact Telephone

Exhibit 10.1

Purchase Orders should be directed to [***]

The Parties understand and agree that all terms and conditions set forth in a purchase order are null and void, it being understood and agreed that this Project Agreement provides the terms and conditions governing the relationship between the Parties.