

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

FORTIS ADVISORS LLC, solely in)
its capacity as representative of former)
stockholders of Auris Health, Inc.,)

Plaintiff,)

v.)

C.A. No. 2020-0881-LWW

JOHNSON & JOHNSON, ETHICON,)
INC., ALEX GORSKY, ASHLEY)
MCEVOY, PETER SHEN, and)
SUSAN MORANO,)

Defendants.)

MEMORANDUM OPINION

Date Submitted: May 22, 2024
Date Decided: September 4, 2024

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WILL, Vice Chancellor

Earnout provisions are common risk allocation tools in merger agreements, particularly involving private company sellers. The buyer pays an upfront sum and an additional amount if the seller's business achieves specific targets by a deadline. This contingent approach lessens the buyer's risk of overpaying where the seller's future performance is uncertain. The seller, however, risks losing the earnout payment along with operational control after closing. A seller may be loath to agree to an earnout structure without contractual assurances from the buyer and a strong belief in the value of its business.

The seller in this case had both. Auris Health, Inc. was a venture-backed startup on a path to bring life-changing technologies to market. Led by Dr. Frederic Moll, the visionary architect of robotic surgery, Auris had developed two novel surgical robots in record time: Monarch and iPlatform. Monarch had unmatched capability to diagnose and treat lung cancer. And iPlatform took Moll's original market-leading surgical robot to new heights with innovative features for laparoscopic and endoscopic procedures.

While Auris was making strides, Johnson & Johnson was attempting to develop its own surgical robot called Verb. Entering the surgical robotics market was vital for J&J. Yet Verb was falling increasingly behind the schedule J&J had announced to the market, despite J&J's colossal investments. J&J looked to Auris as a solution.

Auris was well funded and had strong prospects. It was wary of an acquisition, especially by J&J since Verb was a potential competitor of iPlatform. J&J understood Auris's hesitations and put together a proposal it would not refuse.

J&J offered to pay \$3.4 billion up front and another \$2.35 billion upon the achievement of two commercial and eight regulatory milestones—five for iPlatform, two for Monarch, and one that could be satisfied by either robot. The regulatory milestones were ambitious, but corresponded to approvals for procedures that the Auris robots were on track to complete. Auris agreed to an earnout component after securing J&J's commitment to devote commercially reasonable efforts befitting a “priority medical device” in furtherance of the milestones.

J&J's promise to Auris was broken almost immediately after closing. Instead of providing efforts and resources to achieve the regulatory milestones, J&J thrust iPlatform into a head-to-head faceoff against Verb called “Project Manhattan.” Verb and iPlatform were forced to complete a series of procedures to be ranked against one another. Auris feared that a poor performance would be the end of iPlatform since it had learned J&J's robotics budget left no room for Verb and iPlatform to be developed in parallel. J&J would either combine the robots or kill one.

The iPlatform alpha robot was months old. Verb was in its beta iteration after years of development. For iPlatform to survive a surgical showdown against the more advanced robot, the Auris team spent countless hours creating engineering and

software workarounds. Progress toward iPlatform's regulatory milestones ceased while technical debt from shortcuts in its development amassed.

Both robots successfully completed the assigned procedures. J&J decided that iPlatform was the better bet. But for iPlatform, winning Project Manhattan was losing. To salvage its years of investment in Verb, J&J directed that Verb's hardware and team be added to iPlatform. The iPlatform robot effectively became a parts shop for Verb.

J&J knew Project Manhattan would hinder, rather than promote, iPlatform's achievement of the regulatory milestones. It also knew that combining iPlatform and Verb would cause further complications. But J&J viewed the resulting delays as beneficial since it could avoid making the earnout payment. When J&J's actions put the first iPlatform milestone out of reach, the other milestones fell like dominos.

J&J wrote off the iPlatform milestones under the pretext of an unforeseen policy change that would require the robot to achieve regulatory clearance through a different pathway than the one listed in the merger agreement. J&J then implemented an employee incentive plan with different targets. Auris's former stockholders proceeded to sue for breach of contract, breach of the implied covenant of good faith and fair dealing, and fraud.

J&J's defenses to these claims take two main forms. First, J&J asserts that the merger agreement gave it broad discretion to use the Auris products in a way that

advanced J&J's overall robotics strategy without regard to the milestones. The merger agreement says otherwise. Second, J&J blames the missed milestones on iPlatform's technical problems. This defense is dubious; it was concocted after J&J was sued. The record indicates that the technical issues were both expected and solvable.

After weighing an abundance of evidence, I find that J&J breached its contractual obligations. The bespoke earnout provision negotiated by the parties required J&J to treat iPlatform as a priority device, to provide efforts in support of the regulatory milestones, and to avoid making decisions based on the contingent payment. J&J violated each obligation—most blatantly when iPlatform was made to compete against and combine with Verb. J&J also breached the implied covenant of good faith and fair dealing when it failed to devote efforts to achieve the revised regulatory pathway. But J&J did not breach the merger agreement in relation to the Monarch regulatory milestones.

Additionally, Auris claims that J&J fraudulently induced it to merge by promising vast resources and a “light touch” integration. For the most part, the challenged statements are fluffy, forward-looking, and aspirational. There is an exception. One Monarch milestone involved regulatory clearance by a near-term deadline using a J&J-developed catheter. J&J told Auris that this milestone was so certain to be met that J&J viewed the associated payment as up front consideration.

J&J neglected to mention that it was under a regulatory investigation because a patient in a clinical study using the catheter had recently died, which put the milestone in doubt.

Auris is entitled to damages for J&J's breaches of contract and of the implied covenant of good faith and fair dealing as they relate to the iPlatform regulatory milestones. It is also entitled to damages for fraud concerning the Monarch milestone. Damages with interest exceed \$1 billion, which compensates Auris's former stockholders for the earnout payment they would have received absent J&J's failed efforts and fraud. What remains irretrievably lost is the transformative potential of Auris's robots.

I. BACKGROUND

The following facts were stipulated to by the parties or proven by a preponderance of the evidence at trial.¹ The record supporting these findings of fact includes the testimony of 23 fact and 9 expert witnesses over 10 trial days, 78 deposition transcripts, and 6,209 joint exhibits.²

A. Dr. Moll and the da Vinci Robot

Robotically assisted surgery allows physicians to perform minimally invasive operations with computer-assisted equipment.³ Surgical robots, or Robotically Assisted Surgical Devices (RASDs), are used to perform these procedures. RASDs typically comprise several components and subsystems, including a surgeon console, a computing tower, and a surgical bed or cart with mounted robotic arms attached to instruments.⁴

Dr. Frederic Moll first witnessed early progress in robotic surgery as part of a Stanford Research Institute (SRI) project funded by the United States Department of

¹ Joint Pre-trial Stipulation and Order (Dkt. 523) (“PTO”).

² Facts drawn from exhibits jointly submitted by the parties are referred to by the numbers provided on the parties’ joint exhibit list and cited as “JX –” unless otherwise defined. *See* Dkt. 575. Pin cites for joint exhibits refer to the page of the exhibit as marked rather than internal or Bates pagination, unless otherwise noted. Deposition transcripts are cited as “[Name] Dep.” *See* Dkt. 509. Trial testimony is cited as “[Name] Tr.” *See* Dkts. 545-54.

³ PTO ¶ 75.

⁴ *Id.* ¶ 76.

Defense several decades ago.⁵ SRI's objective was to create a means for surgeons to operate remotely on patients in the battlefield.⁶ Though rudimentary, the device SRI developed could transmit a surgeon's hand movements from a computer to actuators in the field that controlled a robotic instrument.⁷

Moll saw the “potentially transformative” promise of robotic-assisted surgery as having “enormous implications in laparoscopy.”⁸ Laparoscopy is a minimally invasive surgical technique in which narrow tubes are inserted into the abdomen or pelvis through puncture wounds.⁹ Moll had been exposed to emerging laparoscopy techniques during his medical residency and turned his focus to developing safe laparoscopic tools and methods.¹⁰ He observed that a trade-off to minimal openings in the body is the difficulty surgeons face in reaching the relevant anatomy.¹¹ Using the insights gained at SRI, Moll imagined that computer replication of hand movements outside the body to robotic hands inside the body could resolve laparoscopic access barriers.¹²

⁵ Moll. Tr. 9-10.

⁶ *Id.*

⁷ *Id.* at 10.

⁸ *Id.*

⁹ *Id.* at 6-7.

¹⁰ *Id.* at 6.

¹¹ *Id.* at 10.

¹² *Id.*

In 1995, Moll founded Intuitive Surgical, Inc. to pursue the objective of making laparoscopic surgery intuitive.¹³ He developed a product called the da Vinci robot—a cart-based system with two arms to hold surgical instruments and a third arm for a viewing laparoscope.¹⁴ Moll’s vision was to “mimic the capabilities of open surgery inside the body” by using a computer interface to transmit movements to tiny tools inside the abdomen in a “systematic and controlled way.”¹⁵

Developing the da Vinci robot was no small feat. The Intuitive team encountered many technical challenges, including problems with tool function, software stability, arm collisions, and intra-device heat distribution.¹⁶ The issues were addressed with mitigation strategies now typical to robotic surgery.¹⁷ Dr. Barry Gardiner, a physician who pioneered laparoscopy in general surgery, contributed vital clinical knowledge to solve these issues and develop the robot.¹⁸

The da Vinci system was not Moll’s only innovation at Intuitive. He also instituted the minimally viable product (MVP) approach, which has become the

¹³ PTO ¶ 77; Moll Tr. 11-12.

¹⁴ Moll Tr. 11-12.

¹⁵ *Id.* at 13.

¹⁶ *Id.* at 16-17.

¹⁷ *Id.* at 17-19 (discussing the use of surgical assistants to move and adjust the robot during a procedure, which remains standard today).

¹⁸ Moll Tr. 14; *see* JX 2598 at 3.

industry standard for bringing new, complex medical devices to market.¹⁹ The MVP development strategy involves creating a functional prototype to gain feedback from an engineering and clinical standpoint before adding more complex features.²⁰ This method increases efficiency by allowing for testing of a lower-risk device before making further investments.²¹ Regulatory approval is sought for the stripped-down version, ensuring that it meets patient safety and effectiveness requirements.²²

Intuitive followed an MVP strategy with the da Vinci system. It first sought regulatory approval for a basic three-arm version of the device.²³ In 2000, the Food and Drug Administration (FDA), which regulates the sale of medical devices in the United States and monitors their safety and effectiveness, approved the minimally viable da Vinci robot through the 510(k) process.²⁴

The 510(k) (or Premarket Notification) process is one of three regulatory pathways through which high or moderate risk medical devices obtain FDA approval.²⁵ The 510(k) pathway is for low to moderate risk devices with a legally

¹⁹ Moll Tr. 15-17; *see* Gompers Tr. 1935-36; Grennan Dep. 71-72; Shen Tr. 1169.

²⁰ Moll Tr. 15-16.

²¹ *Id.* at 16; *see* Khan Tr. 3041-3042.

²² Moll Tr. 16.

²³ JX 14; *see* Moll Tr. 15-16.

²⁴ Moll Tr. 19; PTO ¶ 79.

²⁵ PTO ¶ 81.

marketed predicate device.²⁶ It involves a comprehensive review of appropriate safety and performance data to determine if a new device is substantially equivalent to an approved predicate.²⁷ The second pathway is a De Novo Classification Request, which is used when a novel low to moderate risk device lacks a legally marketed predicate.²⁸ De Novo approval often requires clinical testing data to demonstrate a device's safety and effectiveness.²⁹ The third pathway, called Premarket Approval (PMA), is the most onerous and required for high risk devices.³⁰

Consistent with its MVP strategy, Intuitive went on to pursue and receive 510(k) clearance for a four-arm version of the robot in 2002.³¹ The da Vinci robot was rapidly adopted by customers and Intuitive became focused on manufacturing and selling the system. Moll, having achieved his objective, moved on to “continue down a path of innovation.”³²

Today, Intuitive is considered the market leader in RASDs.³³ It has a market capitalization of over \$100 billion and controls a majority of the surgical robotics

²⁶ *Id.*

²⁷ *Id.* ¶ 82; *see* JX 4492 (“Wittwer Rep.”) ¶ 137.

²⁸ PTO ¶ 81.

²⁹ Wittwer Rep. ¶ 137.

³⁰ PTO ¶ 81; *see* Wittwer Rep. ¶ 148.

³¹ *See* JX 4511 (“Tillman Rep.”) ¶ 94.

³² Moll Tr. 21.

³³ PTO ¶ 77.

market.³⁴ Intuitive’s robots have performed hundreds of thousands of procedures worldwide, cementing Moll’s legacy as the “father of robotic surgery.”³⁵

B. Auris and the Next Generation of Surgical Robots

Moll set out to start a new RASD innovation company called Auris Health, Inc. In 2009, Moll raised Auris’s seed funding.³⁶ Early investors included venture capital funds such as J&J Innovation, a subsidiary of Johnson & Johnson.³⁷

Moll intended that Auris would advance RASDs beyond the base architecture of da Vinci to match strides in minimally invasive surgery—specifically in endoscopy.³⁸ Endoscopy involves inserting a flexible tube called an endoscope into the body through its natural openings.³⁹ He hoped to improve endoscopic technique with robotics as he had done for laparoscopy.⁴⁰

Early-stage Auris was a “vision-oriented, mission-oriented” company.⁴¹ Its visionary leaders included not only Moll but also Gardiner, who remained

³⁴ Moll Tr. 21; *see* JX 711 at 19-22; Royan Tr. 1376-77.

³⁵ JX 1868; *see* Moll Tr. 21; JX 1868; Shen Tr. 1106; Grennan Tr. 2555.

³⁶ PTO ¶ 87.

³⁷ *Id.* ¶ 88.

³⁸ Moll Tr. 22-23.

³⁹ *Id.* at 23.

⁴⁰ *Id.* at 23-24.

⁴¹ DeFonzo Tr. 316, 319.

instrumental in providing clinical expertise.⁴² A combination of leadership and dynamism gave Auris the momentum to rapidly develop its first RASD, called ARES, and secure FDA clearance.

1. ARES

Auris began developing the ARES robot in 2012.⁴³ It was designed for endoscopic procedures.⁴⁴ David Mintz, an engineer who had worked alongside Moll since Intuitive's early days, was tapped to spearhead the project.⁴⁵

After 18 months of development, Auris began using ARES in overseas clinical studies for endourology (or urology) and bronchoscopy.⁴⁶ Endourology involves the use of endoscopic surgical techniques to treat conditions affecting the urinary tract.⁴⁷ Bronchoscopy is a procedure in which a flexible tube called a bronchoscope is passed through a patient's throat to view or treat the lungs and airways.⁴⁸

⁴² Moll Tr. 27.

⁴³ Mintz Tr. 554-55.

⁴⁴ *Id.*

⁴⁵ Moll Tr. 24-25.

⁴⁶ Mintz Tr. 555.

⁴⁷ *See* Moll Tr. 64; *see also* PTO ¶ 154.

⁴⁸ *See* Moll Tr. 33; *see also* PTO ¶ 147.

ARES received 510(k) clearance for bronchoscopy in May 2016, using Intuitive’s da Vinci robot as its predicate device.⁴⁹ It was never commercialized. ARES was, instead, a step in Auris’s MVP strategy. Auris assessed ARES’s clinical capabilities first before building commercial RASDs with the benefit of that knowledge.⁵⁰

2. Monarch

Auris’s Monarch robot was the “commercial embodiment” of ARES.⁵¹ In 2016, Moll hired Richard Leparmentier, an experienced engineering manager, to lead the Monarch project.⁵²

Monarch is a revolutionary RASD. It can send a flexible endoscope through lung airways to locate, identify, and biopsy lesions found on preoperative computed tomography (CT) scans.⁵³ Its initial iteration, called Monarch Bronch 1.0, could navigate the outer lung non-invasively. In March 2018, it became the first in the Monarch device line to receive 510(k) clearance.⁵⁴ The next iteration of Monarch—

⁴⁹ JX 275.

⁵⁰ Moll Tr. 25.

⁵¹ *Id.* at 26.

⁵² *Id.* at 32-33.

⁵³ JX 5054; Moll Tr. 33.

⁵⁴ PTO ¶ 91; JX 334; JX 331; *see* Leparmentier Tr. 979.

an endourology-focused device called Monarch Uro—received pre-submission feedback from the FDA in November 2018.⁵⁵

3. iPlatform

In 2016, Auris began to create another robot in parallel with Monarch: the iPlatform surgical system. Mintz was put in charge of the iPlatform project.⁵⁶ Josh DeFonzo was hired as Auris’s head of operations to oversee both the iPlatform and Monarch programs.⁵⁷

iPlatform was devised as a bed based RASD with integrated surgical arms, a physician console, and a control tower.⁵⁸ It would be differentiated from da Vinci in several ways. Unlike the cart-based da Vinci system, which could only fit in large or custom-built operating rooms, iPlatform had “zero footprint” since its robotic arms were mounted beneath a surgical bed.⁵⁹ Though iPlatform would first be developed for laparoscopic applications (like da Vinci), it would eventually gain concomitant (laparoscopic and endoscopic) capabilities.⁶⁰ iPlatform had six robotic arms versus da Vinci’s four.⁶¹

⁵⁵ JX 858; *see* JX 637.

⁵⁶ Moll Tr. 26.

⁵⁷ *Id.* at 27.

⁵⁸ PTO ¶ 99; Moll Tr. 26-31; JX 5064.

⁵⁹ Mintz Tr. 566.

⁶⁰ Mintz Tr. 567; Moll Tr. 32; *see* JX 1347 at 5.

⁶¹ Mintz Tr. 567; *see* JX 1347 at 5.

Within a year, the iPlatform prototype was completing labs on human cadavers using three robotic arms.⁶² Cadaver labs are considered the ideal, ethical way to test a RASD's safety and effectiveness before live experimentation.⁶³ By summer 2017, iPlatform was completing cadaver lab procedures using five robotic arms.⁶⁴

In December 2017, iPlatform reached “concept freeze”—a “critical step” where a design concept is deemed viable.⁶⁵ The design included iPlatform's bed-based architecture, six so-called “Silverton” robotic arms, insertion tools, and more.⁶⁶ Mintz presented its risk case and solutions to Auris's executive team for approval.⁶⁷ The conceptual design was approved, and iPlatform proceeded to the next stage of product development.

Auris began to work iteratively with the FDA on a plan for regulatory approval for iPlatform. In August 2018, Auris made its first 510(k) pre-submission to the FDA, listing a cart-based da Vinci RASD as the predicate device.⁶⁸ Auris's pre-submission form discussed a bronchoscopy indication for iPlatform.

⁶² JX 292 at 7; Gardiner Tr. 743-47; *see also* JX 5012 at 1.

⁶³ Gardiner Tr. 745.

⁶⁴ JX 292 at 7; *see* JX 1347.

⁶⁵ Mintz Tr. 557-59; JX 1347.

⁶⁶ JX 292 at 5-6, 30, 35-37, 57, 84.

⁶⁷ Mintz Tr. 560-6; JX 292 at 20, 141.

⁶⁸ JX 545 at 34.

In October 2018, the FDA provided feedback to Auris, including that it would require clinical testing and data to be presented with iPlatform’s application.⁶⁹ The FDA also explained that the listed indication was a mismatch for the predicate device.⁷⁰ Because the cited predicate device lacked a bronchoscope and did not perform the bronchoscopic procedures iPlatform’s application contemplated, the FDA said that it was “unclear if the 510(k) pathway [wa]s appropriate.”⁷¹ In response, Auris withdrew bronchoscopy from iPlatform’s 510(k) application and changed the predicate device to a more apt da Vinci robot.⁷² Auris believed that if it addressed the FDA’s feedback and provided appropriate clinical data, iPlatform would receive 510(k) clearance.⁷³

Auris continued to refine its iPlatform prototype. Prostatectomy and Nissen fundoplication cadaver procedures were successfully completed in the fall of 2018.⁷⁴

⁶⁹ JX 743 at 5.

⁷⁰ *Id.* at 4.

⁷¹ *Id.* at 3.

⁷² JX 2468 at 5; Mintz Tr. 604-06.

⁷³ JX 743 at 3; Mintz Tr. 605-06; *see also* JX 2468.

⁷⁴ JX 699; Gardiner Tr. 748-49. A prostatectomy is a procedure to remove all or part of the prostate. A Nissen fundoplication is an upper abdominal procedure that treats gastroesophageal reflux disease. *See Prostatectomy*, Mayo Clinic, <https://www.mayoclinic.org/tests-procedures/prostatectomy/about/pac-20385198> (last visited Aug. 31, 2024); *Nissen Fundoplication*, Cleveland Clinic, <https://my.clevelandclinic.org/health/treatments/4200-nissen-fundoplication> (last visited Aug. 31, 2024); *see also* Gardiner Tr. 728-30; Mintz Tr. 580.

By December 2018, the “alpha” version of iPlatform had been built, roughly a year after the concept freeze stage.⁷⁵

C. J&J’s Verb Robot

As robotic surgery gained momentum, Johnson & Johnson desired RASD market share. A significant portion of J&J’s revenue came from its subsidiary Ethicon, Inc.’s sales of surgical instruments.⁷⁶ J&J recognized an “existential threat” to its instrument business as Intuitive-branded instruments were sold for the growing number of da Vinci robots in hospitals.⁷⁷

In 2012, with new Chief Executive Officer Alex Gorsky at the helm, J&J partnered with SRI to develop a RASD to compete with da Vinci.⁷⁸ Pablo Garcia Kilroy was the lead engineer on the project.⁷⁹ When the RASD showed commercial potential in 2015, J&J formed a joint venture called Verb Surgical Inc. with Verily Life Sciences LLC (a subsidiary of Alphabet Inc.).⁸⁰ Kilroy became Verb’s lead engineer.⁸¹

⁷⁵ Mintz Tr. 569-70; PTO ¶ 99.

⁷⁶ JX 1529 at 7 (2018 tax form showing the largest portion of J&J’s revenues was from surgical and medical instruments sales, totaling over \$4.149 billion). This decision refers to Ethicon and Johnson & Johnson as “J&J.”

⁷⁷ JX 215 at 4; Morano Tr. 1435; *see also* JX 5019 at 23.

⁷⁸ Kilroy Tr. 2139; Shen Dep. 10-12; JX 2661 at 6.

⁷⁹ Kilroy Tr. 2078.

⁸⁰ PTO ¶ 72; Kilroy Tr. 2078.

⁸¹ Kilroy Tr. 2079.

Verb's robotic surgery system had three main structures: a table-mounted center component with four robotic arms, a user console for the surgeon to operate the robot, and a tower containing the controller for the robot and a vision system.⁸² The user input devices for controlling the Verb robot were novel. Instead of using physical controls, magnetics tracked the surgeon's hand movements in an open console and reproduced them to guide the robot.⁸³

Like iPlatform, Verb encountered challenges during the design process. They included dexterity issues both inside the body (like suturing and tying knots) and outside the body (involving arm collisions and maneuverability).⁸⁴ Dexterity came with a trade-off in stiffness, which allowed for control of flexible apparatuses and surgical tools.⁸⁵ Verb also faced user interface issues, impairing the surgeon's ability to complete a procedure with ease in the open console.⁸⁶

But unlike iPlatform, Verb was plagued by delays. By fall 2017, Gorsky learned that Verb had fallen significantly behind schedule.⁸⁷ J&J nonetheless aimed

⁸² *Id.* at 2082.

⁸³ *Id.* at 2084.

⁸⁴ *Id.* at 2085, 2087-88; *see also* JX 912 at 13-18; Kilroy Dep. 62:4-17.

⁸⁵ Kilroy Tr. 2084-85

⁸⁶ *Id.* at 2087.

⁸⁷ *See* JX 224 at 21 (J&J Sept. 28, 2017 Digital Surgery Update to Gorsky: "Verb launch is delayed, increasing hurdles to achieving the plan . . ."); *id.* at 33 ("Verb is our largest bet to establish a leading robotics presence. However, we do not believe it is currently on a path to deliver this."); *id.* at 41 (reflecting that since Q1 2015 to the present (3Q 2017),

for a 2020 commercial release. During an earnings call in January 2018, Gorsky said that Verb was “on track” for a 2020 launch date.⁸⁸

The next month, Gorsky asked J&J’s Board of Directors for an additional \$400 million of funding for Verb to advance a “Gen 1 system towards launch in 2020.”⁸⁹ While preparing for the meeting, Gorsky recognized the “significant importance of the project” and questioned whether J&J had the “right capabilities” to deliver the robot.⁹⁰ Susan Morano, J&J’s Vice President of Business Development for the Medical Devices group who reported to Gorsky, conveyed to her colleagues that Gorsky had asked her “[h]ow did we get this so wrong (internally and with Verb)[?]”⁹¹

In June 2018, Ashley McEvoy became J&J’s Executive Vice President, Worldwide Chairman of MedTech (f/k/a Medical Devices).⁹² She reported directly to Gorsky during his tenure.⁹³ As the head of MedTech, McEvoy appreciated the

Verb had fallen two years behind schedule for a U.S. launch date and required pre-launch funding of \$430 million versus the anticipated \$200 million).

⁸⁸ JX 290 at 18 (Gorsky: “I got a chance to visit see the prototype. I would say overall that it[’]s on track and we’re continuing to make refinements in it . . . So overall the project remains on track with our timelines and we’re excited about it.”).

⁸⁹ JX 647 at 2, 17.

⁹⁰ JX 295 at 2-3.

⁹¹ *Id.* at 2.

⁹² McEvoy Tr. 2565.

⁹³ *Id.*

need for J&J to disrupt the RASD market before more competitors could enter the space.⁹⁴ Gorsky told McEvoy to “take lead” on the Verb initiative and tackle risks to the project’s announced 2020 launch date.⁹⁵

Two months later, in August 2018, McEvoy sent Peter Shen to visit Verb for a “deep dive.”⁹⁶ Shen, a mechanical engineer by training with limited robotics experience, was J&J’s Global Head of MedTech Research & Development.⁹⁷ After his visit, Shen told McEvoy that despite some progress, the Verb team had yet to “declare [a] design concept” and suffered from “[c]hurning and lack of focus.”⁹⁸ J&J’s internal consulting group, Accelerando, was then asked to assess Verb’s status. Its conclusions resulted in a revised launch date of 2022, which was given an 85% probability of success.⁹⁹ In October 2018, J&J set a reduced scope for the Verb RASD with a planned initial release outside the United States.¹⁰⁰

⁹⁴ *Id.* at 2567.

⁹⁵ JX 504; JX 711.

⁹⁶ JX 533; *see* McEvoy Tr. 2573.

⁹⁷ Shen Tr. 1102.

⁹⁸ JX 533.

⁹⁹ JX 711 at 3 (“Accelerando process was initiated resulting in revised delivery timelines of 2022 (vs. 2020).”); *id.* at 9 (“85% confidence date: Q4 2022”).

¹⁰⁰ *Id.*

D. J&J's Interest in Auris

While Verb's setbacks compounded, J&J began to consider other ways to enter the RASD market. In early 2017, it evaluated investing in Auris, which J&J personnel had been aware of and impressed by since 2015.¹⁰¹ Morano visited Auris and described it as a "key hedge" for J&J.¹⁰²

In May 2017, J&J invested \$45 million in Auris's Series D round and secured a board observer seat.¹⁰³ The investment followed extensive due diligence by J&J into the Monarch platform, including technical assessments by third-party product development consultant Sagentia Innovation.¹⁰⁴ By late 2017, J&J (including Morano) had learned about iPlatform and worried it could "take the wind out of Verb."¹⁰⁵

In May 2018, J&J's Chief Scientific Officer William Hait, who led the company's Lung Cancer Initiative, visited Auris. After seeing Monarch's potential to diagnose and treat cancer in otherwise inaccessible areas of the lung, he became

¹⁰¹ JX 142; JX 186; Morano Tr. 1438-40.

¹⁰² Morano Tr. 1438-40; JX 186 at 3-4.

¹⁰³ JX 195; PTO ¶ 107.

¹⁰⁴ JX 475; Kozak Tr. 1579.

¹⁰⁵ JX 261 ("Big learning is that [Auris has] been quietly developing a mainframe [with] the potential to really disrupt as it combines their arms with their endoluminal . . . And they say it will launch in 2 years which if true will completely take the wind out of Verb.").

“maniacally focused” on gaining access to the robot.¹⁰⁶ Hait returned to J&J and gave a presentation to its executive committee on Monarch’s unique potential to advance the Lung Cancer Initiative.¹⁰⁷ Gorsky asked Hait to be a point of contact for a J&J team exploring a deeper relationship with Auris.¹⁰⁸ Sagentia was charged with conducting additional technical due diligence into Auris’s technology.¹⁰⁹

In July 2018, Morano recommended to Gorsky that J&J invest another \$200 million in Auris (called “Antwerp” internally at J&J).¹¹⁰ Although the initial focus was on accessing Monarch given Hait’s enthusiasm, iPlatform became a crucial factor. Shen expressed to Morano that he was “very concerned” Verb was “significantly behind” and suggested “explor[ing]” “iPlatform as a backup plan” for Verb.¹¹¹ At the same time, Gorsky told Morano that he “want[ed] [A]ntwerp added to [V]erb” with the “back end tech” shared.¹¹² To address this directive, Morano and her team prepared a presentation for Gorsky that outlined Auris’s “‘hybrid’

¹⁰⁶ Hait Tr. 921-23; *see* Hait Dep. 266-68.

¹⁰⁷ Hait Tr. 922-23; *see* JX 95.

¹⁰⁸ JX 95.

¹⁰⁹ JX 447; JX 487; Kozak Tr. 1580-82.

¹¹⁰ JX 495 at 9.

¹¹¹ JX 481.

¹¹² JX 485 (Morano reporting her conversation with Gorsky to McEvoy: “He wants antwerp added to verb – which I told I don’t think makes sense but that it could absolutely be a separate endoluminal system . . . which he was ok with but wants the ‘back end tech’ shared – which I believe is our strategy.”).

laparoscopic/[e]ndoluminal opportunity,” including a “potential partnership with Verb.”¹¹³

At Gorsky’s request, Hait and Shen began collaborating on a plan to “mesh” Verb and iPlatform.¹¹⁴ Gorsky felt the need to be “fully engaged” beyond his typical involvement with an investment because of Auris’s importance to J&J’s “future surgical and digital/robotics platform.”¹¹⁵

E. J&J’s Acquisition Strategy

By August 2018, J&J hoped to obtain a controlling interest in or outright acquire Auris. McEvoy approved an acquisition assessment but asked that it be “done VERY quietly” since “Verb [was] in a fragile state.”¹¹⁶ Due diligence continued.¹¹⁷ J&J’s engineers visited the Auris site, spending hours asking Mintz

¹¹³ JX 495 at 10.

¹¹⁴ JX 507 (Hait to Shen: “I am now more fully aware of Antwerp in the context of your broader robotic/digital surgery initiative and would be happy to work closely with you to plan a strategy where we can mesh the two.”); *see* Hait Tr. 941; *see also* JX 598 (Hait to McEvoy: “I reviewed VERB with the Med Device team and was impressed with the passion and progress but also heard significant challenges. Auris will likely be best in-class endoluminal robotic surgery and have a competitive laparoscopic instrument whereas VERB is likely to have the most sophisticated data analytics. Alex has challenged us to find a way to ‘mesh’ the two projects.”).

¹¹⁵ JX 506.

¹¹⁶ JX 527 at 1.

¹¹⁷ *See* JX 557.

“good, hard, technical questions, challeng[ing] [Auris] on the right points,” and examining the robot.¹¹⁸ Sagentia participated in J&J’s technical diligence.¹¹⁹

Given the sensitivities with Verb, J&J proceeded cautiously. In September, Hait wrote to Shen: “[W]hat if we combine the engineering expertise of Auris and the iPlatform laparoscopic and endoluminal device with the data analytics of VERB[?] In this way, we will have hedged out bets in robotics, take[n] the lead in endoluminal, and protect[ed] at least some of our investment in VERB.”¹²⁰ Shen responded that “there [were] major complexit[ies] and implications to this discussion” and asked to keep “the conversation within a small group for now.”¹²¹ Shen asked to talk when the two were together in Shanghai later that month.¹²²

In the interim, J&J learned that Medtronic—a competitor—was interested in acquiring Auris.¹²³ The news prompted “a critical moment that require[d] [J&J] to accelerate.”¹²⁴ Auris falling into a competitor’s hands was a “doomsday scenario” for J&J.¹²⁵ In considering next steps, Shen told Morano that “iPlatform c[ould] be a

¹¹⁸ Mintz Tr. 575-77.

¹¹⁹ JX 557 at 3.

¹²⁰ JX 600.

¹²¹ *Id.*

¹²² *Id.*

¹²³ JX 619.

¹²⁴ *Id.*

¹²⁵ JX 670 (Hait to Shen); *see also* JX 679.

plan B for [J&J]” but questioned whether J&J could “do both (Verb and iPlatform).”¹²⁶

In late September, Shen and Hait met in Shanghai and discussed plans for Auris.¹²⁷ Shen later recapped the meeting for McEvoy, highlighting a “complementary” approach where Verb would focus on general surgery and iPlatform would have “combo capabilities” including endoluminal surgery.¹²⁸ He believed this was a “Fail Safe plan for [J&J’s] robotic strategy.”¹²⁹ With the “go” from McEvoy, Shen and Hait presented their plan to Gorsky, who was “pleased.”¹³⁰

F. J&J’s Acquisition Strategy

Hait was tasked with initiating acquisition discussions with Moll.¹³¹ In his first outreach on October 1, 2018, Hait praised Monarch’s unmatched capability to screen for lung cancer. He also shared that “[J&J’s] medical device group ha[d] become increasingly impressed with iPlatform, as [the Auris] team makes

¹²⁶ JX 619.

¹²⁷ JX 664.

¹²⁸ JX 660.

¹²⁹ *Id.*

¹³⁰ *Id.*; JX 664.

¹³¹ JX 661 at 2.

extraordinary progress.”¹³² Hait told Moll that J&J was interested “in exploring a more substantial relationship.”¹³³

Auris was, at the time, considering a new investment round to support the independent development of its robots. It was not searching for a buyer.¹³⁴ Auris’s leadership felt that a merger, particularly with a large company, could cause a loss of the autonomy that had made its success possible.¹³⁵ With J&J in particular, Auris feared that Verb could displace iPlatform.¹³⁶

J&J understood these concerns and strategized on finding “what matter[ed] most” to Auris.¹³⁷ Given the “criticality” of this issue, McEvoy and Gorsky “le[d] from the top” on strategy.¹³⁸ They—with Shen, Hait, Morano, and other senior leadership—prepared for an in-person meeting at Auris’s Redwood City, California headquarters by assessing Auris’s “[v]ision and [i]nterests.”¹³⁹ These interests included Auris’s desire to understand J&J’s “vision [on] how Antwerp and Verb

¹³² JX 661 at 2.

¹³³ *Id.* at 2.

¹³⁴ *See* Hebert Tr. 1398-99; Salehizadeh Tr. 1345.

¹³⁵ Moll Tr. 38-40.

¹³⁶ *Id.* at 40.

¹³⁷ JX 736 at 1.

¹³⁸ *Id.*

¹³⁹ JX 838 at 4.

coexist.”¹⁴⁰ Gorsky’s talking points for the Redwood City meeting said: “We see the Verb and Antwerp programs as complementary.”¹⁴¹ Gorsky represented as much to Moll during dinner in California, emphasizing that Verb and iPlatform would be developed in parallel and that iPlatform was a priority for J&J.¹⁴²

On November 28, Gorsky called Moll to propose acquiring a 51% equity stake in Auris.¹⁴³ Auris had no interest in selling a majority of its business.¹⁴⁴ By mid-December, J&J began preparing a full acquisition proposal, including an earnout component based on regulatory and sales milestones.¹⁴⁵

On January 2, 2019, Gorsky presented Moll with an offer to acquire Auris for a \$3 billion upfront payment and \$2 billion in potential earnout payments.¹⁴⁶ Gorsky represented that J&J would “spend multiples” of what Auris alone could invest in developing its robots.¹⁴⁷ Further diligence and negotiations ensued, with Auris

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 7.

¹⁴² Moll Tr. 42; *see also* JX 838 (prepared talking points for Auris meeting); Morano Tr. 1517; DeFonzo Tr. 326-331.

¹⁴³ Gorsky Dep. 210-13; Morano Tr. 1458; JX 852; JX 837 at 28; JX 5100 at 4.

¹⁴⁴ *See* JX 929; Huffines Dep. 426-27.

¹⁴⁵ JX 934.

¹⁴⁶ PTO ¶ 110.

¹⁴⁷ JX 1004 at 6; Moll Tr. 45.

continuing to question whether J&J would expect iPlatform to compete with Verb, and J&J assuring Auris that it planned to fund and launch both products.¹⁴⁸

G. The Ashley Challenge

Meanwhile, J&J was exploring a budget for its entire robotics division. McEvoy decided that the total robotics budget including “[V]erb, instruments, IT, [and] Antwerp” would be capped at “\$500-\$600” million per year.¹⁴⁹ This budget cap would later be called the “Ashley Management Decision” or “Ashley Challenge.”¹⁵⁰ At J&J, a “management decision” is a top-down “budget challenge” for a division.¹⁵¹

On January 10, 2019, McEvoy’s team sent her an estimated profit and loss statement for the robotics program.¹⁵² The total expenses for Verb, Auris, and “Orthopedics” for 2019 through 2022 were projected to be \$3.167 billion.¹⁵³ Hours later, a revised draft was circulated reflecting McEvoy’s feedback.¹⁵⁴ A line item called “AAM RISK ADJUSTMENT” was added, which reduced total projected

¹⁴⁸ JX 1028; JX 1032; *see* DeFonzo Tr. 480; Morano Dep. 218.

¹⁴⁹ JX 846.

¹⁵⁰ *Id.*; *see* JX 1090; McEvoy Tr. 2603-06.

¹⁵¹ *See* Lenard Tr. 1787; Shen Tr. 1247.

¹⁵² JX 1118 at 5.

¹⁵³ McEvoy Tr. 2610-15.

¹⁵⁴ JX 1119 at 1.

expenses for 2019 through 2022 to \$2.296 billion.¹⁵⁵ McEvoy explained that the “AAM risk adjusted line-item” was “in reference to a proposed synergy between Verb/[iP]latform.”¹⁵⁶ She felt these “synergies” were “potentially achiev[able]” once J&J brought “both platform teams together,” after J&J had “more time to understand the synergy opportunities.”¹⁵⁷

H. Negotiations Progress.

J&J continued to conduct diligence throughout January. It learned about trade-offs in iPlatform’s design and other system issues that the Auris team was working to resolve.¹⁵⁸ Both parties agreed to a three-stage diligence process and to defer further technical due diligence.¹⁵⁹

Negotiations on deal terms progressed. On January 18, Auris sent J&J a counteroffer for \$3.9 billion in upfront consideration and \$3.5 billion in contingent payments based on regulatory and sales milestones for iPlatform and Monarch.¹⁶⁰ The regulatory milestones would be tied to 510(k) approval, which was the expected

¹⁵⁵ *Id.* at 6.

¹⁵⁶ JX 1139 at 1; *see* McEvoy Tr. 2607-16.

¹⁵⁷ JX 1135 at 1.

¹⁵⁸ JX 1141; JX 1145; JX 1284.

¹⁵⁹ Morano Tr. 1477; JX 1077; JX 1052.

¹⁶⁰ JX 1210.

pathway.¹⁶¹ J&J offered that net sales milestones include sales of not only iPlatform and Monarch but also Verb “to address [Auris’s] concerns about Verb.”¹⁶²

On January 24, Gorsky called Moll to deliver J&J’s formal counteroffer. It included upfront cash consideration of \$3.4 billion and a total potential earnout of \$2.2 billion.¹⁶³ J&J spread the contingent payments across six milestones—four regulatory and two sales based.¹⁶⁴ One of the proposed milestones provided Auris with \$100 million upon Monarch receiving FDA 510(k) approval for lung tissue ablation. Gorsky told Moll that this milestone was so “high[ly] certain[.]” of being achieved that J&J viewed it as “effective ‘up front’” consideration.¹⁶⁵

I. The NeuWave Patient Death

The Monarch lung tissue ablation milestone required the use of an Ethicon device called the NeuWave FLEX Microwave Ablation System. The NeuWave FLEX is a catheter-based instrument that delivers microwave energy to ablate or destroy tissue.¹⁶⁶ At the time of J&J’s January 24 offer, FLEX had regulatory approval for soft tissue ablation but not a lung-specific use.¹⁶⁷ Monarch, by contrast,

¹⁶¹ JX 1072 at 4; DeFonzo Tr. 363-64; Moll Tr. 58-59.

¹⁶² JX 1072; JX 1027; JX 1077; JX 1145.

¹⁶³ JX 1215 at 5.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* at 6; *see also* JX 1249 at 3; Moll Tr. 51.

¹⁶⁶ Moll Tr. 50.

¹⁶⁷ JX 161 at 3.

had already attained FDA clearance for bronchoscopy and was approved only for lung procedures.¹⁶⁸

In June 2018, NeuWave Medical (a subsidiary of J&J's Ethicon subsidiary) initiated a ten-patient study using FLEX to treat lung lesions.¹⁶⁹ On December 4, 2018, a study participant died weeks after being treated with FLEX.¹⁷⁰ J&J immediately reassigned leadership of the study to Hait, who suspected that the FDA would place the study on hold for some period.¹⁷¹

Hait was right. Nine days after the patient death was reported to the FDA, the FDA launched a for-cause inspection into whether the study violated FDA rules because NeuWave had not obtained an investigation device exemption (IDE) in advance.¹⁷² An IDE provides FDA approval to perform a clinical trial of a device that has not been cleared for marketing or the intended indication.¹⁷³ The FDA investigation involved an in-person investigation at Ethicon's "sponsor site from December 13, 2018 to December 19, 2018."¹⁷⁴

¹⁶⁸ See *supra* note 54 and accompanying text.

¹⁶⁹ JX 1901 at 25; see JX 4511 at 88.

¹⁷⁰ JX 1901 at 30.

¹⁷¹ Hait Tr. 961-63.

¹⁷² JX 1673; JX 1550 at 157; see JX 2648 at 35, 36; JX 2313 at 8-9, 13.

¹⁷³ Wittwer Rep. ¶ 87.

¹⁷⁴ JX 1673 at 2; see also Wittwer Tr. 1964-65.

On January 14, 2019, J&J’s Auris deal team was briefed on the NeuWave patient death.¹⁷⁵ They sought to understand whether the “patient death was going to affect the overall value of Auris.”¹⁷⁶ Team members preparing talking points for Gorsky to deliver to Moll were mindful of the “nuances” to the Monarch lung tissue ablation milestone “and what will be required for the FDA approval (still in discussion).”¹⁷⁷ As of January 22, J&J’s team believed that a to-be-offered year-end 2022 target for the Monarch lung tissue ablation milestone remained “achievable.”¹⁷⁸

On March 20, the FDA sent J&J a letter stating that it had concluded the use of FLEX on lung lesions posed a “significant risk” to participants and that J&J should have applied for an IDE before launching the study.¹⁷⁹ J&J received the FDA’s letter on April 3.¹⁸⁰ J&J would need to conduct a new clinical study under an IDE, then obtain a lung-specific approval for FLEX—a process that could take several years.¹⁸¹ Only then could Monarch obtain clearance for use with FLEX.¹⁸²

¹⁷⁵ JX 1182; JX 1171.

¹⁷⁶ Kozak Tr. 1572; *see* JX 1182 at 1.

¹⁷⁷ JX 1239.

¹⁷⁸ JX 1220; *see also* JX 1239; JX 6028.

¹⁷⁹ JX 1673 at 2.

¹⁸⁰ *Id.* at 1; Bryant Tr. 2490-91.

¹⁸¹ Wittwer Tr. 1966-68; Wittwer Rep. ¶¶ 95-101.

¹⁸² Wittwer Tr. 1967-68.

Moll was not told about the NeuWave patient death until shortly after the merger closed in early April 2019.¹⁸³

J. The Merger Agreement

J&J's preliminary draft merger agreement included ten potential earnout milestones.¹⁸⁴ Two Monarch-specific milestones concerned 510(k) approval for certain indications, including lung tissue ablation.¹⁸⁵ Six milestones concerned iPlatform regulatory approvals for general surgery, a gastrointestinal (GI) surgery, and four to-be-determined "umbrella" procedures that Auris was to fill in.¹⁸⁶ There were also two net sales milestones.¹⁸⁷

Auris sent back a revised draft of the merger agreement with revisions to the proposed milestones.¹⁸⁸ The Monarch lung tissue ablation milestone was changed to "soft tissue ablation," which Auris believed would not require clinical testing.¹⁸⁹ As for iPlatform, Auris proposed milestones in line with its MVP strategy that began with less complex procedures and built to more complex procedures.¹⁹⁰

¹⁸³ JX 1730; Moll Tr. 174.

¹⁸⁴ JX 5016 § 2.07.

¹⁸⁵ *Id.* § 2.07(a)(i)-(ii); *see supra* note 165 and accompanying text.

¹⁸⁶ JX 5016 § 2.07 (a)(iii)-(vii); DeFonzo Tr. 366-68.

¹⁸⁷ *Id.* § 2.07 (a)(ix)-(x).

¹⁸⁸ JX 1278; JX 1285.

¹⁸⁹ JX 1278 at 227; DeFonzo Tr. 361-63; JX 1334.

¹⁹⁰ DeFonzo Tr. 369; *see* JX 1620 (the "Merger Agreement") § 2.07(a).

All of the iPlatform milestones were for laparoscopic procedures, rather than more complex concomitant ones.¹⁹¹ Auris insisted that approval of any “upper abdominal” and “lower abdominal” procedures by year end 2021 would satisfy the first iPlatform regulatory milestone.¹⁹² This was in contrast to the “general surgery” indication suggested by J&J, which would have required Auris to demonstrate the safety and effectiveness for the most complex procedure in the “general surgery” umbrella.¹⁹³ The subsequent milestones matched specific umbrella procedures that Auris was targeting.¹⁹⁴ J&J accepted these changes.

The agreed-upon regulatory milestones for iPlatform were:

1. General Surgery Milestone: \$400,000,000 if iPlatform obtained “510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering, with a specific indication for one upper abdominal surgical procedure and one lower abdominal procedure” by the end of 2021 (the “General Surgery Milestone”);¹⁹⁵
2. Upper Abdominal Umbrella Milestone: \$150,000,000 if iPlatform obtained “510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . .

¹⁹¹ Merger Agreement § 2.07(a)(i)-(viii); *see* Moll Tr. 49-50.

¹⁹² *See* JX 5016 at 3-4; Merger Agreement § 2.07(a)(iii); DeFonzo Tr. 365-67.

¹⁹³ DeFonzo Tr. 364-65; *compare* JX 5016 § 2.07(a)(iii) (J&J draft proposing regulatory approval on iPlatform “for general surgery procedures”), *with* Merger Agreement § 2.07(a)(iii) (final version requiring iPlatform regulatory approval for “one upper abdominal surgical procedure and one lower abdominal surgical procedure”).

¹⁹⁴ DeFonzo Tr. 366-68; *compare* JX 5016 § 2.07(a)(iv)-(vii) (J&J leaving brackets for umbrella milestones for Auris to fill in), *with* Merger Agreement § 2.07(a)(iv)-(vii) (listing specific indications).

¹⁹⁵ Merger Agreement § 2.07(a)(iii).

upper abdominal Umbrella Procedure(s)” by the end of 2023 (the “Upper Abdominal Milestone”);¹⁹⁶

3. Colorectal/Lower Abdominal Umbrella Milestone: \$150,000,000 if iPlatform obtained “510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . . urological Umbrella Procedure(s)” by the end of 2023 (the “Lower Abdominal Milestone”);¹⁹⁷
4. Urologic Umbrella Milestone: \$150,000,000 if iPlatform obtained “510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . . colorectal/lower abdominal Umbrella Procedure(s)” by the end of 2023 (the “Urologic Milestone”);¹⁹⁸ and
5. Gynecologic Surgery Umbrella Milestone: \$150,000,000 if iPlatform obtained “510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . . gynecological Umbrella Procedure(s)” by the end of 2023 (the “Gynecologic Milestone”).¹⁹⁹

The Monarch-related milestones were:

6. Endourology Milestone: \$100,000,000 if Monarch obtained “510(k) premarket notification(s) allowing marketing and sale of a Monarch Product offering, with a specific indication for endourology procedure(s)” by the end of 2020 (the “Endourology Milestone”);²⁰⁰ and
7. Robotic Soft Tissue Ablation Milestone: \$100,000,000 if Monarch obtained “510(k) premarket notification(s) allowing

¹⁹⁶ *Id.* § 2.07(a)(iv). “Umbrella Procedure” is defined as “any procedure or procedure category within a specialty, which represents higher complexity or risk and when cleared by the FDA includes covered procedures of less complexity or lower risk within that specialty.” *Id.* § 10.03(uuu).

¹⁹⁷ *Id.* § 2.07(a)(v).

¹⁹⁸ *Id.* § 2.07(a)(vi).

¹⁹⁹ *Id.* § 2.07(a)(vii).

²⁰⁰ *Id.* § 2.07(a)(i).

marketing and sale of a Monarch Product offering, with a specific indication for robotically driven (or controlled) soft tissue ablation” by the end of 2022 (the “Soft Tissue Ablation Milestone”).²⁰¹

An additional regulatory milestone could be satisfied by either iPlatform or Monarch:

8. Robotic GI Endoluminal Milestone: \$150,000,000 if either iPlatform or Monarch obtained “510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering (or, alternatively . . . a Monarch product offering), with a specific indication for procedure(s) specifically including Endoscopic Submucosal Dissection (ESD)” by the end of 2023 (the “GI Milestone”).²⁰²

Finally, there were two commercial milestones that could be satisfied by either Verb or Auris products:

9. First Step Net Sales Milestone: \$500,000,000 if Robotics Net Sales before the end of 2022 reached or exceeded “\$575 million in the aggregate”;²⁰³ and
10. Second Step Net Sales Milestone: \$500,000,000 if Robotics Net Sales before the end of 2022 reached or exceeded “\$575 million in the aggregate.”²⁰⁴

Auris’s markup of the draft merger agreement proposed a one-way anti-reliance clause favoring Auris. It also included a provision that would obligate J&J to take efforts to develop and commercialize the Auris robots consistent with “a

²⁰¹ *Id.* § 2.07(a)(ii).

²⁰² *Id.* § 2.07(a)(viii).

²⁰³ *Id.* § 2.07(a)(ix).

²⁰⁴ *Id.* § 2.07(a)(x).

company in the medical devices industry of comparable size and resources to J&J.”²⁰⁵ Auris had Intuitive in mind as the measure of industry standard efforts.²⁰⁶

J&J accepted the one-way anti-reliance clause but proposed an inward-facing efforts provision.²⁰⁷ The efforts supplied were to be measured by J&J’s own standards, which J&J assured Auris was beneficial since J&J was “the biggest healthcare company in the world” with standards exceeding the industry.²⁰⁸ J&J agreed that these “commercially reasonable efforts” would be to the end of achieving the iPlatform and Monarch regulatory milestones.²⁰⁹ As a residual assurance, Auris negotiated for language that tied J&J’s efforts to its “usual practice” for “priority medical device products.”²¹⁰

The final Merger Agreement was executed on February 12, 2019 by Ethicon, Antwerp Merger Sub, Inc., Auris, and Fortis as the Auris stockholders’ representative.²¹¹ At the time, Auris had a high level of confidence in achieving regulatory clearance via the 510(k) pathway, in iPlatform’s and Monarch’s ability to

²⁰⁵ JX 1278 at 159, 232; *see* DeFonzo Tr. 381-82.

²⁰⁶ DeFonzo Tr. 381.

²⁰⁷ *Id.* at 381-83; *see also* Hinchliffe Tr. 3145-46; Hinchliffe Dep. 206-07.

²⁰⁸ DeFonzo Tr. 382.

²⁰⁹ Merger Agreement § 2.07(e)(i), (ii); *see* Shen Tr. 1152.

²¹⁰ Merger Agreement § 2.07(e)(ii); *see* DeFonzo Tr. 382-83; Hinchliffe Tr. 3145-46.

²¹¹ PTO ¶ 111.

deliver on the milestones, and a shared vision with J&J for the robots.²¹² The merger was set to close on April 1.

K. Pre-Closing Preparations

Verb continued to struggle. McEvoy told Gorsky as much on March 10, prompting Gorsky to ask why Verb’s timelines “continue to change with multiple explanations for delays and issues.”²¹³ To address Gorsky’s concerns, Shen proposed an “assessment between Verb and iPlatform from a portfolio perspective.”²¹⁴ Celine Martin, who oversaw J&J’s robotics and digital surgery program, was “aligned” with the proposal.²¹⁵

Shen’s “worry” about “Verb vs. iPlatform” was that the “Verb team [would] know [the J&J’s leadership team’s] hesitation.”²¹⁶ As he told McEvoy, they must be “all in for Verb.”²¹⁷ Shen believed that “Verb + iPlatform [wa]s [J&J’s] bullet proof strategy to compete.”²¹⁸ As he wrote on the day the Auris merger closed: “Delivering of Verb milestones is our No. 1 priority.”²¹⁹

²¹² DeFonzo Tr. 363-64; Gardiner Tr. 748-61.

²¹³ JX 1581; *see also* JX 1590 at 2; Shen Tr. 1112-14.

²¹⁴ JX 1581 at 1.

²¹⁵ *Id.*

²¹⁶ JX 1630.

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ JX 1663; *see* Shen Tr. 1152, 1308. During his testimony, Shen said that this was “not false.” Shen Tr. 1308.

L. Project Manhattan

Four days after closing, Shen drafted a “Plan to Technically Assess Verb Platform and iPlatform.”²²⁰ He wrote that the objective was “to assess the robotic system (Digital Surgery) development status from Verb and Auris and recommend an optimal path to bring the system(s) to market, considering factors such as launch schedule, project risk identification and mitigation, specialty indication launch cadence, surgeon preference, etc.”²²¹ He described three possible outcomes. First, J&J could “[d]evelop both systems in parallel and the[n] make the final commercialization decision.” Second, it could “[c]hoose one of the two” systems. Or, third, it could “[m]erge them into a single development by combining the best of each.”²²²

Shen sent a draft of the plan to Martin, writing: “I am still thinking about how we do this highly sensitive assessment work. We cannot lose [the] Verb team at this point.”²²³ He also sent a draft to Kilroy—Verb’s lead engineer. Kilroy envisioned

²²⁰ JX 1702.

²²¹ JX 1703.

²²² JX 1702.

²²³ JX 1703.

that the robots would be merged into a combined system.²²⁴ He suggested that Shen revise “framing the project objective in a way that is less controversial.”²²⁵

Shen then edited the document. The new version stated that the objective of the assessment was to “find synergies between platforms to decrease project risk and accelerate time to commercialization.”²²⁶ He removed the description of the three post-assessment “potential scenarios” outlined in his prior draft.²²⁷ He titled the assessment “Project Manhattan.”²²⁸

Shen sent the revised version to Moll on April 9.²²⁹ Moll was aghast. During negotiations, J&J had told Auris it would perform a post-closing “technology audit” to understand Auris’s systems and ways that J&J’s “global candy store” of resources could be beneficial to Auris.²³⁰ DeFonzo’s discussions with J&J similarly led him to understand that a “technology audit” would be conducted to understand “technologies available within Ethicon unrelated to Verb” that could help Auris.²³¹

²²⁴ Kilroy Tr. 2143; Kilroy Dep. 43-44.

²²⁵ JX 1710.

²²⁶ JX 1725 at 2.

²²⁷ JX 1703 at 2; *see* JX 1725.

²²⁸ JX 1725. “Manhattan” was an internal code name for Verb. *See* JX 2833 (discussing “Manhattan” as “Verb”); Lenard Tr. 1799; JX 2658 at 1.

²²⁹ JX 1719; JX 1725. The version sent to Martin and Kilroy was never shared with Moll.

²³⁰ Moll Tr. 47-48.

²³¹ DeFonzo Tr. 400-01.

But a comparative assessment between Verb and iPlatform had not been mentioned.²³²

On April 22, Shen formally introduced Project Manhattan to the Verb and Auris teams, describing it as a “Technical Assessment of Verb Surgical Platform and Auris iPlatform.”²³³ He said that a “deep dive assessment” would be conducted “in the following areas” for each platform:

- Master controller or [user input device]
- Robotic components and systems
- Instrumentation
- Visualization system
- Data connectivity
- Machine learning and [d]ata analytics.²³⁴

Shen said that Project Manhattan would be “co-le[d]” by Kilroy and Mintz and completed over the “next 60-70 days.”²³⁵

Moll promptly told Shen of his concern that “[s]upporting a complex and detailed 90 day technical review by all Auris technical heads w[ould] affect [Auris’s] ability to stay on schedule.”²³⁶ Shen responded that “the system should stay as it is (no need to be dressed up) for review.”²³⁷ By this point, though, Moll and the Auris

²³² See Moll Tr. 70-72; JX 1500.

²³³ JX 1813; see Shen Tr. 1158.

²³⁴ JX 1813 at 1-2.

²³⁵ *Id.*

²³⁶ JX 1830; see Moll Tr. 76.

²³⁷ JX 1838.

team had learned that J&J capped the robotics budget (i.e., the Ashley Management Decision), leading them to doubt that Verb and iPlatform would be developed on “parallel path[s].”²³⁸ It seemed to them that Project Manhattan was a “bakeoff” between Verb and iPlatform.²³⁹ The Auris team feared that only one robot could win; the loser would be deprioritized, deemphasized, and cease to exist.²⁴⁰

Auris’s suspicions were well placed. Amid Project Manhattan, Martin wrote that she did not “see [J&J] running parallel path [V]erb-Auris all the way to 510k” because “P&L will not support it and it is very inefficient.”²⁴¹ An internal J&J retrospective document from the next year recognized that “[Project Manhattan was [a] financial necessity[.]” given the significant expense of “[d]eveloping 2 complex robots at the same time.”²⁴² The probable end goal was to find ways to “mesh” the robots, consistent with Gorsky’s earlier aspirations and the budget set by the Ashley Management Decision.²⁴³

Auris leadership thus viewed Project Manhattan as an existential threat to iPlatform. Because the months-old iPlatform alpha robot would be pitted against a

²³⁸ Moll Tr. 76; *id.* at 47-48; Mintz Tr. 586-87.

²³⁹ Moll Tr. 72; DeFonzo 403-06.

²⁴⁰ Moll Tr. 72.

²⁴¹ JX 1947.

²⁴² JX 2774 at 5.

²⁴³ *See supra* notes 114, 156-57 and accompanying text; JX 2656; Lenard Day 2 Dep. 23-24.

Verb post-beta robot that had been through years of iterations, Auris had to quickly prepare to “survive.”²⁴⁴ Mintz focused on creating “workarounds” for system “bugs,” which he described as “the engineering and software equivalent of Band-Aids, duct tape, and baling wire.”²⁴⁵ iPlatform incurred a significant “technical debt” from going “backwards rather than forwards in development [] to prop up a system” for an unanticipated head-to-head evaluation.²⁴⁶ In exchange for short term stability to compete against Verb, iPlatform largely suspended its development plan, MVP strategy, and beta version progress.²⁴⁷

Project Manhattan consisted of seven procedures performed by eight “key opinion leader” surgeons (“KOLs”). Most of the KOLs were experienced on the Verb device but had never used iPlatform.²⁴⁸ Two of the KOLs had worked closely on Verb’s development.²⁴⁹ The procedures performed were: Roux-en-Y gastric bypass (RYGB), low anterior resection (LAR), ventral hernia, partial nephrectomy,

²⁴⁴ Mintz Tr. 588-89

²⁴⁵ *Id.* at 589.

²⁴⁶ Moll Tr. 76; Mintz Tr. 590.

²⁴⁷ *See* Mintz Tr. 587-88; JX 1793.

²⁴⁸ JX 2125 at 2.

²⁴⁹ These KOLs were Dr. Monika Hagen and Dr. Keith Kim. Hagen Tr. 2282; Hagen Dep. 16-18; Kim Dep. 28, 28-49. Moll asked that Gardiner, who was experienced with iPlatform, be a KOL. His request was rejected. Mintz Tr. 594-95; Moll Dep. 633-34.

hysterectomy, and lobectomy.²⁵⁰ After the procedures, the KOLs rated each system's capabilities.²⁵¹

Both iPlatform and Verb successfully completed all seven procedures.²⁵² The KOLs gave iPlatform positive feedback and rated the system somewhat or nearly ready for clinical use, with the exception of lobectomy.²⁵³ iPlatform's performance in one RYGB lab and the hysterectomy lab were rated equal to that of da Vinci.²⁵⁴

²⁵⁰ JX 2103; JX 2125; JX 2131. RYGB surgery, also called bariatric surgery, reduces the size of the stomach and reroutes part of the small intestine. LAR surgery treats rectal cancer by removing part of the rectum and reconnecting the rectum to the colon. Ventral hernia surgery repairs protrusions of the intestine or other tissue through the abdominal wall. Partial nephrectomy involves removing a portion of the kidney to treat disease or injury. A hysterectomy is a procedure to remove the uterus. A lobectomy is a procedure to remove a lobe of the lung, including to treat cancer. See Stanford Medicine, *General Surgery – Common Surgical Procedures*, Stanford Health Care, <https://stanfordhealthcare.org/medical-treatments/g/general-surgery/procedures.html> (last visited Aug. 31, 2024); *Roux-en-Y Gastric Bypass Weight-Loss Surgery*, Johns Hopkins Medicine, <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/rouxeny-gastric-bypass-weightloss-surgery> (last visited Aug. 31, 2024); Timothy J. Ridolfi, MD et al, *Low Anterior Resection Syndrome: Current Management and Future Directions*, 29 *Clinics in Colon and Rectal Surgery* 239, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4991969/>; *Nephrectomy (kidney removal)*, Mayo Clinic, <https://www.mayoclinic.org/tests-procedures/nephrectomy/about/pac-20385165> (last visited Aug. 31, 2024); *Lobectomy*, Johns Hopkins Medicine, <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/lobectomy> (last visited Aug. 31, 2024).

²⁵¹ Mintz Tr. 594-95.

²⁵² *Id.* at 592-98; JX 2125; JX 1878.

²⁵³ JX 2131.

²⁵⁴ *Id.* at 26-28.

The hysterectomy lab was a breakthrough for the iPlatform team, since it marked the first time a surgeon was able to perform a procedure using all six robotic arms.²⁵⁵

Overall, the KOLs “were confident that both systems w[ould] be clinically capable.”²⁵⁶ Although they raised problems with iPlatform (and Verb), the Auris team left Project Manhattan feeling encouraged with iPlatform’s performance.²⁵⁷ The first iPlatform milestone (the General Surgery Milestone) was still 2.5 years away, with subsequent milestones to be completed in 4.5 years.

M. iPlatform “Wins” the Bake-Off

On June 16, 2019, Martin reported to McEvoy and other J&J leaders that iPlatform “performed well and managed to complete” all KOL procedures.²⁵⁸ By this point, Martin and Shen had agreed that parallel pathing both robots would be an unsuccessful strategy.²⁵⁹ They believed that only one system should be brought to market. After considering KOL feedback, along with the vision and unique features of iPlatform, Shen and Martin recommended to McEvoy that J&J prioritize iPlatform.²⁶⁰

²⁵⁵ Mintz Tr. 596-98; *see* Pl.’s Trial Demonstrative (“Pl.’s Dem.”) 8 (video of the lab being performed).

²⁵⁶ JX 2131 at 18.

²⁵⁷ Moll Tr. 80; Mintz Tr. 598-600.

²⁵⁸ JX 2103.

²⁵⁹ JX 2144.

²⁶⁰ JX 2164; JX 2236.

But “go[ing] with iPlatform” did not mean abandoning Verb.²⁶¹ Consistent with J&J’s goals and budget, Shen, Martin, and others discussed combining the systems instead.²⁶² Shen thought that “[c]ombining 2 programs into 1 ma[de] all the sense from [a] traditional development standpoint – focus, budget, priority” to compete with Intuitive.²⁶³

The J&J team prepared a recommendation to Gorsky, which projected iPlatform 2019, 2020, and 2021 launch dates and a Verb launch date sometime after 2021.²⁶⁴ A slide showing the technical synergies between iPlatform and Verb identified where iPlatform parts could be “plan B option[s]” should Verb’s development stall.²⁶⁵ Gorsky asked that more elements of Verb be added to iPlatform.²⁶⁶

In late September, Martin recommended to Gorsky that J&J pursue a combination system of iPlatform “augmented by incremental [V]erb capabilities

²⁶¹ JX 2164.

²⁶² JX 2180.

²⁶³ *Id.*

²⁶⁴ JX 2275 at 32.

²⁶⁵ *Id.* at 45.

²⁶⁶ DeFonzo Tr. 408-09 (“Celine informed me sometime in mid-July that Alex had asked the team to go back and find more elements of Verb to include in the iPlatform.”). Martin could not remember this discussion, or most of the other deliberations from this period. *See* Martin Tr. 1684-1689. DeFonzo’s testimony was overall credible, supported by Gorsky’s hope of meshing the robots, and the subsequent events.

incl[uding] the Verb surgeon console.”²⁶⁷ Gorsky questioned why the financial valuations for Verb and iPlatform were higher separately than when the systems were combined and noted that the combination would “lead[] to some delay.”²⁶⁸ When McEvoy asked for clarification, J&J Chief Financial Officer Flavia Pease explained that the lower valuation “still assumes all Auris milestones being paid in full” and offered to “discuss further live.”²⁶⁹ McEvoy subsequently told Gorsky that the combined Verb/iPlatform valuation improved “when you consider what will also happen with contingent payment”—meaning the earnout.²⁷⁰ Gorsky gave the team the “green light” to proceed with next steps.²⁷¹

N. The FDA’s New Pathway Guidance

Despite the challenges of Project Manhattan, Auris strove to get iPlatform back on track for regulatory approval. On June 28, Auris sent the FDA a pre-submission for iPlatform with RYGB and inguinal hernia repair indications.²⁷²

²⁶⁷ JX 2594 at 20; Martin Tr. 1683-84.

²⁶⁸ JX 2599.

²⁶⁹ *Id.*

²⁷⁰ JX 2606; McEvoy Tr. 2637; McEvoy Dep. Day 2 207-08; *see also* JX 2584 at 26.

²⁷¹ Martin Tr. 1693.

²⁷² JX 2328 at 43. A laparoscopic inguinal hernia procedure repairs a hernia in the groin area through small incisions. *See Inguinal hernia*, Mayo Clinic, <https://www.mayoclinic.org/diseases-conditions/inguinal-hernia/diagnosis-treatment/drc-20351553> (last visited Aug. 31, 2024).

Auris also selected a different da Vinci predicate device than the one it had listed in its prior submission to address the FDA’s initial feedback.²⁷³

In a Verb-related meeting with the FDA on August 5, J&J learned that “going forward,” the agency believed that the 510(k) pathway would be closed for any new RASD.²⁷⁴ The FDA reached this decision due to the systems’ “complexity” and difficulties “mak[ing] a substantial equivalence determination” for a predicate device.²⁷⁵ The FDA “indicated” that the “De Novo pathway [wa]s still a potential option” versus the more complex PMA pathway.²⁷⁶ In assessing the effect of this pathway change on Verb’s launch schedule, J&J’s regulatory team concluded that De Novo review would yield “[n]o significant timeline differences compared to a 510(k)” review.²⁷⁷

The next month, the FDA notified J&J that the 510(k) pathway was likewise closed to iPlatform.²⁷⁸ On January 6, 2020, the FDA confirmed that iPlatform could seek approval through the De Novo pathway instead of PMA.²⁷⁹ This was seen as a

²⁷³ JX 2328 at 46; *see supra* notes 70-72 and accompanying text.

²⁷⁴ JX 2512 at 5.

²⁷⁵ *Id.*

²⁷⁶ *Id.*

²⁷⁷ JX 2396 at 12-13.

²⁷⁸ JX 6116 at 4; *see also* JX 2620; JX 6117.

²⁷⁹ JX 2951 at 6; Shen Tr. 1174; *see also* JX 2396 at 2; Bryant Tr. 2514-16.

positive outcome.²⁸⁰ It was still within the five-month buffer built into iPlatform’s timeline to achieve its 2021 General Surgery Milestone, not to mention the longer timelines for the 2023 milestones.²⁸¹ And once iPlatform obtained De Novo approval, it could use the 510(k) pathway for future indications by serving as its own predicate device.²⁸²

O. Manhattan

On December 5, 2019, J&J management recommended to the J&J Board that the company proceed with “a combined platform where Auris’ iPlatform is augmented by Verb assets including the open surgeon console, intra-procedure data capabilities and the surgeon portal.”²⁸³ The combination robot, called “iPlatform+,” was described as a “[n]ext generation robotic platform designed with more flexibility, more control, and more information to elevate [the] surgeon experience [and] improve patient care.”²⁸⁴

As part of the combination plan, the J&J Board approved a full acquisition of Verb by buying out residual assets from Verily.²⁸⁵ On December 19, J&J “signed

²⁸⁰ See Shen Tr. 1174.

²⁸¹ JX 1689 at 13.

²⁸² JX 2396 at 12.

²⁸³ JX 2732 at 4; see Martin Tr. 1693.

²⁸⁴ JX 2800 at 4.

²⁸⁵ JX 2732 at 4.

the Manhattan (Verb) option agreement.”²⁸⁶ J&J “execute[d] Manhattan” on February 19, 2020 for a purchase price of approximately \$155 million.²⁸⁷

Afterward, J&J worked to integrate Verb’s resources into Auris. The Auris leadership team was largely sidelined. A “[f]ull [s]peed [m]igration” of more than “200 [Verb] employees” to the iPlatform team commenced.²⁸⁸ A calamity of excess and redundancy resulted.²⁸⁹ Hostility abounded between the two factions, which had just faced off in Project Manhattan for the survival of their respective projects.²⁹⁰ J&J soon announced layoffs on both teams.²⁹¹

Within a year of the integration, every engineer from legacy Auris’s iPlatform clinical engineering team left the company—a “devastating” loss for the program.²⁹² Meanwhile, Verb software engineers insisted on re-writing iPlatform’s code.²⁹³ Significant attrition of legacy Auris software engineers followed.²⁹⁴

²⁸⁶ JX 2833 (“Manhattan signed!”).

²⁸⁷ JX 3407; JX 2656 at 1.

²⁸⁸ JX 2743 at 11; *see* Mintz Tr. 609-11.

²⁸⁹ JX 3094.

²⁹⁰ JX 2743 at 11; DeFonzo Tr. 425-427; *see also* JX 2991 at 4.

²⁹¹ JX 3272 at 12; JX 3280.

²⁹² Mintz Tr. 616-17.

²⁹³ *Id.* at 613-14; JX 3194.

²⁹⁴ Pl.’s Dem. 7; Mintz Tr. 612-615.

P. The Milestone Write-down

In April 2020, J&J internally wrote down the value of the iPlatform and GI regulatory milestones to zero.²⁹⁵ J&J also wrote down the net sales milestones.²⁹⁶ These write-downs created an on-the-books profit of \$983.6 million for J&J.²⁹⁷ An internal memo stated that the write-down was prompted by the FDA's shift from the 510(k) to the De Novo pathway for iPlatform.²⁹⁸

J&J publicly announced the write-down on April 14.²⁹⁹ Auris leadership learned about the write-downs around that time.³⁰⁰ McEvoy and Shen told Moll that change was a result of the FDA's pathway change.³⁰¹ Fortis sent J&J an information request, and J&J issued a litigation hold on April 24.³⁰²

With the milestones written off and litigation looming, J&J instituted a “new reality” for Auris.³⁰³ Martin and her team rolled out an employee incentive plan that

²⁹⁵ JX 3139; Shen Tr. 1171; Lenard Tr. 1827-28. Internal communications suggest that J&J finance leaders had been considering the potential effects of writing down the milestones since October 2019. *See* JX 2675.

²⁹⁶ JX 3139.

²⁹⁷ *Id.*; *see also* JX 5149 at 26.

²⁹⁸ JX 3139. Draft talking points for a first quarter earnings call referred to the milestone-related profit as a “material” amount of money to the company. JX 3112 at 9.

²⁹⁹ JX 3168; PTO ¶ 161.

³⁰⁰ Moll Tr. 95-96; Mintz Tr. 617. DeFonzo learned about the milestones from Martin a day before the announcement. DeFonzo Tr. 428.

³⁰¹ JX 3193; Moll Tr. 95-96, 195, 198; *see also* JX 3253; Lenard Tr. 1830; JX 3392 at 15.

³⁰² JX 5015; Shen Tr. 1174-75; JX 4490 at 9-10.

³⁰³ Moll Tr. 95.

had been first discussed in late 2019.³⁰⁴ The revised employee “milestones” included bonuses upon iPlatform receiving FDA approval for “general surgery,” which was different from the first iPlatform regulatory milestone in the Merger Agreement.³⁰⁵ The new incentive plan lacked any incentives for umbrella procedures and all GI-related incentives were removed.³⁰⁶

Two months after the write-down of the iPlatform regulatory and GI milestones, J&J announced the formation of a “Tiger Team” to simplify iPlatform’s reporting structure.³⁰⁷ The iPlatform operational team was to report to Steve Joachim, who effectively replaced Mintz.³⁰⁸ Joachim was a leader of the Ethicon instrument development group that supported J&J’s robotics program.³⁰⁹ A systems engineer by training, he lacked prior experience with RASDs.³¹⁰

J&J also invested significant financial resources into the iPlatform/Verb program.³¹¹ By the end of November, McEvoy had requested \$200 million to

³⁰⁴ JX 2675 at 1; Moll Tr. 95-97; Mintz Tr. 617-18.

³⁰⁵ JX 3641 at 3-4; DeFonzo Tr. 430-32; Pl.’s Dem. 6.

³⁰⁶ See Pl.’s Dem. 6.

³⁰⁷ JX 3363 at 5; JX 3391 at 9.

³⁰⁸ JX 3391 at 10.

³⁰⁹ JX 2233 at 2; Joachim Tr. 2156-57.

³¹⁰ Joachim Tr. 2157, 2241; Mintz Tr. 618-19.

³¹¹ JX 3417 at 6, 8-9; JX 3465 at 13; Lenard Tr. 1858-62.

develop the combined system.³¹² J&J’s allocation of resources to iPlatform 16 months post-merger proved too little, too late.

Q. This Litigation

On October 12, 2020, Fortis Advisors LLC filed a Verified Complaint against J&J, Ethicon, Gorsky, McEvoy, Shen, and Morano.³¹³ Fortis brought the suit in its capacity as the representative of former Auris stockholders. It advanced 12 causes of action, including equitable fraud, common law fraud, breach of the Merger Agreement, reformation, mutual mistake, civil conspiracy, breach of the implied covenant of good faith and fair dealing, and specific performance.

R. J&J’s New Narrative

The iPlatform beta prototype—the second iteration of the full system—came online at the end of 2020.³¹⁴ Auris had planned to go to clinical trials with, obtain FDA clearance for, and launch the beta version of iPlatform.³¹⁵ The system experienced technical complications, including thermal, stability, and workspace issues.³¹⁶ These were issues Auris had been aware of during the alpha iteration and viewed as “imminently solvable” until progress was derailed by Project

³¹² JX 5231 at 20.

³¹³ Dkt. 1.

³¹⁴ JX 4181.

³¹⁵ Mintz Tr. 662-63.

³¹⁶ *Id.* at 619-20; Khan Tr. 3021; JX 3764 at 10-11, 21, 66, 83.

Manhattan.³¹⁷ The integration of the Verb system created an added layer of stability complications for iPlatform.³¹⁸

A new account of the Auris acquisition began to emerge at J&J. In March 2021, Shen sent Joachim an email titled “Very important thinking” that attached a “narrative document” outlining Shen’s own “reflection” on iPlatform.³¹⁹ Shen wrote that the “original plan was to launch the Verb system first, giving [iPlatform] [a] 3-year time[line] to fully prove concept feasibility.”³²⁰ Shen noted that J&J’s “current challenge” with iPlatform was due to “design problems,” including “Work Space (Reach, Access and Collision Prevention, etc.).”³²¹

In early May, Joachim circulated a deck to J&J leadership citing technical issues as the reason for iPlatform program delays.³²² Joaquin Duato, who replaced Gorsky as CEO in early 2022, asked why Shen had been unaware of iPlatform workspace issues sooner.³²³ Joachim began searching old due diligence files,

³¹⁷ Mintz Tr. 619-22.

³¹⁸ *Id.* at 686.

³¹⁹ JX 3814 at 1. The presentation referred to iPlatform as “Ottava,” which was the robot’s name at this point.

³²⁰ *Id.* at 5.

³²¹ JX 3814 at 5.

³²² JX 5036.

³²³ JX 5247 at 1.

focusing on reports about arm design.³²⁴ The pre-merger design choice Auris engineers made between so-called “Silverton” and “Superton” style robotic arms was cast as evidence of Auris’s deceit during due diligence.³²⁵

By the end of 2021, iPlatform was shelved.³²⁶ J&J pivoted to a system utilizing Verb’s bed-based architecture combined with certain iPlatform components and accessories.³²⁷

S. Litigation Continues

While iPlatform sat idle, Fortis’s litigation proceeded apace.

On December 13, 2021, Fortis’s equitable fraud, reformation, and civil conspiracy claims were dismissed.³²⁸ Individual defendants Gorsky, McEvoy, Shen, and Morano were also dismissed for lack of personal jurisdiction.³²⁹

³²⁴ JX 3960.

³²⁵ JX 6149; Shen Tr. 1289-90; McEwen Dep. 161-62; Joachim Tr. 2218-19; Mintz Tr. 718.

³²⁶ JX 4322 at 2.

³²⁷ *Id.*

³²⁸ Dkt. 102.

³²⁹ *Id.*

A ten-day trial began on January 16, 2024.³³⁰ Just before trial began, Fortis voluntarily dismissed its mutual mistake and unjust enrichment claims.³³¹ Post-trial briefing and argument were completed on May 22, 2024.³³²

II. ANALYSIS

Fortis advances both contract and fraud claims against J&J. Its contract-based contentions include that J&J repudiated and breached the Merger Agreement and breached the implied covenant of good faith and fair dealing. As to fraud, Fortis argues that J&J deceived Auris into merging and accepting a contingent payment for the Monarch Soft Tissue Ablation Milestone.

I begin with the contract theories. Fortis proved that J&J breached its efforts obligation and the implied covenant regarding the iPlatform regulatory milestones but not the Monarch-related or net sales milestones. It did not prove that J&J repudiated the Merger Agreement.

As to its fraud theories, Fortis met its burden regarding J&J's statements about the Monarch Soft Tissue Ablation Milestone. It did not prove that J&J's more general statements about future intentions for Auris amount to fraud.

³³⁰ Dkt. 539.

³³¹ Dkts. 527-28.

³³² Fortis Advisors LLC's Opening Post-trial Br. (Dkt. 561) ("Pl.'s Opening Post-trial Br."); Defs.' Answering Post-trial Br. (Dkt. 562); Fortis Advisors LLC's Reply Post-trial Br. (Dkt. 566); *see also* Dkts. 571-72.

Fortis is entitled to damages for the breach of contract, implied covenant, and fraud claims on which it prevails. Damages total \$1,011,271,21.009, inclusive of pre-judgment interest for milestones that expired before trial and exclusive of pre-judgment interest owed since then.

A. Breach of Contract

“Under Delaware law, the elements of a breach of contract claim are: 1) a contractual obligation; 2) a breach of that obligation by the defendant; and 3) resulting damage to the plaintiff.”³³³ Fortis has the burden to prove each element by a preponderance of the evidence.³³⁴ “Proof by a preponderance of the evidence means proof that something is more likely than not.”³³⁵

“A contract’s express terms provide the starting point in approaching a contract dispute.”³³⁶ “Delaware law adheres to the objective theory of contracts,” meaning that “a contract’s construction should be that which would be understood by an objective, reasonable third party.”³³⁷ “When interpreting a contract, [the]

³³³ *H-M Wexford LLC v. Encorp, Inc.*, 832 A.2d 129, 140 (Del. Ch. 2003).

³³⁴ *Narayanan v. Sutherland Global Hldgs. Inc.*, 2016 WL 3682617, at *8 (Del. Ch. July 5, 2016) (citing *Agilent Techs., Inc. v. Kirkland*, 2010 WL 610725, at *13 (Del. Ch. Feb. 18, 2010)).

³³⁵ *inTEAM Assoc., LLC v. Heartland Payment Sys., Inc.*, 2016 WL 5660282, at *13 (Del. Ch. Sept. 30, 2016)), *aff’d in part, rev’d in part on other grounds sub nom. Heartland Payment Sys., LLC v. Inteam Assocs., LLC*, 171 A.3d 544 (Del. 2017).

³³⁶ *Ostroff v. Quality Servs. Labs., Inc.*, 2007 WL 121404, at *11 (Del. Ch. Jan. 5, 2007).

³³⁷ *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) (citation omitted).

Court ‘will give priority to the parties’ intentions as reflected in the four corners of the agreement.’”³³⁸ “Absent some ambiguity, Delaware courts will not distort or twist contract language under the guise of construing it.”³³⁹ These principles guide my review of the Merger Agreement.

1. The Earnout Structure

Fortis, on behalf of Auris’s former stockholders, seeks recovery of the contingent consideration memorialized in the Merger Agreement. Auris received \$3.4 billion in cash at closing.³⁴⁰ Its stockholders stood to gain another \$2.35 billion in earnout payments, \$1.15 billion of which was conditioned on iPlatform obtaining regulatory approval for increasingly complex procedures by staged deadlines.³⁴¹

“An earn-out is a provision in an acquisition agreement that makes a portion of the purchase price payable to the seller if/when certain post-closing performance targets are achieved.”³⁴² It is a popular means to bridge price gaps between buyers

³³⁸ *Salamone v. Gorman*, 106 A.3d 354, 368 (Del. 2014) (quoting *GMG Cap. Inv., LLC v. Athenian Venture P’rs I, L.P.*, 36 A.3d 776, 779 (Del. 2012)).

³³⁹ *Allied Cap. Corp. v. GC-Sun Hldgs., L.P.*, 910 A.2d 1020, 1030 (Del. Ch. 2006). Neither party argues that the relevant provisions of the Merger Agreement are ambiguous, and I find no ambiguity.

³⁴⁰ Merger Agreement §§ 2.03(a)(ii), 10.03(l), 10.03(w).

³⁴¹ *Id.* § 2.07(a).

³⁴² Richard De Rose, *The Ins and Outs of Earn-Outs: A Delaware Perspective*, ABA Business Law Today (Mar. 2022), https://www.americanbar.org/groups/business_law/resources/business-law-today/2022-march/the-ins-and-outs-of-earn-outs-a-delaware-perspective/.

and sellers, with different considerations for each.³⁴³ Buyers can mitigate valuation risk since the contingent payment is based on the seller’s actual future performance rather than its projections. Sellers give up guaranteed cash but stand to gain a greater payment overall than they might otherwise receive upfront if defined milestones are met.

A key point of tension in negotiating an earnout structure is allocating post-closing operational control.³⁴⁴ The buyer prefers to freely manage the post-closing activities of the business and to minimize earnout payments. For the buyer, a favorable approach grants it the right to operate the business in its sole discretion, limited only by good faith.³⁴⁵ The seller, by contrast, would rather retain a say in the acquired business and to maximize earnout payments. It may bargain for a contractual assurance that the buyer will devote certain “efforts” toward meeting the milestones.³⁴⁶

³⁴³ JX 3955 at 4 (Leonidas G. Barbopoulos & Jo Danbolt, *The Real Effects of Earnout Contracts in M&As*, 44 J. Fin. Rsch., 607, 610 (2010) (citation omitted)).

³⁴⁴ See JX 4046 at 3-4 (Richard Harroch, *Understanding Earnouts in Mergers and Acquisitions*, Forbes (June 26, 2021), <https://forbes.com/sites/allbusiness/2021/06/26/understandingearnoutsin-mergers-and-acquisitions/>).

³⁴⁵ See, e.g., *LaPoint v. AmerisourceBergen Corp.*, 2007 WL 2565709, at *10 (Del. Ch. Sept. 4, 2007) (considering a provision requiring that the buyer “act in good faith during the Earnout Period” and not “undertake any actions during the Earnout Period any purpose of which is to impede the ability of the [seller’s] [s]tockholders to earn the Earnout Payments”).

³⁴⁶ See *Himawan v. Cephalon, Inc.*, 2024 WL 1885560, at *7 (Del. Ch. Apr. 30, 2024) (discussing a buyer-friendly efforts standard where the buyer was given “complete discretion with respect to all decisions” related to purchased asset, limited only by an

“Variations on the ‘efforts’ concept include commitments to make: ‘good faith efforts,’ ‘commercially reasonable efforts,’ ‘reasonable efforts,’ ‘reasonable best efforts’ and ‘best efforts.’”³⁴⁷ From a transactional standpoint, these variations reflect “a hierarchy from lowest (good faith efforts) to highest (best efforts) level of commitment.”³⁴⁸ This is logical as a matter of plain English since the words used have different meanings.³⁴⁹ But there is no agreement in case law over whether they create different standards. Delaware courts have viewed variations of efforts

obligation to use commercially reasonable efforts to earnout milestones); *see also* *Neurvana Medical, LLC v. Balt USA, LLC*, 2020 WL 949917, at *15-16 (Del. Ch. Feb. 27, 2020) (interpreting an asset purchase agreement that gave the buyer “sole discretion and authority post-closing” to make decisions about a product, which discretion was limited by an “outward facing” commercially reasonable efforts requirement).

³⁴⁷ Peter Atkins & Edward Micheletti, “‘Reasonable Efforts’ Clauses in Delaware: One Size Fits All, Unless . . . ,” Harvard Law School Forum on Corporate Governance (Nov. 22, 2018), <https://corpgov.law.harvard.edu/2018/11/22/reasonable-efforts-clauses-in-delaware-one-size-fits-all-unless/> (last visited Aug. 30, 2024).

³⁴⁸ *Id.*; *see also* 1 ABA Mergers and Acquisitions Committee, *Model Stock Purchase Agreement with Commentary* 212 (2d ed. 2010) (describing a “general sense of hierarchy of various types of efforts clauses”); 2 Lou R. Kling et al., *Negotiated Acquisitions of Companies, Subsidiaries and Divisions* § 13.06 (2024) (“[M]ost practitioners treat ‘reasonable efforts,’ ‘commercially reasonable efforts’ and ‘reasonable best efforts’ as all different from, and as imposing less of an obligation than, ‘best’ efforts. There is no universal agreement, however, as to whether these three standards are, as a practical matter, any different from each other; notwithstanding the fact that ‘reasonable best efforts’ *sounds* as if it imposes more of an obligation than ‘commercially reasonable efforts.’”).

³⁴⁹ *E.g.*, *Best*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/best> (last visited Aug. 31, 2024) (defining “best” as “excelling all others” or “most productive of good; offering or producing the greatest advantage, utility, or satisfaction”); *Reasonable*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/reasonable> (last visited Aug. 31, 2024) (defining “reasonable” as “being in accord with reason” or “moderate, fair”).

clauses—particularly those using the term “reasonable”—as largely interchangeable.³⁵⁰

More important, then, is carefully drafting language that delineates the efforts expected of the buyer relative to the achievement of the milestones. The parties can set an outward facing efforts definition that looks to an industry standard or other industry participants as a yardstick.³⁵¹ This is generally seller friendly because the seller can cite external standards by which to measure the buyer’s efforts. Alternatively, the parties can set an inward facing definition, which applies the

³⁵⁰ See *Williams Cos., Inc. v. Energy Transfer Equity, L.P.*, 159 A.3d 264, 272 (Del. 2017) (holding that “commercially reasonable efforts” and “reasonable best efforts” both “impose obligations to take all reasonable steps to solve problems and consummate the transaction”); *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347, at *87 (Del. Ch. Oct. 1, 2018) (observing the lack of support in case law “for the distinctions that transactional lawyers draw” between the various efforts clauses), *aff’d*, 198 A.3d 724 (Del. 2018) (TABLE); *Channel MedSystems, Inc. v. Boston Sci. Corp.*, 2019 WL 6896462, at *37 n.410 (Del. Ch. Dec. 18, 2019) (noting that a “commercially reasonable efforts” provision is functionally the same under Delaware law as a “reasonable best efforts provision” (citing *Akorn*, 2018 WL 4719347, at *87 & n.796)); 1 ABA Mergers and Acquisitions Committee, *Model Stock Purchase Agreement with Commentary* 213 (“[C]ase law offers little support for the position that ‘reasonable best efforts,’ ‘reasonable efforts,’ or ‘commercially reasonable efforts’ will be interpreted as separate standards less demanding than ‘best efforts.’”).

³⁵¹ See Kristian A. Werling & Richard B. Smith, “Commercially Reasonable Efforts” Diligence Obligations in Life Science M&A, 18 *The M&A Lawyer* (June 2014); *e.g.*, *Himawan*, 2024 WL 1885560, at *11 (evaluating a merger agreement defining “commercially reasonable efforts” as “the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [the buyer], with due regard to the nature of efforts and cost required for the undertaking at stake”); *Neurvana*, 2020 WL 949917, at *16-17 (dismissing a claim for breaching a commercially reasonable efforts provision that imposed an “outward facing definition” that applied “an industry-standard requirement . . . to define the diligence obligations of the buyer” where the complaint failed to identify comparators).

buyer’s own diligence standards.³⁵² This is often more buyer friendly since the buyer can compare its past practices in similar situations to its present efforts.

As the Merger Agreement here demonstrates, however, these generalizations are subject to exception given the highly customized nature of earnout structures. J&J and Auris agreed to an inward facing provision to measure J&J’s “commercially reasonable efforts” in advancing Auris’s products. But Auris bargained for three crucial protections. First, J&J’s efforts were to be in furtherance of “achiev[ing] each of the Regulatory Milestones”—not J&J’s other corporate goals.³⁵³ Second, J&J was required to devote efforts consistent with its “usual practice” for a “priority medical device.”³⁵⁴ This was doubly advantageous to Auris. Efforts to achieve the regulatory milestones must be at the high level J&J—a top company in the industry—set for itself, and for “priority” devices within J&J.³⁵⁵ Third, J&J was

³⁵² See Werling, *supra* note 351; e.g., *FMLS Holding Co. v. Integris BioServices, LLC*, 2023 WL 7297238, at *7 (Del. Ch. Oct. 30, 2023) (considering a claim based on an inward-looking definition of commercially reasonable efforts, which looked to how the business was operating pre-merger); *Banas v. Volcano Corp.*, 47 F. Supp. 3d 941, 946 (N.D. Cal. 2014) (reviewing an inward facing “commercially reasonable efforts” clause requiring the buyer to use “efforts, sales terms, expertise and resources normally used by [Volcano] for other products, which, as compared with [products developed from the plaintiffs’ assets]; are of similar market potential at a similar stage in its development or product life, taking into account all reasonable relevant factors affecting the cost, risk and timing of development and the total potential of the applicable [developed products], all as measured by the facts and circumstances at the time such efforts are due”).

³⁵³ Merger Agreement § 2.07(e)(i).

³⁵⁴ *Id.* § 2.07(e)(ii).

³⁵⁵ See DeFonzo Tr. 381-82 (recalling that Morano encouraged Auris to accept an inward facing standard by assuring it that J&J’s standard exceeded industry standards); *id.* at 382-

prohibited from acting “based on taking into account the cost of making any Earnout Payment(s).”³⁵⁶ This limitation is more restrictive than the typical requirement that a buyer not affirmatively act (or fail to act) for the purpose of thwarting an earnout payment.³⁵⁷ The Merger Agreement also lacks language granting J&J complete discretion over decisions relating to Auris’s business.³⁵⁸

With these assurances, Auris agreed to a deal with an earnout component.³⁵⁹ That is, it forewent guaranteed cash in exchange for assurances that J&J would promote—not impair—its ability to reach the regulatory milestones. For J&J, this

83 (discussing the choice of “priority medical device” language as a “residual assurance” that iPlatform would be prioritized within J&J). J&J put forth the expert opinion of Peter Hinchliffe on whether J&J’s conduct was commercially reasonable. The Fortis expert he was rebutting—Dr. Paul Gompers—did not opine on this matter. To the extent that Hinchliffe offered any proper rebuttal testimony, much of it verged on legal opinions that I decline to accept. But even Hinchliffe acknowledged that the inward facing efforts standard in the Merger Agreement favored Auris. Hinchliffe Tr. 3145-46 (agreeing that the “inward-facing standard in the contract” favored Auris due to J&J’s “high standards relative to the rest of the industry”).

³⁵⁶ Merger Agreement § 2.07(e)(iii).

³⁵⁷ See *S’holder Rep. Servs. LLC v. Albertsons Cos.*, 2021 WL 2311455, at *1 (Del. Ch. June 7, 2021) (discussing a “typical” provision in which the buyer “bargained for the right to operate [the seller] post-closing in its discretion limited only by its express commitment not to operate [the seller] in a manner intended to avoid the obligation to pay the earnout”); see also *infra* note 391 (citing precedent).

³⁵⁸ See *supra* note 346 and accompanying text (discussing precedent).

³⁵⁹ See JX 278 at 6-7 (Luca Viarengo et al., *Enforcement Quality and the Use of Earnouts in M&A Transactions: International Evidence*, 45 J. Bus. Fin. & Acct., 437, 442-43 (2018) (observing that a seller may agree to an earnout clause if the contractual protections are “strong,” making the seller “more confident that it will obtain what it is due”).

meant that it paid less upfront but lost the ability to exercise unchecked discretion over the Auris products.

As discussed below, Auris's expectations went unmet. J&J did not devote commercially reasonable efforts to achieve the milestones consistent with those given to a priority device. Instead, it repeatedly impeded and impaired the development of Auris's products. J&J's efforts might have been beneficial to its broader robotics program, its profit margins, or its commercialization strategy. But they were wholly inconsistent with J&J's promises to Auris.

2. Whether J&J Breached the Efforts Provision

The Merger Agreement includes a bespoke “[e]fforts” clause.³⁶⁰ Section 2.07(e)(i) imposes on J&J an affirmative obligation to use “commercially reasonable efforts” to advance the achievement of the iPlatform and Monarch regulatory milestones.

From and after the Closing Date until the earlier to occur of the latest Earnout Period End Date with respect to the Regulatory Milestones or the date on which each of the Regulatory Milestones have been achieved in accordance with this Agreement, Parent shall, and shall cause its Affiliates (including the Surviving Corporation) to, use commercially reasonable efforts to achieve each of the Regulatory Milestones (excluding, once achieved, any such Regulatory Milestones that may have been achieved).³⁶¹

³⁶⁰ Merger Agreement § 2.07(e) (“Efforts; Certain Transfers”).

³⁶¹ *Id.* § 2.07(e)(i).

The express requirement that J&J’s objective be “to achieve each of the Regulatory Milestones” stands in stark contrast to J&J’s understanding that it could “make whatever decisions needed to be made” about the Auris products “in the context of the rest of [J&J’s] business.”³⁶²

Delaware courts have interpreted “commercially reasonable efforts” clauses as requiring a party “to take all reasonable steps” toward an end.³⁶³ Here, the parties bargained for a meaning. Section 2.07(e)(ii) of the Merger Agreement defines “commercially reasonable efforts” as:

the expenditure of efforts and resources in connection with research and development and obtaining and furnishing of information to and communications with applicable Governmental Entities in connection with obtaining the applicable 510(k) premarket notification with respect to the applicable Robotics Products consistent with the usual practice of Parent and its Affiliates with respect to priority medical device products of similar commercial potential at a similar stage in product lifecycle to the applicable Robotics Products[.]³⁶⁴

³⁶² Morano Tr. 1532-34 (“[I]f we were spending \$3.4 billion on [Auris], we were going to own the company, and we wanted and needed the right to be able to make whatever decisions needed to be made appropriately moving forward in the context of the rest of our business.”); *e.g.*, JX 2339 (Martin to DeFonzo: “As a general note, we will manage the milestones to do what is the right for the business. They are meant to be collective incentives to drive the business in the right direction in service of maximizing value.”); Martin Day 2 Dep. 564-65 (testifying that the goal was to “develop a system to delight the customers” because the “marketplace [] was waiting for a system from Johnson & Johnson”); *see also* JX 1663; JX 6206.

³⁶³ *Williams Cos.*, 159 A.3d at 273; *see also Akorn*, 2018 WL 4719347, at *86-88; *Himawan v. Cephalon, Inc.*, 2018 WL 6822708, at *7 (Del. Ch. Dec. 28, 2018) (citation omitted).

³⁶⁴ Merger Agreement § 2.07(e)(ii); *see also id.* § 10.03(eee) (defining “Robotics Products”).

The definition goes on to list ten factors J&J may “take into account” in setting its level of efforts for a “priority medical device”:

(A) issues of efficacy and safety, (B) the risks inherent in the development and commercialization of such products, (C) the expected and actual competitiveness of alternative products sold or licensed by third parties in the marketplace, (D) the expected and actual patent and other proprietary position of the product, (E) the likelihood and difficulty of obtaining FDA and other regulatory approval given the nature of the product and the regulatory structure involved, (F) the regulatory status of the product and scope of any marketing approval, (G) pending or actual legal proceedings with respect to the applicable Robotics Product, (H) whether the product is subject to a clinical hold, recall or market withdrawal, (I) input from regulatory experts and any guidance or developments from the FDA or similar Governmental Entity, including as it may affect the data required to obtain premarket approval from the FDA or any similar approval from another Governmental Entity and (J) the expected and actual profitability and return on investment of the product, taking into consideration, among other factors, the expected and actual (1) third party costs and expenses, (2) royalty and other payments and (3) pricing and reimbursement relating to the product(s).³⁶⁵

Section 2.07(e)(iii) prohibits J&J from making decisions to avoid, or based on, the milestones:

Parent shall not, and shall cause its Affiliates (including the Surviving Corporation) not to, take any actions, or refrain from taking any actions, concerning the business or operations of Parent or any of its Affiliates (including the Surviving Corporation) (A) with the intention of avoiding any of Parent’s obligations to pay any Earnout Payment or (B) based on taking into account the cost of making any Earnout Payment(s) made,

³⁶⁵ *Id.* § 2.07(e)(ii).

or actually or potentially to be made, pursuant to this Agreement.³⁶⁶

Together, these provisions provide several layers of protection for Auris.

Although the ten factors J&J could consider in expending efforts and resources gave it some measure of discretion, the mandate that J&J follow its “usual practice” for “priority medical device[s]” cabined it.³⁶⁷ The phrase “priority medical device” is undefined in the Merger Agreement. Based on its usual meaning, a “priority” device is one given “superiority in rank, position, or privilege.”³⁶⁸ J&J identified a single comparator “priority medical device at a similar stage in product lifecycle” to iPlatform and Monarch: an orthopedic RASD called Velys.³⁶⁹

Velys was developed through an MVP strategy starting with simple, buildable functionality and a single indication.³⁷⁰ It lacked perfect performance statistics before receiving its first FDA clearance in January 2021 and was not superior (or

³⁶⁶ *Id.* § 2.07(e)(iii).

³⁶⁷ *Id.* § 2.07(e)(ii).

³⁶⁸ *Priority*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/priority> (last visited Aug. 30, 2024); *Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 738 (Del. 2006) (“Under well-settled case law, Delaware courts look to dictionaries for assistance in determining the plain meaning of terms which are not defined in a contract.”).

³⁶⁹ *See* Heda 30(b)(6) Dep. 29-32; PTO ¶ 164; *cf. Banas*, 47 F. Supp. 3d at 947 (applying Delaware law; discussing the importance of considering a relevant comparator device by which to measure commercially reasonable efforts where no adequate comparator was identified).

³⁷⁰ *See* PTO ¶ 164; JX 4246 at 3; Waterson Dep. 98-99; Shen Tr. 1227-28.

even equivalent) to its market-leading rival upon launch in August 2021.³⁷¹ Velys employees were given cash incentives to achieve rapid FDA clearance.³⁷²

iPlatform received starkly different treatment than Velys. Instead of being prioritized, J&J subjected iPlatform to efforts that impaired its development and ability to secure planned clearances. J&J's efforts benefitted another device—Verb—at iPlatform's expense. It is obvious from the record that J&J's efforts toward the iPlatform regulatory milestones were not commercially reasonable, as defined in the Merger Agreement. J&J's breaches are, instead, reasonably certain to have caused iPlatform to miss its regulatory milestones.

I reach a different conclusion regarding Monarch. J&J diminished aspects of the Monarch program while prioritizing others. Fortis did not prove that these actions reflect a breach of J&J's efforts obligation.

a. Efforts Towards the iPlatform and GI Milestones

The Merger Agreement required J&J to use “commercially reasonable efforts,” as defined in Section 2.07(e)(ii), to achieve the regulatory milestones.³⁷³ Six regulatory milestones are tied to FDA clearance of iPlatform for increasingly

³⁷¹ See Waterson Dep. 180-81; JX 3717; JX 3963; JX 4481 at 19-20; *see also* PTO ¶¶ 165-66.

³⁷² Waterson Dep. 103-106.

³⁷³ Merger Agreement § 2.07(e)(ii); *see* Shen Tr. 1150-51 (confirming his understanding that J&J had an obligation to “exercise priority efforts to achieve the regulatory milestones in the merger agreement”).

complex laparoscopic procedures.³⁷⁴ A seventh—the GI Milestone—concerned clearance for an endoluminal procedure and could be satisfied with either iPlatform or Monarch.³⁷⁵ J&J did not bestow on iPlatform the efforts and resources to achieve these milestones that would benefit a “priority” device.³⁷⁶

Instead, J&J thrust iPlatform into a showdown with Verb. The fallout from Project Manhattan grew when the iPlatform robot and team were forced to merge with Verb. Compounding iPlatform’s challenges, the iPlatform and GI regulatory milestones were deprioritized when they were written off and different incentives were imposed. This is the antithesis of the commercially reasonable efforts expected for a “priority” device.

i. *Project Manhattan*

Within weeks of closing, iPlatform was pitted against the Verb robot for the Project Manhattan competitive assessment.³⁷⁷ To prevail, Auris had to prepare for a series of in-house surgical challenges rather than progress iPlatform’s development. Auris’s engineering team scrambled to gain functional system stability so that the fledgling iPlatform alpha robot could face the post-beta Verb—

³⁷⁴ Merger Agreement § 2.07(a)(iii)-(vii).

³⁷⁵ *Id.* § 2.07(a)(viii).

³⁷⁶ *Id.* § 2.07(e)(ii).

³⁷⁷ *See supra* Section I.L; *see also* JX 1702 (“Plan to Technically Assess Verb Platform and iPlatform”).

taking on extensive “technical debt” in the process.³⁷⁸ The legacy Auris team saw no alternative, since both iPlatform and Verb were “fighting for their lives.”³⁷⁹ Over 80 Auris personnel were diverted to “support a 25-day lab period.”³⁸⁰ Many of the Project Manhattan procedures assigned to iPlatform were more advanced than those Auris intended to use to satisfy Regulatory Milestones.

J&J insists that imposing Project Manhattan on iPlatform did not breach its efforts obligation because the exercise was meant to “identify synergies in order to accelerate the development of the robots.”³⁸¹ But Project Manhattan had no upside for Auris. It did not advance iPlatform’s development, provide it with resources, or bring it closer to regulatory approval. Quite the opposite.

For iPlatform, Project Manhattan caused needless setbacks and resource drains. To make matters worse, J&J delayed making resource decisions for Auris

³⁷⁸ See Mintz Tr. 589-91 (describing how the workarounds to prepare for Project Manhattan eliminated any “firm foundation” to fix problems in a “measured, controlled way” necessary for a complex robot and created problems to solve later); Moll Tr. 254 (explaining that Shen did not understand “all of the work that needed to be done just to get ready for any sort of technical assessment” and the “technical debt” Auris incurred “just to show up for this evaluation”); *see also* JX 4207.

³⁷⁹ DeFonzo Tr. 406 (“[W]e were in a fight for our lives. . . . Verb us, and us Verb.”); *see also* Moll Tr. 72 (“So we quickly characterized this as a bakeoff because the pitting of two systems against each other was – couldn’t have been more different than the description of a technology audit that had nothing to do with Verb, that had everything to do with iPlatform and Monarch and how it could be – progress could be accelerated by resources from J&J.”).

³⁸⁰ JX 2389 at 9; *see also* JX 2444 at 8; JX 2330.

³⁸¹ Defs.’ Answering Post-trial Br. 6 (emphasis removed).

until the assessment was complete.³⁸² For Verb, though, it was a boon. Through the assessment, J&J identified synergies between the robots so that iPlatform could optimize Verb.³⁸³ Doing so gave J&J something to show the market and its Board for years of substantial investments in Verb while staying within the Ashley Management Decision budget. This result might be appropriate if I were considering whether J&J had used commercially reasonable efforts to develop Verb as a priority device. But J&J agreed to devote such efforts to iPlatform in pursuing the regulatory milestones. The iPlatform milestones were sacrificed to aid the Verb program.³⁸⁴

³⁸² See JX 2103 (“July is a critical month with Manhattan project concluding. Auris’s future needs to be assessed against the outcome of these strategic decisions.”); Moll Tr. 86; *see also* JX 2403; JX 2019.

³⁸³ *E.g.*, JX 6206 (Shen: “My original thought is to get Verb to market asap, and then iPlatform. Leverage as much as possible behind the scene. The overall consolidation of both platforms will take 5-10 years. The Tech Assessment will take us to the final decision.”); Lenard Day 2 Dep. 23-24 (“If there are ways for us to take those two—and combine them to optimize what would eventually be our value—I never heard about [Project Manhattan] as a comparison between the two.”). Lenard was J&J’s Vice President of Finance for J&J’s Robotics and Digital Solutions Group from 2019 until October 2022. Lenard Tr. 1785-1786.

³⁸⁴ JX 1630 (Shen to McEvoy: “[i]Platform is exciting, but there is so much we do not know. Verb has challenges, but we already have a working prototype which can perform preclinical surgeries. Instrument is also developed. We need to be all in for Verb. Verb + iPlatform is our bullet proof strategy to compete.”); *see also* JX 1820 (Shen: “The Tech Assessment is the No. 1 priority at this point for all of us.”); JX 1703.

Project Manhattan alone is sufficient to find that J&J breached its efforts obligation in Section 2.07(e) of the Merger Agreement. A “priority” device would not have to endure a costly battle merely to remain operative.³⁸⁵ But there is more.

ii. *The Verb Combination and Integration*

iPlatform’s success in Project Manhattan came at a crippling cost. It led to the iPlatform system being meshed with Verb components, including certain hardware.³⁸⁶ The complete integration of Verb into Auris followed.

Combining the RASDs hampered iPlatform’s launch and milestone achievement.³⁸⁷ Contemporaneous documents reflect that J&J knew pursuing the “[s]ingle, [o]ptimized [p]latform” would negatively affect iPlatform’s development schedule.³⁸⁸ Worse, J&J anticipated that the delay would frustrate the iPlatform

³⁸⁵ Nothing of the sort was required of Velys. *See supra* notes 370-72 and accompanying text.

³⁸⁶ JX 2594 at 20 (recommending “[g]o to market with Combination platform defined as ‘iPlatform’+ (6-arm robotic architecture) augmented by incremental Verb capabilities incl. Open Console, Verily scope, Digital Assets at launch, followed by further iterations including UID integration”).

³⁸⁷ *See* Mintz Tr. 686 (discussing the difficulties faced by iPlatform’s beta version due to “integration challenges”); *see also* Gardiner Tr. 822 (recounting that beta’s software “crashed” when it was brought online).

³⁸⁸ *See* JX 2566 at 10 (Sept. 2019 Manhattan Financials Update: “Single, Optimized Platform launching in 2024 (+1 Year Delay to Combine)”); McEvoy Tr. 2635 (acknowledging that combining the systems would mean a longer time to market for Auris); Lenard Tr. 1802-04; JX 2584 at 26 (draft investor presentation discussing “[l]onger time to market for Auris impacting retention” and “[m]ilestone [r]evisions for Auris employees” as considerations for combining Verb and iPlatform); *see also* JX 2554 at 23 (J&J Sept. 2019 deck suggesting two year delay for combination); JX 5122 at 19-20 (J&J employee texts expressing concern that a deck indicating delay from the combination could

regulatory milestones.³⁸⁹ Gorsky endorsed the combined system after understanding that J&J had a “good overall value case” from a fair market value perspective considering “what [w]ould also happen with the contingent payment.”³⁹⁰ This was not only inconsistent with J&J’s obligation to use commercially reasonable efforts to achieve the milestones. It was also contrary to J&J’s promise not to act “based on taking into account the cost of making any Earnout Payment(s).”³⁹¹

be “used against us in litigation”); *compare* Dougherty Dep. 400-02, 404-05 (testifying that he was concerned Auris would learn about “scenario planning” to form a single platform), *with* Dougherty Tr. 3170-72 (attempting to walk back his deposition testimony).

³⁸⁹ Unfortunately, Gorsky declined to attend trial and shed light on this exchange. Other potentially relevant evidence was lost because Gorsky failed to turn off auto-delete on his cell phone after receiving a litigation hold notice (in this and other litigation). Fortis moved for sanctions in October 2022. *See* Pl.’s Mot. to Compel Discovery and for Sanctions (Dkt. 214). I reserved judgment on the motion until trial. With the benefit of a full record, I conclude that Gorsky’s failure to retain text messages is far from ideal, but it was neither reckless nor intentional. *See Seibold v. Camulos P’rs LP*, 2012 WL 4076182, at * (Del. Ch. Sept. 17, 2012) (explaining that “dispositive sanctions are “only appropriate where a party acts to intentionally or recklessly destroy evidence” (citation omitted)). Upon receiving the hold memo, Gorsky asked his assistant to ensure that he complied. Aff. of Alex Gorsky in Supp. of Defs.’ Opp’n to Pl.’s Mot. to Compel Discovery and for Sanctions (Dkt. 226) Ex. A. This instruction shows an intention to comply. He also testified during his deposition that he had enabled auto-delete on his phone years ago and simply forgot. Gorsky Dep. 323-24. Gorsky was negligent. He did not, however, spoliage evidence.

³⁹⁰ JX 2606 at 1-2 (Oct. 1, 2019 email from McEvoy to Gorsky, in response to his inquiry about why the combined system had a lower valuation); *see also* JX 2599 at 2 (CFO Pease explaining, before McEvoy emailed Gorsky, that the lower valuation was based on assuming that the iPlatform milestones were paid); McEvoy Tr. 2636-37 “Q: [T]he contingent payment you wrote about there included the milestones that you were contemplating writing down; correct? A: I presume so.”).

³⁹¹ Merger Agreement § 2.07(e)(iii). This provision lacks an intent requirement. *Cf. Lazard Tech. P’rs, LLC v. Qinetiq N. Am. Operations LLC*, 114 A.3d 193, 194 (Del. 2015) (discussing a provision in a merger agreement prohibiting a buyer from “taking any action to divert or defer [revenue] with the intent of reducing or limiting the Earn-Out Payment”); *id.* at 195 (explaining that the Court of Chancery “properly held that [a] buyer’s action had

The detrimental effects of the combination on iPlatform intensified when the entire Verb group was thrust upon Auris, which was trying to regain its footing after Project Manhattan.³⁹² In J&J’s view, the integration is indicative of commercially reasonable efforts because Verb’s resources were being devoted to iPlatform.³⁹³ In reality, it was “highly disruptive,” as J&J had predicted.³⁹⁴ The Verb team, which had just learned it lost Project Manhattan, suddenly had to support a competitor robot. The iPlatform team went from nimble and focused to redundant and divided.³⁹⁵ The “devastating” departure of the entire legacy iPlatform clinical

to be motivated at least in part by [an] intention” to avoid an earnout and was not required to find that avoidance was the buyer’s sole purpose).

³⁹² I do not necessarily view the integration as a separate breach. It was a continuation of the injury from Project Manhattan and the robot combination. iPlatform could no longer pursue its development and commercialization strategy. It, instead, had to battle, merge, and integrate with a competitor device.

³⁹³ See Defs.’ Answering Post-trial Br. 98-99.

³⁹⁴ JX 2743 at 11 (J&J presentation describing the integration strategy as a “[o]ne time, highly-disruptive change”); see DeFonzo Tr. 425-27 (describing the integration as a “horrible experience” for both Auris and Verb since they had been “pitted against one another,” which created a “toxic culture where, essentially, one program wins and the other program loses . . . [a]nd now, all of a sudden, it’s, like, let’s integrate these things”); JX 2921 at 1 (DeFonzo expressing his concern to J&J that the directive to “integrate as quickly as possible” is “unreasonable if we expect it not to disrupt development activities and core business unit objectives”).

³⁹⁵ See JX 3094 (J&J’s Lenard: “After the Verb acquisition, I REALLY need to initiate layoffs – not just for my budget . . . but also for the good of the business. We have so many people now that we don’t know what do to with everyone and it’s slowing down our progress.”); Mintz Tr. 613 (“Verb’s software team at this point was almost twice the size. So now we have a situation where the team that sort of lost their baby was brought in to join this team, and they outnumbered them two to one. There’s a dynamic there, even in the best of times.”); see also JX 4495 (“Gompers Rep.”) ¶ 69 (describing the importance of “firm-specific” human capital for entrepreneurial endeavors).

engineering team, and a number of Auris software engineers, resulted.³⁹⁶ With Verb tethered to iPlatform, the swift pace Auris had once achieved was disrupted.³⁹⁷

J&J also argues that the combination and integration of Verb with iPlatform was a “commercially reasonable business decision[.]” falling “well within J&J’s discretion under the contract.”³⁹⁸ This reflects a fundamental misreading of the Merger Agreement. J&J could consider various factors in assessing the level of efforts to devote. But the end goal of those efforts was to achieve the iPlatform regulatory milestones—not to further J&J’s robotics program.³⁹⁹ A “priority” device would not have its system, technology, and team diluted to fix another device’s problems.⁴⁰⁰

iii. *Thwarting of iPlatform’s MVP Strategy*

The milestone structure that J&J and Auris agreed upon reflected an MVP strategy, albeit not explicitly. The first iPlatform regulatory milestone—the General Surgery Milestone—could be satisfied by any upper and any lower abdominal

³⁹⁶ See Mintz Tr. 612, 614-15 (explaining the “step back” to engineering and system stability caused by the integration and “significant” attrition that resulted); JX 3194.

³⁹⁷ See JX 2991 at 4 (Feb. 2020 internal J&J presentation stating “[w]e can’t underestimate the impact the ‘non bake-off bake-off’ has had on both companies”); Gompers Rep. ¶ 112 (opining that by “impos[ing] integration burdens on Auris management,” J&J “impeded Auris’ ability to achieve the Acquisition milestones”).

³⁹⁸ Defs.’ Answering Post-trial Br. 103.

³⁹⁹ Merger Agreement § 2.07(e)(i).

⁴⁰⁰ Velys was never forcibly combined with another program. See Thomson Dep. 85-87; Waterson Dep. 328-39.

procedures.⁴⁰¹ From there, iPlatform would build towards more specialized procedures to achieve the 2023 umbrella and GI regulatory milestones J&J had allowed iPlatform to select.⁴⁰² The milestones proceeded iteratively from relatively simple to complex, without regard to architecture (e.g., number of arms used).⁴⁰³

At first, Auris considered pursuing either five-arm Nissen fundoplication or RYGB for the upper abdominal procedure and inguinal hernia repair for the lower abdominal procedure to satisfy the General Surgery Milestone.⁴⁰⁴ Choosing RYGB for the upper indication was ambitious yet ideal, since Auris would have met two milestones at once (the General Surgery and Upper Abdominal Milestones).⁴⁰⁵ But after Project Manhattan caused delay, Auris worried that RYGB was out of reach for 2021. It sought to simplify iPlatform’s initial indications and features for regulatory approval purposes.⁴⁰⁶

⁴⁰¹ Merger Agreement § 2.07(a)(iii).

⁴⁰² *Id.* § 2.07(a)(iv)-(viii); *see supra* note 186 and accompanying text; *supra* note 194.

⁴⁰³ *See* Khan Tr. 3039-40.

⁴⁰⁴ JX 1729 at 21-22; Mintz Tr. 691-93 (explaining that Moll initially preferred to work towards five-arm procedures); JX 824 at 29; *see supra* notes 74, 250, 270.

⁴⁰⁵ Sheehy Dep. 110-11 (Auris clinical engineer testifying: “If we could get two milestones at the same time with the same set of activities, that would have been more efficient than sequentially going from milestone 1 to milestone 2.”). Auris was confident at the time, based on its lab results, that iPlatform could perform RYGBs. *See infra* notes 541-43 and accompanying text.

⁴⁰⁶ JX 2199 (Moll suggesting to Shen and Martin that iPlatform “go with [the] smallest and most efficient clinical effort to achieve desired regulatory clearances → ie work to and only to FDA defined clinical activities” to “accelerate [its] momentum”); Moll Tr. 86-90; *see also* JX 6206.

Moll’s requests to pursue an MVP version of iPlatform for its initial regulatory clearance, using simplified procedures that iPlatform was “very capable” of performing, were rebuffed by J&J.⁴⁰⁷ J&J continued to insist that iPlatform focus on RYGB—a procedure that would promote Ethicon instrument sales and broad commercialization while putting achievement of the General Surgery Milestone in peril.⁴⁰⁸ When Shen learned in May 2019 that Mintz planned to make “instrument trade-offs” to pursue 510(k) with a simplified indication, he asked a colleague to “intervene.”⁴⁰⁹

J&J believes that the ten factors listed in the Merger Agreement’s definition of commercially reasonable efforts allowed it to drive iPlatform towards the more complex procedure.⁴¹⁰ For example, “expected and actual profitability” would be furthered by an RYGB indication using high margin Ethicon instruments.⁴¹¹

⁴⁰⁷ Moll Tr. 88 (“RYGB is a more complex procedure. There are more questions with regard to port placement. There was more questions with regard to arm movement. We had lots of success in the lab with the single-quadrant procedures of gallbladders and Nissens and hernias and hysterectomies. We knew that we were very capable in those procedures.”); *id.* at 89-91.

⁴⁰⁸ *Id.* at 89-90.

⁴⁰⁹ JX 6206 at 1 (Shen: “We cannot do the wrong things for the sake of [the] timeline.”); *see also* JX 2172 at 1 (June 2019 email from Shen to Martin: “Another thing that bothers me is our milestone incentives. That may not drive the right behaviors.”); Shen Tr. 1164-65.

⁴¹⁰ *E.g.*, Shen Tr. 1170-71 (stating that he believed the Auris team was too focused on the milestones as “opposed to a great product” with commercial viability); *see also* Defs.’ Answering Post-trial Br. 44 (“Pursuing RYGB made commercial sense.”).

⁴¹¹ Merger Agreement § 2.07(e)(ii)(J); *see* Moll Tr. 89-91.

iPlatform’s “expected and actual competitiveness” versus da Vinci could also improve using a five or six-arm architecture.⁴¹² Still, J&J’s insistence that iPlatform’s foray into regulatory approval involve a complex five-arm procedure impeded the achievement of the 2021 milestone. It did not provide “efforts and resources . . . in connection with obtaining the applicable 510(k) premarket notification . . . consistent with the usual practice of [J&J] with respect to [a] priority medical device.”⁴¹³

Although J&J was entitled to consider certain factors in devoting efforts and resources to iPlatform, its discretion was not free floating. J&J was not, for example, permitted to prioritize commercialization, product differentiation, or short-term profitability at the expense of achieving the milestones.

Even if it could, those considerations were promoted through an MVP approach for regulatory approval. Auris proved that:

- “[I]ssues of efficacy and safety” counsel in favor of starting with a basic device and simple procedures before adding complexity in later iterations.⁴¹⁴

⁴¹² Merger Agreement § 2.07(e)(ii)(C).

⁴¹³ *Id.* § 2.07(e)(ii).

⁴¹⁴ *Id.* § 2.07(e)(ii)(A); *see* Shen Tr. 1168-69; Moll Tr. 16.

- “[T]he risks inherent in [] development” are lower with an MVP strategy. It simplifies the system to ensure speed, flexibility, and reliability, which reduces development risk.⁴¹⁵
- “[T]he likelihood and difficulty of obtaining FDA and other regulatory approval” favors starting with a narrow indication before seeking to expand the device’s approval.⁴¹⁶
- Commercial considerations—including “profitability and return on investment,” the “competitiveness of alternative products,” and the “risks inherent in . . . commercialization”—support an MVP strategy.⁴¹⁷ An MVP approach would have allowed J&J to assess the valuable aspects of iPlatform before investing in the development of a fully featured product.⁴¹⁸ Even a minimally viable version of iPlatform using fewer arms would have “plenty of differentiation” from da Vinci to drive adoption.⁴¹⁹

Numerous witnesses at trial confirmed that it is industry standard to follow an MVP strategy for the development and regulatory approval of complex medical

⁴¹⁵ Merger Agreement § 2.07(e)(ii)(B); *see* Khan Tr. 3042 (J&J’s technical expert confirming that an MVP strategy promotes system speed, flexibility, and reliability); *see also* Khan Day 1 Dep. 214 (“The simpler the system at the initial stages, the easier it is to ensure system stability and solve other problems.”); Grennan Dep. 112-14 (J&J’s rebuttal economics expert testifying about MVP); Gompers Rep. ¶ 62 (“[T]he MVP approach accelerates time to market relative to the product-development model used by established companies to enter known markets.”).

⁴¹⁶ Merger Agreement § 2.07(e)(ii)(E); *see* Tillman Tr. 2825-27 (J&J’s regulatory expert acknowledging that it is a common regulatory practice to seek clearance of an early device with limited functionality, which can be a predicate for future iterations); *accord* Wittwer Tr. 1959; *see also* Shen Tr. 1166-67; Moll Tr. 293-94; Khan Day 1 Dep. 209.

⁴¹⁷ Merger Agreement § 2.07(e)(ii)(B), (C), (J); *see* Gompers Tr. 1935-36; Grennan Dep. 112-14.

⁴¹⁸ *E.g.*, Shen Tr. 1169; Grennan Tr. 2545; Gompers Tr. 1916-18, 1935-36; Khan Tr. 3041-42; Lopes Tr. 2444.

⁴¹⁹ Moll Tr. 90; *id.* at 294-95; *see also* Shen Tr. 1167; Grennan Dep. 58.

devices.⁴²⁰ For RASDs in particular, the approach is highly efficient.⁴²¹ In terms of priority devices, J&J’s own practice for Velys was to follow an MVP strategy.⁴²² Gorsky also had asked that an MVP approach be used for Verb.⁴²³ Thus, J&J’s insistence that iPlatform focus on a complex umbrella procedure to satisfy the General Surgery Milestone was not commercially reasonable in view of J&J’s obligation to devote efforts befitting a priority medical device.

iv. *The New Incentives*

In April 2020, J&J wrote down the iPlatform and GI regulatory milestones to \$0.⁴²⁴ This was an accounting measure; it did not eliminate J&J’s contractual obligation to fund earnout payments if Auris timely met milestones.⁴²⁵ But the write-

⁴²⁰ See Shen Tr. 1164, 1169; Khan Tr. 3041-42; Khan Day 1 Dep. 207, 209; Moll Tr. 15-16.

⁴²¹ See *supra* notes 19-22 and accompanying text.

⁴²² See JX 4246 at 3 (“As part of the deal model, it was agreed that we would do a true MVP with the objective to enter the US market as quickly as possible.”); Waterson Dep. 98-99; Shen Tr. 1227-28.

⁴²³ See JX 255 at 1 (“Alex has asked us to . . . make sure we hit the goals and deliver the first general ‘minimally viable product’”); JX 711 at 3 (targeting “1 indication” for a “[r]educed program scope” to accelerate launch); Shen Tr. 1167.

⁴²⁴ JX 3139 at 2; PTO ¶ 161.

⁴²⁵ Defs.’ Answering Post-trial Br. 111-12.

down was accompanied by an employee incentive program with targets different from the milestones in the Merger Agreement.⁴²⁶

In contrast to the General Surgery Milestone that Auris had bargained for, the new regulatory approval incentive was based on FDA approval of iPlatform for a “general surgery” indication (like RYGB).⁴²⁷ The program set a target date for iPlatform’s initial FDA approval at the end of 2023—two years later than the deadline in the Merger Agreement.⁴²⁸ All other regulatory milestones for iPlatform and GI-related incentives were absent from the program.⁴²⁹

These different inducements, coupled with J&J’s communications to Auris that the milestones were “canceled,”⁴³⁰ negatively affected employees’ motivation to work towards the iPlatform and GI regulatory milestones in the Merger Agreement.⁴³¹ J&J was not using “commercially reasonable efforts” toward meeting

⁴²⁶ JX 2675 at 1 (discussing, in October 2021, the potential need to “construct an employee specific plan to ‘restore’ milestone achievability through creating a new separate retention program”); Moll Tr. 95-97; Mintz Tr. 617-18.

⁴²⁷ Compare JX 3641 at 5, with Merger Agreement § 2.07(a)(iii); see also *supra* note 193 and accompanying text.

⁴²⁸ Compare JX 3641 at 5, with Merger Agreement § 2.07(a)(iii).

⁴²⁹ Compare JX 3641 at 5, with Merger Agreement § 2.07(a)(iv)-(viii). It also replaced gross revenue-based sales milestones with incentives based on profitability and overseas expansion. Compare JX 3641 at 5, with Merger Agreement §§ 2.07(a)(ix)-(x).

⁴³⁰ See Moll Tr. 95-96, 195, 198; see also JX 3193.

⁴³¹ See Gompers Rep. ¶ 117.

the regulatory milestones “consistent with [J&J]’s usual practice” for a “priority” device.⁴³² It was redirecting efforts toward different goals.

This is not to say that J&J had to pursue the milestones without any regard to commercial reasonableness. But though J&J could reasonably calibrate its efforts, it could not try to re-write or deprioritize the milestones themselves. Velys never received similar treatment.⁴³³

* * *

J&J was required to utilize commercially reasonable efforts to meet the iPlatform and GI regulatory milestones, consistent with those given to a priority medical device. Its actions beginning with Project Manhattan were anything but. A priority device benefitting from such efforts by J&J would not be embattled, derailed, and enmeshed with another. Velys was not.

Regardless, J&J insists that the efforts devoted to iPlatform were commercially reasonable because iPlatform’s funding vastly exceed that of Velys (or any other medical device program at J&J).⁴³⁴ J&J invested over \$2.25 billion in the Auris program (broadly speaking) from 2019 to 2022.⁴³⁵ It also purchased a

⁴³² Merger Agreement § 2.07(e)(ii).

⁴³³ See *supra* notes 370-72 and accompanying text.

⁴³⁴ Defs.’ Answering Post-trial Br. 102. J&J makes similar arguments about staffing, which fail for the same reasons as its financing arguments and those discussed above regarding the post-integration debacle.

⁴³⁵ See JX 4516 (“Malackowski Rep.”) 283-84; Defs.’ Answering Post-trial Br. 102.

company called Vytronus for \$20 million to buttress Auris’s capabilities, at Moll’s request.⁴³⁶

It is an oversimplification to view these funds as furthering the achievement of the iPlatform regulatory milestones. For example, \$112 million of the funds J&J claims were for iPlatform were spent on the Verb robot and instrument R&D, \$89 million was spent on Ethicon legal fees (including this litigation), and \$90 million was spent to acquire the remaining interest in Verb.⁴³⁷ Much of the investment came post-write-down, and one-third of the cited total was spent after J&J abandoned iPlatform in 2022.⁴³⁸ An obligation to use commercially reasonable efforts in pursuit of the iPlatform regulatory milestones is not equivalent to spending large sums on J&J’s robotics program. J&J fell short of the promise it made in Section 2.07(e) of the Merger Agreement.

b. J&J Efforts Towards the Monarch Milestones

The Merger Agreement includes two regulatory milestones for Monarch: one focused on soft tissue ablation and the other on endourology. J&J’s contractual

⁴³⁶ JX 2825 at 1; Martin Tr. 1767-68; Leparmentier Dep. 210-12.

⁴³⁷ See Malackowski Rep. 283-84; see also Defs.’ Trial Demonstrative (“Defs.’ Dem.”) 10. Other expenditures included \$214 million for additional instruments R&D, \$60 million for marketing products other than iPlatform and Monarch, and \$75 million for standalone “Digital Solutions” software products. See Malackowski Rep. 283-84; Kilroy Dep. 263-64; see also Defs.’ Dem. 10.

⁴³⁸ See Malackowski Rep. 283-84; see also Defs.’ Dem. 10.

obligations extended to these milestones.⁴³⁹ Fortis contends that J&J failed to use commercially reasonable efforts to achieve them.

Monarch's story is distinct from iPlatform's. Monarch was not subjected to Project Manhattan. Its system was not joined with another robot. It was largely permitted to follow an MVP strategy. And its regulatory milestones were not written down until September 2020.⁴⁴⁰

Fortis's arguments regarding the Monarch milestones are, at bottom, disagreements with how J&J engaged with the FDA and prioritized aspects of the Monarch program. Funding was allocated towards some Monarch indications instead of others, there were hiring gaps, and J&J's actions towards solving the NeuWave FLEX problem were bungled. These actions, or lack thereof, were flawed and may prompted unintended delays, but they are not commercially unreasonable under Section 2.07(e).

i. *Soft Tissue Ablation*

The Monarch Soft Tissue Ablation Milestone contemplated 510(k) approval for a "specific indication for robotically driven (or controlled) soft tissue ablation,"

⁴³⁹ Merger Agreement § 2.07(e)(i); *id.* § 10.03(zz) (defining "Regulatory Milestones" to include "the Monarch Endourology Milestone" and the "Monarch Soft Tissue Ablation Milestone").

⁴⁴⁰ JX 3504 at 3. The new employee incentive plan did, however, prioritize reusable bronchoscopes rather than the Soft Tissue Ablation Milestone and lacked any endourology incentives. *See* JX 3641 at 5.

including “instruments and accessories required to perform such ablation” by the end of 2022.⁴⁴¹ To meet the milestone, Monarch would need to use the NeuWave FLEX catheter.⁴⁴² But FLEX was in regulatory limbo after the patient death during its lung tissue study.⁴⁴³ A “microwave pole” being developed by another company, which could have replaced FLEX to perform the ablation procedure, became unavailable after its developer was acquired.⁴⁴⁴

Fortis argues that J&J’s efforts obligation required it to promptly conduct a new clinical study on FLEX.⁴⁴⁵ It disagrees with J&J’s initial strategy of advocating to the FDA that an IDE was unnecessary.⁴⁴⁶ Fortis—with the benefit of hindsight—may be correct that J&J’s strategy flopped. That does not mean, however, that J&J’s attempts were commercially unreasonable in real time.

J&J engaged in multiple discussions with the FDA to find the shortest path to regulatory clearance for FLEX, consistent with the Soft Tissue Ablation Milestone.⁴⁴⁷ That the FDA continued to insist J&J conduct clinical trials and seek

⁴⁴¹ Merger Agreement § 2.07(a)(ii).

⁴⁴² Moll Tr. 51.

⁴⁴³ *See supra* notes 172-74 and accompanying text.

⁴⁴⁴ Leparmentier Tr. 995.

⁴⁴⁵ Pl.’s Opening Post-trial Br. 122 (citing Wittwer Tr. 1968-69).

⁴⁴⁶ *Id.* at 80 (arguing that “J&J squandered a meeting with the FDA”); *see* JX 2313 at 8-10; JX 2648 at 35-36.

⁴⁴⁷ *See* Bryant Tr. 2500-01.

an IDE for FLEX related to lung tissue ablation is no fault of J&J. In 2020, at the FDA’s encouragement, J&J obtained a Breakthrough Device Designation for FLEX.⁴⁴⁸ The Breakthrough Device Program is a priority FDA program for devices offering a public health benefit with “significant regulatory advantages.”⁴⁴⁹ By the end of 2020, the FLEX team made several regulatory submissions, held multiple meetings with the FDA, and completed pre-clinical animal studies.⁴⁵⁰ As a result of those efforts, in November 2021, the FDA conditionally approved an IDE for FLEX in lung treatment.⁴⁵¹ Despite that, the remaining clinical data and regulatory submissions for final approval meant that Monarch could not meet the 2022 milestone.

Setting aside whether J&J should have told Auris about the patient death sooner,⁴⁵² J&J’s efforts were commercially reasonable. The delay caused by the patient death and the resulting requirements imposed by the FDA were not in J&J’s control. Although Velys never faced a similar regulatory hurdle, J&J’s iterative and consistent engagement with the FDA for Monarch reflects the sort of efforts one

⁴⁴⁸ JX 3294; *see also* JX 2313 at 10.

⁴⁴⁹ Tillman Rep. ¶ 29.

⁴⁵⁰ *See* JX 3657 at 11.

⁴⁵¹ *See* Tillman Rep. ¶ 288.

⁴⁵² As discussed below, Auris is entitled to recover for this milestone due to fraud. *See infra* Section II.B.4.

would expect it to undertake for a priority device. In setting the level of its efforts, J&J was entitled to consider “the regulatory status of the product and scope of any marketing approval, . . . whether the product is subject to a clinical hold, recall or market withdrawal, [and] input from regulatory experts and any guidance or developments from the FDA.”⁴⁵³ Had J&J succeeded in persuading the FDA that an IDE was not needed for FLEX, it would have saved time for Monarch to meet the Soft Tissue Ablation Milestone.

ii. *Endourology*

The Endourology Milestone required Monarch to obtain 510(k) approval “for endourology procedure(s)” by the end of 2020.⁴⁵⁴ Auris had solved major scientific problems with the procedure and planned to satisfy the milestone with an MVP approach.⁴⁵⁵ Fortis argues that J&J failed to provide adequate resources to do so.⁴⁵⁶ Instead, to address a “known budget gap” in 2020, J&J decided that the “[p]rimary Monarch focus” would be bronchoscopy rather than endourology.⁴⁵⁷

⁴⁵³ Merger Agreement § 2.07(e)(ii)(F), (H)-(I).

⁴⁵⁴ *Id.* § 2.07(a)(i).

⁴⁵⁵ Leparmentier Tr. 983-84, 1017-18.

⁴⁵⁶ Pl.’s Opening Post-trial Br. 81.

⁴⁵⁷ JX 3091 at 3.

Velys received requested funding, space, and personnel.⁴⁵⁸ By comparison, endourology was 15% understaffed and partially underfunded.⁴⁵⁹ But even if Monarch’s endourology team had proportionately less resources than Velys, it is not apparent that J&J’s efforts deviated from its usual practice in supporting research, development, and regulatory interactions for a priority device. J&J logically prioritized a staged approach to Monarch’s development.

Monarch Uro’s planned 510(k) submission depended upon the to-be-approved Monarch Bronch 2.0 three-arm cart first receiving 510(k) clearance.⁴⁶⁰ Monarch could not seek approval for Uro until after Bronch 2.0 obtained it in April 2020.⁴⁶¹ J&J’s efforts and resources in furtherance of bronchoscopy necessarily advanced Monarch’s chance of achieving the Endourology Milestone. The Merger Agreement permitted J&J to consider “the likelihood and difficulty of obtaining FDA and other regulatory approval” in setting the level of its efforts, which would reasonably include focusing on an indication necessary for a subsequent clearance.⁴⁶²

⁴⁵⁸ See JX 356; Thomson Dep. 55; Waterson Dep. 130-31, 341.

⁴⁵⁹ See Leparmentier Tr. 1019-21; JX 3195; JX 3091 at 3.

⁴⁶⁰ See JX 975 at 4 (communicating this plan to the FDA); see also JX 637 at 9-12; JX 673 at 5. Bronch 1.0, which already had 510(k) clearance, only had two arms. Monarch Uro required the Bronch 2.0 three-arm version to be cleared.

⁴⁶¹ Tillman Rep. ¶¶ 223-25.

⁴⁶² Merger Agreement § 2.07(e)(ii)(E).

3. Whether Fortis Was Damaged

Fortis must next prove with “reasonable certainty” that J&J’s breaches of the Merger Agreement caused it injury.⁴⁶³ Fortis contends that J&J’s failure to use commercially reasonable efforts prevented Auris from achieving the iPlatform regulatory, GI, and net sales milestones.⁴⁶⁴ J&J, for its part, asserts that Fortis cannot prove that its injury “flowed from [J&J’s] violation of the contract” rather than “other intervening causes.”⁴⁶⁵ I consider these arguments for iPlatform milestone by milestone.⁴⁶⁶

a. iPlatform Regulatory Milestones

The Merger Agreement outlines six regulatory milestones for iPlatform: the General Surgery Milestone, four umbrella procedure milestones (the Upper Abdominal Milestone, the Lower Abdominal Milestone, the Urologic Milestone,

⁴⁶³ *Siga Techs., Inc. v. PharmAthene, Inc.* (“*Siga II*”), 132 A.3d 1108, 1111 (Del. 2015) (“[W]hen a contract is breached, expectation damages can be established as long as the plaintiff can prove the fact of damages with reasonable certainty.” (emphasis removed)); see also *Cura Fin. Servs. N.V. v. Elec. Payment Exch., Inc.*, 2001 WL 1334188, at *19-20 (Del. Ch. Oct. 22, 2001) (“[R]easonable certainty is not equivalent to absolute certainty; rather, the requirement that plaintiff show defendant’s breach to be the cause of his injury with ‘reasonable certainty’ merely means that the fact of damages must be taken out of the realm of speculation.” (quoting *Tanner v. Exxon Corp.*, 1981 WL 191389 (Del. Super. July 23, 1981))).

⁴⁶⁴ See Pl.’s Opening Post-trial Br. 121-26.

⁴⁶⁵ Defs.’ Answering Post-trial Br. 112 (quoting *LaPoint*, 2007 WL 2565709, at *9).

⁴⁶⁶ Because Fortis did not prove a breach of contract as to J&J’s Monarch-focused efforts, I do not consider whether Fortis suffered damages related to Monarch.

and the Gynecologic Milestone), and the GI Milestone.⁴⁶⁷ Pre-merger, J&J estimated an 85% probability of meeting the General Surgery Milestone and an 75% probability of meeting the umbrella and GI milestones.⁴⁶⁸ J&J insists that its predictions were misguided for two overarching reasons: technical issues and regulatory challenges.⁴⁶⁹

On the technical front, J&J points to evidence of “problems with workspace, thermal issues, system stability, emergency patient access, and instrument performance.”⁴⁷⁰ To be sure, these were challenges that the iPlatform team would need to solve. J&J obstructed Auris’s ability to do so by imposing Project Manhattan shortly after closing, and then combining iPlatform with Verb.

Beyond that, I view J&J’s insistence that technical deficiencies led to the failed milestones with skepticism. J&J engaged in multiple rounds of due diligence, involving experienced Verb engineers and outside robotics experts at Sagentia.⁴⁷¹ J&J gained direct insight through its Auris board observer seat.⁴⁷² J&J knew about iPlatform’s strengths and weaknesses before projecting that the milestones would

⁴⁶⁷ Merger Agreement § 2.07(a)(iii)-(viii).

⁴⁶⁸ JX 3139.

⁴⁶⁹ Defs.’ Answering Post-trial Br. 112-13.

⁴⁷⁰ *Id.*

⁴⁷¹ *E.g.*, JX 447; JX 1076; Mintz Tr. 575-78; *see also* DeFonzo Tr. 354-57.

⁴⁷² *See* PTO ¶ 107; Morano Tr. 1445-47; Mintz Tr. 575-78; McEwen Dep. 71; *supra* note 103 and accompanying text.

likely be achieved and acquiring Auris.⁴⁷³ When J&J wrote down the milestones in April 2020, it cited the FDA pathway change to De Novo—not technical issues—as the basis.⁴⁷⁴

It was only after Fortis sued in October 2020 that J&J began searching for diligence files suggesting technical flaws in iPlatform’s system.⁴⁷⁵ This appears to be tactical backfilling.⁴⁷⁶ One frequently cited example is Auris’s selection of the Silverton-style arm for iPlatform rather than the redesigned Superton arm, which J&J calls a hasty choice detrimental to iPlatform’s success that was hidden from J&J.⁴⁷⁷ As Mintz explained, though, iPlatform’s choice was neither rash nor

⁴⁷³ *E.g.*, JX 1284.

⁴⁷⁴ JX 3139 at 2; *see* Lenard Tr. 1830.

⁴⁷⁵ JX 3814 (Shen telling Joachim to be “THE leader to own the [Auris acquisition] narrative”); *see supra* notes 319-21 and accompanying text.

⁴⁷⁶ For instance, J&J argues that “DeFonzo provided J&J with a version of the iPlatform team’s January 2019 quarterly program review that had been doctored to remove references to significant problems with workspace, thermal issues, and instrument performance” and that “Auris similarly altered other technical materials shared with J&J.” Defs.’ Answering Post-trial Br. 41. The internal version and external version are of the quarterly update are different. *Compare* JX 1130, *with* JX 1113 at 8, 29-34, 35, 37. But there is no credible evidence suggesting that Auris set out to hoodwink J&J or “doctor” documents. Instead, Auris’s internal documents were simply cleaned up and revised before being sent to a potential outside investor/acquiror. *See* DeFonzo Tr. 510-14.

⁴⁷⁷ Defs.’ Post-trial Answering Br. 62; *see* Defs.’ Dem. 22 at 53-60. J&J relied on the expert opinion of Dr. Moiz Khan to support its argument that iPlatform’s design and system suffered from fatal flaws. Khan’s critiques of iPlatform were based on his review of a subset of documents and videos. He never operated the robot and saw the robot just once in passing. Khan Tr. 2971-73. Because of his limited exposure to the robot, I give his testimony about specific challenges facing iPlatform little weight.

nefarious; it was strategic and evident.⁴⁷⁸ Nevertheless, I weigh specific arguments in the context of each milestone despite my overarching cynicism that technical problems are to blame for the missed milestones.

On the regulatory front, the primary matter raised by J&J is the FDA's pivot from the 510(k) to the De Novo pathway for RASDs. This change, in J&J's estimation, "doomed any hope of meeting the milestones."⁴⁷⁹ The milestone most directly affected by the pathway change is the General Surgery Milestone. If iPlatform had timely obtained De Novo approval for one upper and one lower abdominal surgical procedure, it could follow the 510(k) pathway for the subsequent regulatory milestones.⁴⁸⁰ As such, I mainly consider the effects of the FDA's

⁴⁷⁸ Mintz Tr. 718 ("So this balance of reach, access, stiffness, bandwidth, you have to get all of those right. And having gotten the stiffness and bandwidth we did in a long, skinny arm was not something to give up lightly. And we were completing procedures."); *id.* at 711 ("None of these risks were hidden."). Mintz was a compelling witness. He had extensive experience developing successful RASDs, including at Intuitive. He was vital to iPlatform's development and has unmatched knowledge of the design and development process from its infancy in 2016 through the selection of the beta design in early 2021. *Id.* at 711-12. Mintz testified candidly about iPlatform's technical challenges and what it took to solve them. *See, e.g., id.* at 619-22. Despite Mintz's passion for the iPlatform system and his financial incentives, his testimony was highly credible relative to that of Khan. .

⁴⁷⁹ Defs.' Answering Post-trial Br. 111.

⁴⁸⁰ *See* Wittwer Rep. ¶ 22 ("If iPlatform had obtained De Novo approval for its general surgery application, J&J could have used iPlatform itself as a predicate device allowing use of the 510(k) pathway for pre-market clearance of further indications contemplated under subsequent 'umbrella' regulatory milestones for iPlatform. This would have reduced the regulatory approval timelines for these later applications."); *see also* Wittwer Tr. 1959.

position change in the context of the General Surgery Milestone. It is with that milestone that I begin.

i. *General Surgery Milestone*

The General Surgery Milestone required iPlatform to receive 510(k) clearance “for one upper abdominal surgical procedure” and “one lower abdominal surgical procedure” by the end of 2021.⁴⁸¹ iPlatform was on track to meet this milestone at the time of the merger. Before closing, iPlatform’s pre-alpha prototype had completed procedures that would have satisfied it.⁴⁸²

iPlatform’s program timeline gave it five months to secure an initial 510(k) approval.⁴⁸³ This was “ambitious.”⁴⁸⁴ To reduce risk, Auris built in a “healthy” buffer of five additional months, ending on the last day of 2021.⁴⁸⁵ Based on iPlatform’s progress and optionality over which upper and lower clinical indications to pursue, the Auris team believed that the iPlatform General Surgery Milestone would likely be met.⁴⁸⁶

⁴⁸¹ Merger Agreement § 2.07(a)(iii).

⁴⁸² See JX 5012 at 1; JX 699 at 9; JX 2610; Mintz Tr. 579-80; Gardiner Tr. 743-51.

⁴⁸³ JX 1689 at 13-14; Mintz Tr. 579-80.

⁴⁸⁴ DeFonzo Tr. 505-06.

⁴⁸⁵ *Id.*; see also Mintz Tr. 659-60 (explaining that the timelines reflected “when we could reasonably, aggressively expect things to go” plus a buffer).

⁴⁸⁶ JX 1413 at 2 (estimating a 65% probability of success for the first milestone); Mintz Tr. 580.

The record supports Auris’s assessment. After the merger, iPlatform continued to receive high marks from surgeons.⁴⁸⁷ It performed well in Project Manhattan.⁴⁸⁸ It went on to successfully complete 40 cadaver labs from mid-2019 to early 2020 in which all milestone procedures were performed—including the most complex LAR and RYGB procedures.⁴⁸⁹ The labs were, at times, imperfect and some physicians disliked the iPlatform system.⁴⁹⁰ But regulatory approval is measured by clinical safety and effectiveness—not commercial readiness.⁴⁹¹ It is

⁴⁸⁷ See generally Pl.’s Dem. 13 (lab results).

⁴⁸⁸ See *supra* notes 252-56 and accompanying text; see Wittwer Tr. 1957 (testifying that, in her opinion as a regulatory expert, iPlatform’s results in Project Manhattan would be “sufficient to . . . proceed to the next stages of product development for certain procedures”).

⁴⁸⁹ Pl.’s Dem. 13, lines 12-51 (showing that iPlatform completed cadaver lab procedures including 14 LARS, 10 RYGBs, 6 ventral hernias, 1 inguinal hernia, 2 partial nephrectomies, and 1 hysterectomy); Gardiner Tr. 752-53, 772, 800-03. Gardiner completed over 30,000 surgeries in his decades-spanning career, with about 30% being performed with a RASD. *Id.* at 722-23. He also instructed other surgeons on how to perform robotic surgeries and worked with Moll at Intuitive in developing the da Vinci robot. *Id.* at 724. Despite his financial incentives as an Auris stockholder, his testimony was highly credible.

⁴⁹⁰ *E.g.*, JX 699 at 37; JX 3047; JX 3550. iPlatform was not for everyone. Hagen, one of the Project Manhattan KOPs involved with developing Verb, strongly disliked the architecture of iPlatform. She preferred a live assistant rather than the fifth robotic arm. Gardiner Tr. 768-71; Hagen Tr. 2344-45.

⁴⁹¹ See Wittwer Rep. ¶ 179 (“Medical devices do not need to be fully ready to enter large-scale commercial distribution before a company seeks regulatory clearance for them.”); Wittwer Tr. 1954; Grennan Tr. 2547 (acknowledging the difference between regulatory maturity and commercial readiness for a complex medical device); see also Gardiner Tr. 726-28.

often desirable to obtain regulatory clearance for a prototype without the full functionality of a planned commercial device.⁴⁹²

In September 2021, J&J acknowledged that iPlatform would be capable of the Nissen fundoplication procedure that would satisfy an upper abdominal surgery indication.⁴⁹³ For the lower abdominal indication, inguinal hernia labs from 2019 through 2020 show iPlatform’s capacity to successfully perform the procedure.⁴⁹⁴ Surgeons performing those labs rated iPlatform’s performance as “superior to” or “competitive with” da Vinci.⁴⁹⁵ In September of 2021, J&J again acknowledged that iPlatform would be capable of inguinal hernia and appendectomy—both lower abdominal procedures that would satisfy the first milestone.⁴⁹⁶ If the results were replicated through the verification and validation phases, there would be sufficient

⁴⁹² See Wittwer Tr. 1955-56 (“[I]t’s actually desirable to submit your first application with fewer features and focusing on a select procedure or two to obtain that first De Novo clearance.”); Wittwer Rep. ¶¶ 179-81. Auris’s ARES robot is one such example. See Leparmentier Tr. 977 (explaining that ARES received FDA clearance using an MVP strategy and was never intended to be commercially launched); Moll Tr. 293-94.

⁴⁹³ JX 4129 at 27 (“Based on experience with primary procedures, system should [] be capable of: . . . Nissen Fundoplication”). As discussed above, Auris initially considered pursuing either Nissen fundoplication or RYGB for its first upper abdominal procedure. See *supra* note 404 and accompanying text; JX 1729 at 21-22.

⁴⁹⁴ See Pl.’s Dem. 13; JX 1541.

⁴⁹⁵ JX 2622 at 15 (four 2019 iPlatform inguinal hernia labs completed with “high confidence” with ratings of “[b]est in class” and “superior to Da Vinci”); JX 3610 at 2 (Gardiner in 2020 reporting to Joachim that iPlatform’s inguinal hernia procedure was “largely cooked” and “already competitive to the predicate”).

⁴⁹⁶ JX 4129 at 16 (“Beta will be capable in Inguinal Hernia[.]”); *id.* at 17 (“Beta system should be capable based on experience with primary procedure(s): Appendectomy[.]”).

data for the FDA to assess iPlatform’s safety and effectiveness for the proposed indication.⁴⁹⁷ iPlatform could obtain approval for a single successful procedure.⁴⁹⁸

Overall, the record supports a finding that iPlatform would likely have met the General Surgery Milestone had J&J fulfilled its promises to Auris. iPlatform was on track to achieve the milestone before Project Manhattan and the Verb integration. J&J’s insistence that iPlatform pursue a five-arm RYGB, instead of simpler procedures using a minimally viable device, made matters worse. J&J’s adoption of new employee incentives in 2020 that conditioned the first payment on achieving a complex general surgery indication further re-directed resources away from the General Surgery Milestone. It is reasonably certain that J&J’s breach of its efforts obligation (and, as discussed below, an implied term regarding the De Novo pathway) damaged Auris by preventing it from timely securing regulatory approval.

Technical Problems. J&J contends that, regardless of its conduct, iPlatform could never have met the General Surgery Milestone because of “fundamental technical challenges” with the system’s workspace.⁴⁹⁹ Workspace relates to the architecture of the robot, such as whether the arms experience collisions during procedures.⁵⁰⁰ The record provides little support for J&J’s assertion. Although

⁴⁹⁷ Wittwer Tr. 1958.

⁴⁹⁸ *Id.* at 1959.

⁴⁹⁹ Defs.’ Post-trial Answering Br. 59.

⁵⁰⁰ Moll Tr. 270-71.

workspace issues arose, numerous lab reports show that iPlatform had the capability to safely and effectively complete procedures to satisfy the milestone.⁵⁰¹

The other technical issues J&J cites were “surmountable.”⁵⁰² They were similar to ones Auris leadership had tackled at Intuitive 20 years earlier.⁵⁰³ Thermal issues made the robot hot to the touch.⁵⁰⁴ iPlatform’s system was sometimes unstable.⁵⁰⁵ And a worst-case scenario persisted since the robot’s arm setup meant that a very large patient could not be transported from the operating table to a gurney if a hospital lost power mid-procedure.⁵⁰⁶ Such engineering challenges are expected while developing a highly complex medical device.⁵⁰⁷

⁵⁰¹ *E.g.*, Pl.’s Dem. 13; JX 3685 at 7 (reporting “[a]dequate approach and workspace for 4-arm RYGB to move forward with US IDE” as of November 2020); JX 4129 at 15-19 (stating that iPlatform would be “capable” in Nissen fundoplication, inguinal hernia, small ventral hernia, appendectomy, prostatectomy, and hysterectomy, among other procedures); *see also* Khan Tr. 3004 (testifying that “capable” means safe, effective, and able to complete the procedure).

⁵⁰² Kilroy Tr. 2136-37 (“Other engineering challenges, I saw them as more surmountable . . . [T]he real showstoppers for the system were workspace and collisions.”); Khan Day 1 Dep. 543 (“I didn’t state many issues being fundamental and existential. I only said that to the workspace . . .”).

⁵⁰³ Mintz Tr. 561.

⁵⁰⁴ This was known to J&J during diligence. *See* JX 1284 at 12; Mintz Tr. 716 (Mintz recalling J&J’s engineer touching an iPlatform arm during diligence and commenting on the temperature).

⁵⁰⁵ Mintz Tr. 572-73.

⁵⁰⁶ Joachim Tr. 2233, 2236-38. J&J cites iPlatform’s poor instrument performance as another flaw. As Joachim admitted, however, instrument performance would not prevent iPlatform from meeting regulatory milestones. *Id.* at 2173-77.

⁵⁰⁷ Mintz Tr. 572-73.

Many of these issues would not inhibit straightforward procedures that could satisfy the General Surgery Milestone, such as Nissen fundoplication and inguinal hernia, which the pre-alpha robot had successfully performed. Advanced capabilities, like using five or six arms, were not necessary to perform these procedures safely and effectively for regulatory purposes.⁵⁰⁸ Despite that, the iPlatform team had been working to address various technical problems.⁵⁰⁹ It was derailed when iPlatform was forced to participate in Project Manhattan and then combine with a separate system. These complications—all imposed by J&J—not only delayed iPlatform’s progress but also imposed months of technical debt and unanticipated roadblocks.

Regulatory Problems. J&J also argues that the iPlatform General Surgery Milestone was unmet due to the FDA’s pathway change. The General Surgery Milestone (like all iPlatform regulatory milestones) required iPlatform to obtain “510(k) clearance.”⁵¹⁰ But in August 2019, the FDA said that the 510(k) pathway was unavailable to RASDs.⁵¹¹ iPlatform unexpectedly had to follow the De Novo pathway.

⁵⁰⁸ *Id.* at 580-81.

⁵⁰⁹ Moll Tr. 80-82; Mintz Tr. 550, 582, 620-22.

⁵¹⁰ Merger Agreement § 2.07(a)(iii).

⁵¹¹ JX 2512 at 4-5.

J&J suggests that this position change meant it was off the hook for the General Surgery Milestone. Not so. The obvious goal of the General Surgery Milestone was for iPlatform to obtain FDA approval. In contrast to other provisions of the Merger Agreement, there is no evidence that 510(k) (versus another pathway) was specifically negotiated.⁵¹² That is because at the time of the Merger Agreement, a “510(k) process” was the “only logical pathway for a robotic device.”⁵¹³ When that understanding changed four months after the merger, J&J viewed the availability of De Novo (rather than PMA) as a victory.⁵¹⁴

Yet, the iPlatform General Surgery Milestone expressly contemplates “510(k) premarket notification[],” which was no longer an option for iPlatform post-pathway shift.⁵¹⁵ To address this wrinkle in its breach of contract claim, Fortis presents an implied covenant theory.⁵¹⁶ It asserts that after the FDA’s pathway change, the

⁵¹² DeFonzo Tr. 363-64 (testifying that the parties “never even discussed” a non-510(k) pathway); Moll Tr. 58-59. J&J originally argued that this term was “highly negotiated.” Defs.’ Pre-trial Br. (Dkt. 504) 2. It did not press that argument after trial.

⁵¹³ Moll Tr. 58-59.

⁵¹⁴ Shen Tr. 1174; Wittwer Tr. 1953.

⁵¹⁵ Merger Agreement § 2.07(a)(iii). As noted above, the subsequent umbrella milestones could be obtained through 510(k) if iPlatform received De Novo clearance. *See supra* note 282 and accompanying text; Wittwer Tr. 1949.

⁵¹⁶ PTO ¶ 5. Fortis also advanced a mutual mistake claim that was also premised on the change in FDA policy regarding the availability of the 510(k) pathway for iPlatform. *Id.* Because documents Fortis sought through a FOIA request were not produced in time for trial, Fortis withdrew its mutual mistake claim. *See* Dkts. 525, 527.

implied covenant of good faith and fair dealing required J&J to pursue De Novo approval instead.⁵¹⁷ I agree.⁵¹⁸

Implied Covenant. “The implied covenant [of good faith and fair dealing] is inherent in all contracts.”⁵¹⁹ It “embodies the law’s expectation that ‘each party to a contract will act with good faith toward the other with respect to the subject matter of the contract.’”⁵²⁰ The implied covenant “ensures that parties do not ‘frustrat[e] the fruits of the bargain’ by acting ‘arbitrarily or unreasonably.’”⁵²¹ “The reasonable expectations of the contracting parties are assessed at the time of contracting.”⁵²²

At the time the Merger Agreement was signed, all parties assumed that 510(k) would be an available pathway for iPlatform.⁵²³ The FDA had indicated in October 2018 that iPlatform could receive 510(k) clearance with the appropriate clinical data

⁵¹⁷ Pl.’s Opening Post-trial Br. 130-31.

⁵¹⁸ In my decision denying J&J’s motion to dismiss the implied covenant claim, I noted that this is precisely the sort of situation where the “implied covenant comes into play.” Mem. Op. Regarding the Defs.’ Mot. to Dismiss (Dkt. 44) (“MTD Mem. Op.”) 38. That observation remains true after trial.

⁵¹⁹ *Baldwin v. New Wood Res. LLC*, 283 A.3d 1099, 1116 (Del. 2022) (citation omitted).

⁵²⁰ *Sheehan v. Assured P’rs, Inc.*, 2020 WL 2838575, at *11 (Del. Ch. May 2020) (quoting *Allied Cap.*, 910 A.2d at 1032).

⁵²¹ *Baldwin*, 283 A.2d at 1116 (quoting *Dieckman v. Regency GP LP*, 155 A.3d 358, 367 (Del. 2017)).

⁵²² *Dieckman*, 155 A.3d at 367.

⁵²³ See JX 3253 at 1 (contemporaneous notes of meeting about regulatory affairs from a May 14, 2020 call where Kozak says: “During acquisition [we] had assumed 510k was appropriate.”).

and predicate device.⁵²⁴ It warned only that 510(k) might be unavailable because the proposed predicate device (a da Vinci robot) lacked a bronchoscope and Auris had listed a bronchoscopy indication for iPlatform.⁵²⁵ Auris resolved this mismatch in its subsequent submission by withdrawing bronchoscopy from iPlatform’s planned indication and selecting a more apt da Vinci predicate.⁵²⁶ Neither Auris nor J&J had reason to believe that a more onerous pathway would be required.⁵²⁷ In

⁵²⁴ JX 743 at 3 (“While our review of your pre-submission does not imply that your future submission will necessarily be approved or cleared, FDA intends that this feedback will not change, provided that the information submitted in a future IDE or marketing application is consistent with that provided in this pre-submission and that the data in the future submission do not raise any important new issues materially affecting safety or effectiveness.”); *id.* at 5-6.

⁵²⁵ *Id.* at 4 (“You propose the da Vinci Xi K131861 as the predicate device. While the Indications for Use IFU statements of your subject device and your predicate appear to be similar the intended use of your subject device does not appear to be the same as your proposed predicate device[.] For example your proposed predicate is not intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures and does not contain a bronchoscope.”); *id.* at 1; *see supra* notes 70-71 and accompanying text.

⁵²⁶ JX 2468 at 5 (“[G]iven FDA’s concern of using a predicate not indicated for bronchoscopic procedures, Auris has decided to remove the use of a bronchoscope from the initial submission.”); Mintz Tr. 604-06 (“Question: ‘Was [] the FDA telling Auris it would not approve iPlatform under the 510(k) pathway?’ Mintz: ‘It was not . . . They’re pointing out that the da Vinci Xi does not have bronchoscopic capability . . . so we removed that from our indications for use. . . . There’s another da Vinci 510(k) that uses a robotic bed in conjunction with the system, and that was a more appropriate predicate. So we adjusted our submission to use that more appropriate predicate.’”).

⁵²⁷ *See In re El Paso Pipeline P’rs, L.P. Deriv. Litig.*, 2014 WL 2768782, at *18 (Del. Ch. June 12, 2014) (observing that the implied covenant of good faith and fair dealing is properly invoked where “the parties simply failed to foresee the need for the term and, therefore, never considered to include it”); *see also Nemec v. Shrader*, 991 A.2d 1120, 1128 (Del. 2010).

fact, J&J was surprised in August 2019 when it learned that Verb had to follow the De Novo pathway instead of 510(k).⁵²⁸

J&J argues that requiring 510(k) approval was a material term to the Merger Agreement because the specific pathway affects the time to market, the resources required, and the deal value.⁵²⁹ But there is no evidence that the parties bargained for 510(k) instead of De Novo.⁵³⁰ J&J knew pre-merger that the FDA required extensive clinical testing for iPlatform to secure 510(k) approval.⁵³¹ Though De Novo approval is generally more onerous, the primary difference for iPlatform was FDA review time, which J&J predicted would only add two months of delay.⁵³² The FDA required iPlatform to submit clinical testing data under either the 510(k) or De Novo pathway.⁵³³

⁵²⁸ See JX 2512 at 4-5.

⁵²⁹ Defs.’ Answering Post-trial Br. 51-53.

⁵³⁰ See *supra* note 512; *cf. Aspen Advisors LLC v. United Artists Theatre Co.*, 843 A.2d 697, 707 (Del. Ch. 2004) (explaining that the implied covenant will not fill a gap if the parties discussed and rejected it), *aff’d*, 861 A.2d 1251 (Del. 2004).

⁵³¹ See JX 1284 at 4, 12; JX 1504 at 5.

⁵³² JX 2396 at 15 (predicting a De Novo review would change Verb’s launch from April 2022 to June 2022); *see also* Wittwer Tr. 1949-50 (“Per FDA regulation, a 510(k) is a 90-day review clock. And a De Novo application is a 150-day review time.”); Wittwer Rep. ¶¶ 158-60 (opining that the shift to De Novo review caused an approximately 60 day delay). Wittwer’s opinion was reliable. In addition to her educational and professional background, she has submitted and received FDA clearance on over fifty 510(k) applications and three De Novo applications. Wittwer Rep. ¶ 10.

⁵³³ See JX 2396 at 12 (J&J concluding there was “[n]o significant timeline differences” for Verb to achieve De Novo “as compared to a 510(k)”; Tillman Tr. 2823-24 (acknowledging

Had the parties known that 510(k) would become unavailable for RASDs, they logically would not have listed 510(k) as the method of obtaining regulatory approval in the Merger Agreement.⁵³⁴ The Merger Agreement lacked a term to address what would occur if the 510(k) pathway were closed to iPlatform. When this change arose, however, J&J had an implied obligation—at least for the iPlatform General Surgery Milestone—to use commercially reasonable efforts to achieve De Novo clearance. Doing so would facilitate 510(k) approval for the subsequent milestones, which I address next.⁵³⁵ But J&J failed to utilize such diligence.⁵³⁶ It cannot avoid liability by scapegoating an unforeseen policy change that had an immaterial effect on the time and cost for iPlatform to gain FDA clearance.⁵³⁷

that iPlatform’s 510(k) process would be in the “minority of 510(k) submissions that require clinical data”).

⁵³⁴ See *Oxbow Carbon & Mins. Hldgs., Inc. v. Crestview-Oxbow Acq., LLC*, 202 A.3d 482, 506-07 (Del. 2019) (explaining that the implied covenant exists to address “unanticipated developments”); *Blaustein v. Lord Balt. Cap. Corp.*, 84 A.3d 954, 959 (Del. 2014) (“[T]he implied covenant is used in limited circumstances to include what the parties would have agreed to themselves had they considered the issue in their original bargaining positions at the time of contracting.” (citation omitted)).

⁵³⁵ JX 2396 at 12 (“Once De Novo classification is granted, the device can be used as predicate for future 510(k) submissions.”); Wittwer Tr. 1946, 1959.

⁵³⁶ See *supra* Section II.A.2.a.

⁵³⁷ Because I find that Fortis has prevailed on its implied covenant claim, I need not address its alternate theory that J&J should be ordered to “negotiate in good faith” to modify the Merger Agreement from 510(k) to De Novo to “effect the original intent of the parties.” Merger Agreement § 10.11; see also *id.* § 8.04(b); Pl.’s Opening Post-trial Br. 132-33.

ii. *Umbrella Milestones*

Auris also proved that J&J’s breaches of the Merger Agreement were reasonably certain to have led Auris to miss four 2023 iPlatform regulatory milestones: the Upper Abdominal Milestone, the Lower Abdominal Milestone, the Urologic Milestone, and the Gynecologic Milestone. Had J&J used commercially reasonable efforts in furtherance of the iPlatform General Surgery Milestone, the 510(k) pathway would have been open. The delays caused by Project Manhattan and dysfunction from the Verb combination/integration, among other breaches, led to compounding delays that put the milestones in peril. The evidence demonstrates that each of these umbrella milestones were likely to be met had J&J provided commercially reasonable efforts and resources to iPlatform as a priority device.⁵³⁸

Upper Abdominal Milestone. The Upper Abdominal Milestone required iPlatform to receive 510(k) approval for an “upper abdominal Umbrella Procedure[.]” by the end of 2023.⁵³⁹ The RYGB procedure would have satisfied this milestone.⁵⁴⁰ iPlatform was on track to achieve it.

⁵³⁸ See JX 2683 at 3, 26-27 (Accelerando and Cambridge November 2019 projection that iPlatform could achieve the 2023 milestones).

⁵³⁹ Merger Agreement § 2.07(a)(iv); see *id.* § 10.03(uuu) (defining “Umbrella Procedure” as “any procedure or procedure category within a specialty, which represents higher complexity or risk and when cleared by the FDA includes covered procedures of less complexity or lower risk within that specialty”).

⁵⁴⁰ See JX 1729.

Surgeons using iPlatform successfully completed RYGBs in 12 labs between June 2019 and the first quarter of 2020—both during and after Project Manhattan.⁵⁴¹ Surgeons performed 21 four-arm RYGB cadaver labs from August to November 2020 with iPlatform. Four different surgeons gave iPlatform all A and B grades during the final six “repeatability” labs performed in November, which were designed to test surgical techniques refined during earlier “procedure development” labs.⁵⁴² iPlatform continued to demonstrate capability in RYGB with at least 11 cadaver labs completed in 2021. Although two surgeons gave iPlatform lower (but still adequate) ratings in these labs, three others rated iPlatform A+, A, and B in all categories.⁵⁴³

To the extent J&J argues that technical issues caused iPlatform to miss the milestone, the trial record suggests otherwise. For example, after successful cadaver labs in November 2020, Joachim (who led the iPlatform team at the time) determined there was “[a]dequate approach workspace for 4-arm [RYGB] to move forward” to clinical trials.⁵⁴⁴ Put differently, workspace issues did not prevent iPlatform from

⁵⁴¹ See e.g., JX 2131 at 26-27 (June 2019 five-arm RYGB rated by physician as “nearly ready for clinical use”); JX 3047 at 57 (Nov. 2019 five-arm RYGB rated by same physician as on par with da Vinci); see also Pl.’s Dem. 13.

⁵⁴² JX 3603 at 7.

⁵⁴³ See e.g., JX 3948 at 1 (May 2021 five-arm RYGB by surgeon performing his first lab on iPlatform, rating iPlatform’s performance either A or A+ across the board); see also Pl.’s Dem. 13.

⁵⁴⁴ JX 3685 at 7.

proceeding to clinical trials for the four-arm procedure. This assessment was three years before the milestone deadline.⁵⁴⁵

Lower Abdominal Milestone. The Lower Abdominal Milestone required iPlatform to obtain 510(k) approval for a “colorectal/lower abdominal Umbrella Procedure[]” by the end of 2023.⁵⁴⁶

The LAR procedure could satisfy the milestone. During Project Manhattan, a KOL successfully completed it using iPlatform.⁵⁴⁷ Between July 2019 and January 2020, surgeons performed 14 additional LAR cadaver labs using the iPlatform.⁵⁴⁸ J&J only produced written reports for five of these labs, but all show successful results.⁵⁴⁹ From April to June 2021, surgeons performed 15 more LAR cadaver labs

⁵⁴⁵ J&J’s insistence on a full-featured iPlatform beta that could perform RYGB for the *first* regulatory approval effectively forced iPlatform to meet the Upper Abdominal Milestone two years early. *See supra* Section II.A.2.a.iii.

⁵⁴⁶ Merger Agreement § 2.07(a)(v).

⁵⁴⁷ JX 2125 at 21-22; *see also* JX 1541 (March 2019 report of iPlatform “[s]uccessful access of relevant workspaces for LAR”).

⁵⁴⁸ *See* Pl.’s Dem. 13.

⁵⁴⁹ *See id.* Records for hundreds of iPlatform labs were not produced by J&J. Fortis asks me to conclude that this amounts to spoliation, and that I should infer that the withheld or destroyed lab materials confirm iPlatform’s capabilities. *See* Pl.’s Opening Post-trial Br. 119-120; *see also* Pl.’s Mot. in Limine for an Adverse Inference Due to Spoliation and/or Withholding of Evidence of iPlatform Lab Procedures (Dkt. 465). Though there are gaps in the record where information has been lost, J&J also produced a substantial amount of materials from a design history file and other records. I lack grounds to find that J&J’s non-production rises to the level of reckless or intentional spoliation of evidence and decline to draw an adverse inference. *See Sears, Roebuck & Co. v. Midcap*, 893 A.2d 542, 552 (Del. 2006). At the same time, it would be inequitable to infer that iPlatform did *not* successfully perform these labs based upon J&J’s failure to produce the underlying data. I

on iPlatform. Based on the 11 procedures for which J&J produced lab data, iPlatform performed well. For all but one of these 11 labs, iPlatform was rated above, equivalent to, or near da Vinci on all metrics.⁵⁵⁰ In February 2022, a five-arm LAR was performed that overall met or exceeded da Vinci’s performance.⁵⁵¹

Urologic Milestone. The Urologic Milestone required iPlatform to obtain 510(k) approval for a “urological Umbrella Procedure[]” by the end of 2023.⁵⁵² Lab records show that iPlatform could perform prostatectomy and partial nephrectomy—two procedures that Auris could have used to satisfy the milestone.⁵⁵³

iPlatform demonstrated its capability to perform a prostatectomy as early as 2018.⁵⁵⁴ Post-merger, surgeons completed 19 prostatectomy cadaver labs on iPlatform, rating iPlatform’s performance as above or equivalent to da Vinci on most

view the missing information as neutral. Even without it, Fortis proved by a preponderance of the evidence that iPlatform was on track to meet the milestones before J&J’s breaches.

⁵⁵⁰ See e.g., JX 3992 at 2 (rating iPlatform A+ or A across all metrics, with “[n]o workspace/collision issues” and instrument trajectories superior to da Vinci); see also Pl.’s Dem. 13; Pl.’s Dem. 20 (five-arm LAR lab on iPlatform in June 2021; surgeon reporting “high[] satis[faction]”).

⁵⁵¹ Gardiner Tr. 825-27. J&J produced no records for labs after June 2021. See Pl.’s Dem. 13 at rows 204-35. Gardiner, however, credibly testified to his personal experience with the iPlatform system performing this procedure.

⁵⁵² Merger Agreement § 2.07(a)(vi).

⁵⁵³ See, e.g., JX 2610 at 3, 10 (partial nephrectomy performed with “high confidence”); JX 4013 at 3, 10 (reporting 17 prostatectomy labs “with almost all A ratings, and a good range of patients”); see *supra* notes 73, 255 (explaining these procedures).

⁵⁵⁴ Moll Tr. 87-88; Mintz. Tr. 552-53; Gardiner Tr. 746-49 (“It worked perfectly.”).

metrics.⁵⁵⁵ In 2021, J&J concluded that iPlatform would be capable in prostatectomy.⁵⁵⁶

iPlatform was also successfully performing partial nephrectomies. During Project Manhattan, a KOP completed a partial nephrectomy on iPlatform and rated it “nearly ready for clinical use.”⁵⁵⁷ Two more partial nephrectomy cadaver labs were completed in 2019 with strong results.⁵⁵⁸ From July to December 2021, surgeons completed 12 more partial nephrectomy cadaver labs on iPlatform. Based on the subset of lab results J&J produced, these procedures were also successful and the iPlatform system was rated equivalent to da Vinci on most metrics.⁵⁵⁹

Gynecologic Milestone. The Gynecologic Milestone required iPlatform to obtain 510(k) clearance for a “gynecological Umbrella Procedure[.]” by the end of 2023.⁵⁶⁰ Auris intended to satisfy the milestone with a hysterectomy indication.

⁵⁵⁵ See JX 4013 at 10 (17 surgeons giving almost all A ratings and a few Bs); Gardiner Tr. 812-13; *see also* Pl.’s Dem. 13; Pl.’s Dem. 20 at 4 (two surgeons rating iPlatform with A+s, As, and a few Bs across relevant metrics during five prostatectomies each on iPlatform, with three other surgeons giving similar ratings during one prostatectomy each).

⁵⁵⁶ JX 4129 at 18 (“Beta system will be capable in Prostatectomy[.]”).

⁵⁵⁷ JX 2131 at 21-22.

⁵⁵⁸ See JX 2610 at 10 (surgeon writing: “Everything feels like you could go to market today, the motion of tools feels good and the workspace is great.”); Gardiner Tr. 797-98 (recalling watching this procedure); *see also* Pl.’s Dem. 13.

⁵⁵⁹ Pl.’s Dem. 13; *see also* Gardiner Tr. 821-22 (describing his performance of these procedures).

⁵⁶⁰ Merger Agreement § 2.07(a)(vii).

During Project Manhattan, a KOP successfully completed a hysterectomy with iPlatform’s alpha version.⁵⁶¹ This procedure was especially notable because it was the first using iPlatform’s sixth arm.⁵⁶²

In total, iPlatform completed at least five successful hysterectomy cadaver labs.⁵⁶³ If replicated, these procedures would show that iPlatform was safe and effective in hysterectomy from a regulatory standpoint.⁵⁶⁴ J&J concluded in September 2021 that iPlatform was expected to be capable in hysterectomy.⁵⁶⁵

iii. *GI Milestone*

The GI Milestone required either iPlatform or Monarch to secure 510(k) clearance for “Endoscopic Submucosal Dissection (ESD)” by the end of 2023.⁵⁶⁶ At the time of the merger, it was expected that the milestone could be met by the deadline with iPlatform.⁵⁶⁷

⁵⁶¹ JX 2131 at 27-28.

⁵⁶² *Id.* at 8-9, 27-28; *see also* Mintz Tr. 596-98; Pl.’s Dem. 8 (video of the procedure).

⁵⁶³ JX 2131 at 27-28; JX 2610 at 11 (surgeon: “This is so much easier than what I currently do.”); Pl.’s Dem. 13.

⁵⁶⁴ Wittwer Tr. 1958.

⁵⁶⁵ JX 4129 at 19 (“Beta system expected to be capable in Hyster[e]ctomy[.]”).

⁵⁶⁶ Merger Agreement § 2.07(a)(viii). ESD is a procedure using an endoscope to remove precancerous and cancerous areas in the GI tract. *See Endoscopic Submucosal Dissection*, Johns Hopkins Medicine, <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/endoscopic-submucosal-dissection> (last visited August 31, 2024).

⁵⁶⁷ JX 1729 at 16 (projecting Q2 2023 for iPlatform GI indication clearance and adding in a buffer time period); JX 3139 at 1 (J&J predicting a 75% chance of achieving the eighth regulatory milestone (GI) with iPlatform).

In the year after the merger, a small research team reporting to Leparmentier demonstrated the feasibility of performing ESD on either system.⁵⁶⁸ In December—four years before the milestone deadline—the Monarch team completed a “very successful” ESD on a live pig with Auris-designed instruments that could be used on iPlatform.⁵⁶⁹ Leparmentier was confident at that point that the GI milestone would be met, provided that the GI team was given resources to move toward product development.⁵⁷⁰ But J&J deprioritized GI.⁵⁷¹

In a presentation to J&J leadership on April 6, 2020, the GI team recommended that ESD clearance be pursued on iPlatform first and Monarch later.⁵⁷² Leparmentier supported this strategy, understanding that J&J intended to launch iPlatform in the near term.⁵⁷³ The plan never came to fruition because of Project Manhattan and the Verb integration.

⁵⁶⁸ Leparmentier Tr. 1003-04.

⁵⁶⁹ JX 2867 at 12 (report of “completed” colon ESD procedure “in a live porcine model” on Dec. 18, 2019); Leparmentier Tr. 1004-06.

⁵⁷⁰ Leparmentier Tr. 1006.

⁵⁷¹ See JX 3091 at 3; Leparmentier Tr. 1008; see also JX 3451 (Shen directing the GI team to limit its efforts to “skunk R&D work”—exploratory research with minimal resources).

⁵⁷² JX 3148 at 38-40; Leparmentier Tr. 1010, 1085-86 (describing how pursuing the GI indication on iPlatform made commercial sense for customers and insurers); Lopes Tr. 2441-42 (discussing that GI capability was a “better fit” for iPlatform).

⁵⁷³ Leparmentier Tr. 1010.

The ESD indication is perhaps the one for which iPlatform was least prepared to seek clearance. But J&J's failure to use commercially reasonable efforts derailed iPlatform's plan to build towards endoluminal capability. As iPlatform's MVP approach was lost, so too was its readiness to perform GI procedures.

Having failed iPlatform, one would expect that J&J would redirect its GI Milestone-related efforts to Monarch. Monarch had made strides in ESD during 2019 and 2020.⁵⁷⁴ There is no evidence, though, that J&J tried to use Monarch for the achievement of the GI Milestone.

At trial, J&J spent little time defending its approach to the GI Milestone except to highlight iPlatform's purported technical defects. This is not compelling.⁵⁷⁵ The record supports a finding that J&J's breach of the Merger Agreement is reasonably certain to have harmed to Fortis. Failed efforts and resulting delays snowballed, leaving iPlatform unable to timely meet the GI Milestone.

b. Net Sales Milestone

The Merger Agreement includes two net sales milestones. The first would have been met if J&J's "Robotics Net Sales" reached "\$575 million in the aggregate"

⁵⁷⁴ See JX 2867 at 12: Leparmentier Tr. 1004-06; JX 3075 at 17 (physician in February 2020 praising Monarch GI as an "[i]mmense improvement over traditional ESD" after completing a lab on a porcine colon).

⁵⁷⁵ See *supra* notes 475-78 and accompanying text.

during 2022 or sooner.⁵⁷⁶ The second could be met if “Robotics Net Sales” reached “\$1,650 million in the aggregate” during 2024 or sooner.⁵⁷⁷

By its terms, the efforts provision in Section 2.07(e) does not apply to the net sales milestones.⁵⁷⁸ The sole constraint for J&J with respect to the net sales milestones is in Section 2.07(e)(iii), which bars J&J from taking, or refraining from taking, actions “with the intention of avoiding . . . any Earnout Payment” or “based on taking into account the cost of making any Earnout Payment(s).”⁵⁷⁹ Fortis proved that J&J breached this provision when J&J considered the loss of the contingent payments as a factor when directing that iPlatform combine with Verb.⁵⁸⁰

Fortis did not, however, prove that this breach was a reasonably certain cause of the missed net sales milestones. J&J’s prioritization of Verb over iPlatform would have supported the net sales milestones since Verb sales are included. As Fortis concedes, “it often takes years for an innovative device to become profitable.”⁵⁸¹

⁵⁷⁶ Merger Agreement § 2.07(a)(ix); *see id.* § 10.03(ddd) (defining “Robotics Net Sales”).

⁵⁷⁷ *Id.* § 2.07(a)(x).

⁵⁷⁸ *Id.* § 2.07(e)(i) (requiring J&J to use “commercially reasonable efforts to achieve each of the Regulatory Milestones”).

⁵⁷⁹ *Id.* § 2.07(e)(iii)(A)-(B).

⁵⁸⁰ *See supra* notes 389-91 and accompanying text.

⁵⁸¹ Pl.’s Opening Post-trial Br. 110 (citing Grennan Tr. 2552-53; Shen Tr. 1169; JX 4495 ¶¶ 61, 65).

The fact that iPlatform was on the cusp of regulatory approval is not equivalent to it becoming commercially viable, much less profitable for J&J.⁵⁸²

4. Whether J&J Repudiated the Merger Agreement

Fortis also avers that J&J is liable for repudiating the Merger Agreement.⁵⁸³ “Under Delaware law, repudiation is an outright refusal by a party to perform a contract or its conditions entitling ‘the other contracting party to treat the contract as rescinded.’”⁵⁸⁴ “Repudiation must be ‘positive and unconditional.’”⁵⁸⁵

The purported “repudiation” Fortis complains of does not meet this standard. According to Fortis, J&J’s cancelation of the iPlatform and GI regulatory milestones and the net sales milestones in April 2020 amounts to repudiation. But the write-down was not an “outright refusal” to perform.⁵⁸⁶

The write-down was an accounting exercise by which J&J released reserves; it was not a cancelation of the milestones. If iPlatform (or Monarch) reached any milestone in the Merger Agreement, J&J retained a contractual obligation to make a corresponding earnout payment. In addition, J&J continued to perform in the sense

⁵⁸² See *supra* note 491 and accompanying text.

⁵⁸³ See Pl.’s Opening Post-trial Br. 102-04.

⁵⁸⁴ *CitiSteel USA, Inc. v. Connell Ltd. P’ship*, 758 A.2d 928, 931 (Del. 2000) (quoting *Sheehan v. Hepburn*, 138 A.2d 810, 812 (Del. Ch. 1958)).

⁵⁸⁵ *W. Willow-Bay Court, LLC v. Robino-Bay Court Plaza, LLC*, 2009 WL 458779, at *5 (Del. Ch. Feb. 23, 2009) (quoting *Carteret Bancorp., Inc. v. Home Grp, Inc.*, 1998 WL 3010, at *6 (Del. Ch. Jan. 13, 1988)).

⁵⁸⁶ *CitiSteel USA*, 758 A.2d at 931.

that it provided some resources to the Auris robots post-write-down. J&J may have fallen short of its efforts promise, but that is different from an outright refusal to perform.⁵⁸⁷

B. Fraud

Fortis contends that J&J fraudulently induced Auris to merge.⁵⁸⁸ The elements of common law fraud are:

(1) a false representation, usually one of fact, made by the defendant; (2) the defendant's knowledge or belief that the representation was false, or was made with reckless indifference to the truth; (3) an intent to induce the plaintiff to act or to refrain from acting; (4) the plaintiff's action or inaction taken in justifiable reliance upon the representation; and (5) damage to the plaintiff as a result of such reliance.⁵⁸⁹

⁵⁸⁷ Fortis also claims that J&J failed to provide Fortis with quarterly disclosures, in breach of Section 2.07(d)(i) of the Merger Agreement. Section 2.07(d)(i) provides that J&J must, each quarter, provide “to the Stockholder Representative . . . a reasonable written update on the status of achieving each of the Milestones, including with respect to the Regulatory Milestones, a reasonable update on the actions undertaken by [J&J] . . . pursuant to Section 2.07(e).” Fortis relegated its argument on this claim to a footnote in its opening post-trial brief. Pl.’s Opening Post-trial Br. 133 n.43. To the extent it continues to press the claim, Fortis did not prove a breach of Section 2.07(d)(i). The record reflects that Fortis was given reasonable quarterly disclosures. *See* JX 2528; JX 2530; JX 2665; JX 2978; JX 3218. Even if J&J had breached the provision, Fortis did not prove resulting damage. Moll and DeFonzo also provided information to Fortis’s Advisory Board directly. *See* Salehizadeh Dep. 78-79, 86-90; *see also* Royan Tr. 428-29.

⁵⁸⁸ PTO ¶ 3.

⁵⁸⁹ *Stephenson v. Capano Dev., Inc.*, 462 A.2d 1069, 1074 (Del. 1983); *see Maverick Therapeutics, Inc. v. Harpoon Therapeutics, Inc.*, 2020 WL 1655948, at *26 (Del. Ch. 2020) (“The elements of fraud and fraudulent inducement are the same.”).

The fraud must be “material” and “concern an essential part of the transaction.”⁵⁹⁰ Fraud may arise through misrepresentations, concealment of material facts, or silence under a duty to speak.⁵⁹¹

Fortis advances three fraud theories. First, it claims that J&J’s statements about developing iPlatform and Verb in parallel were false.⁵⁹² Second, it claims that J&J misled Auris by promising a “light touch” integration into J&J.⁵⁹³ And third, it claims that the Soft Tissue Ablation Milestone was not “highly certain” to be met, as J&J assured Auris.⁵⁹⁴

Before addressing the merits, I first resolve J&J’s argument that the Merger Agreement’s integration clause is a barrier to the first and second fraud theories.

1. The Integration Clause

J&J argues that Fortis’s fraud claims based on parallel development and “light touch” integration are barred by the Merger Agreement’s integration clause.⁵⁹⁵ The Merger Agreement’s integration clause is standard.⁵⁹⁶ The Merger Agreement

⁵⁹⁰ *Maverick*, 2020 WL 1655948, at *31 (quoting *Great Hill Equity Partners IV, LP v. SIG Growth Equity Fund I, LLLP*, 2018 WL 6311829, at *33 (Del. Ch. Dec. 3, 2018)).

⁵⁹¹ *Stephenson*, 462 A.2d at 1074.

⁵⁹² Pl.’s Opening Post-trial Br. 88-89.

⁵⁹³ *Id.* at 89-90 (quoting JX 2755).

⁵⁹⁴ *Id.* at 90-91.

⁵⁹⁵ Defs.’ Answering Post-trial Br. 130-32.

⁵⁹⁶ Merger Agreement § 10.07 (“This Agreement, the Escrow Agreement and the Confidentiality Agreement [] constitute the entire agreement, and supersede all prior

contains only an asymmetric anti-reliance provision in which J&J disclaimed reliance on extra-contractual representations.⁵⁹⁷ Auris did not make a similar disclaimer.

In resolving J&J's motion to dismiss, I explained that "a standard integration clause, without anti-reliance language, cannot disclaim reliance of representations outside of the written contract."⁵⁹⁸ I also observed that the one-way anti-reliance clause in the Merger Agreement means "Auris was permitted to rely on the defendants' assurances."⁵⁹⁹ J&J avers that I left open the effect of the integration clause on "alleged extra-contractual promises of future intent."⁶⁰⁰ I see no basis to deviate from my prior ruling.⁶⁰¹ To the extent that J&J is not bound by it or has presented different considerations, J&J's argument fails on the merits.

agreements and understandings, both written and oral, among the parties with respect to the subject matter hereof or thereof").

⁵⁹⁷ *Id.* § 4.08 ("Except for the representations and warranties contained in Article III [of the Merger Agreement], [J&J] and Merger Sub acknowledge that none of [Auris] or any person on behalf of [Auris] makes, and neither [J&J] nor Merger Sub have relied upon, any other express or implied representation or warranty with respect to [Auris] or any of its Subsidiaries or with respect to any other information provided or made available to [J&J] or Merger Sub in connection with the transactions contemplated by this Agreement Each of [J&J] and Merger Sub disclaims any representations and warranties other than those that are expressly set forth in Article III.").

⁵⁹⁸ MTD Mem. Op. 22.

⁵⁹⁹ *Id.* at 29.

⁶⁰⁰ Defs.' Answering Post-trial Br. 130; *see also* Defs.' Pre-trial Br. 78.

⁶⁰¹ *See Advanced Litig., LLC v. Herzka*, 2006 WL 2338044, at *5 (Del. Ch. Aug. 10, 2006).

J&J asserts that “an integration clause alone is sufficient to bar a fraud claim based on expressions of future intent or future promises.”⁶⁰² It cites two decisions in support: *Shareholder Representative Services LLC v. Albertsons Companies, Inc.* and *Black Horse Capital, LP v. Xstelos Holdings, Inc.*⁶⁰³ Nevertheless, the general rule in Delaware is that “integration clauses do not operate to bar fraud claims based on factual statements not made in the written agreement.”⁶⁰⁴ “If parties fail to include unambiguous anti-reliance language, they will not be able to escape responsibility for their own fraudulent representations made outside of the agreement’s four corners.”⁶⁰⁵ There is neither a recognized exception to these principles nor a reason to deviate from them here.⁶⁰⁶

⁶⁰² Defs.’ Answering Post-trial Br. 130 (quoting *Albertsons*, 2021 WL 2311455, at *12).

⁶⁰³ *Albertsons*, 2021 WL 2311455, at *2; see also *Black Horse Cap. L.P. v. Xstelos Hldgs., Inc.*, 2014 WL 5025926, at *24-25 (Del. Ch. Sept. 30, 2014) (holding that an integration clause barred a fraud claim because the statements allegedly relied upon “were not misrepresentations of material fact . . . but rather prior parole evidence that would vary the extant terms in the subsequent integrated writings”).

⁶⁰⁴ *Kronenberg v. Katz*, 872 A.2d 568, 592 (Del. Ch. 2004); see also 11 Williston on Contracts § 33:24 (4th ed.), Westlaw (May 2024 update).

⁶⁰⁵ *Abry P’rs V, L.P. v. F & W Acq. LLC*, 891 A.2d 1032, 1059 (Del. Ch. 2006).

⁶⁰⁶ See *Trifecta Multimedia Hldgs., Inc. v. WCG Clinical Servs. LLC*, 318 A.3d 450, 466-67 (Del. Ch. 2024) (rejecting a similar argument).

On top of that, *Albertsons* and *Xstelos* are inapposite. Neither case involved a contract with a one-sided anti-reliance clause. And unlike here, the purported oral misrepresentations in those cases conflicted with the terms of the contracts.⁶⁰⁷

2. Parallel Pathing and Prioritization

Fortis avers that J&J's senior leadership made various false statements promising to prioritize iPlatform and develop it in parallel with Verb.⁶⁰⁸ Most are the sort of "classically vague statements that a commercial party routinely makes during deal-making courtship."⁶⁰⁹ They include:

- that iPlatform and Verb were "complementary";⁶¹⁰
- that Auris had J&J's "resources at [its] sails" to develop iPlatform;⁶¹¹
- that J&J would spend "multiples" of what Auris alone could devote to its technology;⁶¹²
- that iPlatform was a "priority";⁶¹³ and

⁶⁰⁷ *Albertsons*, 2021 WL 2311455, at *2; *Xstelos*, 2014 WL 5025926, at *22.

⁶⁰⁸ Pl.'s Opening Post-trial Br. 88.

⁶⁰⁹ *Airborne Health, Inc. v. Squid Soap, LP*, 2010 WL 2836391, at *8 (Del. Ch. July 20, 2010).

⁶¹⁰ Pl.'s Opening Post-trial Br. 25 (quoting JX 838).

⁶¹¹ *Id.* at 24 (quoting DeFonzo Tr. 330-31).

⁶¹² *Id.* (quoting JX 1004).

⁶¹³ *Id.* (quoting McEvoy Tr. 2598). This is, of course, different from whether J&J treated iPlatform as a priority device in fulfilling its efforts obligation.

- that Auris could access J&J’s “global candy store” of resources.⁶¹⁴

Statements like these, praising one’s “skills, experience, and resources,” are “mere puffery and cannot form the basis for a fraud claim.”⁶¹⁵

Further, it is not apparent that these statements are false or were made with scienter.⁶¹⁶ The evidence suggests that J&J intended to provide the Auris robots with more resources than Auris had as a standalone company.⁶¹⁷ Auris’s products were given, among other things, substantial funding, access to J&J’s “global candy store,”

⁶¹⁴ *Id.* (quoting JX 920).

⁶¹⁵ *Solow v. Aspect Res., LLC*, 2004 WL 2694916, at *3 (Del. Ch. Oct. 19, 2004) (citing *Kronenberg*, 872 A.2d at 580-81); *see also Trenwick Am. Litig. Trust v. Ernst & Young, L.L.P.*, 906 A.2d 168, 209 (Del. Ch. 2006) (explaining that “statements of expectation or opinion about the future of the company and the hoped for results of business strategies” are “generally not actionable” for fraud claims under Delaware law); *Winner Acceptance Corp. v. Return on Cap. Corp.*, 2008 WL 5352063, at *8 (Del. Ch. Dec. 23, 2008) (describing statements that one’s expertise would help expand the business as “mere pun and puffery”); *Trifecta*, 318 A.3d at 463-64 (holding that statements about a party being “the best partner to accelerate growth” or that the counter-party would benefit from “collaboration, coordination and shared relationship” across thousands of clients were “non-actionable puffery”); *Earth Pride Organics, LLC v. Corona-Orange Foods Intermediate Hldgs., LLC*, 2024 WL 1905384, at *9 (Del. Ch. Apr. 17, 2024) (concluding that statements about resources to “support growth,” company capabilities, and expertise “to execute against new opportunities” were the sort of pre-transaction puffery that could not support a fraud claim).

⁶¹⁶ *See Metro Commc’n Corp. BVI v. Advanced Mobilecomm Techs. Inc.*, 854 A.2d 121, 143 (Del. Ch. 2004); *see also Arwood v. AW Site Servs., LLC*, 2022 WL 705841, at *20 (Del. Ch. Mar. 9, 2022) (explaining that a plaintiff must show that false statements were made “knowingly, intentionally, or with reckless indifference to the truth” and that the speaker “intended to induce [the plaintiff’s] reliance” on the alleged misrepresentation (citation omitted)).

⁶¹⁷ *E.g.*, JX 1150; JX 2873; McEvoy Tr. 2664-65; McEvoy Dep. 281-82; *see also* Shen Tr. 1462-63.

a dedicated “Tiger Team,” and many of Verb’s assets. These resources mostly came too late to support iPlatform’s achievement of the regulatory milestones, or even impaired iPlatform’s success. That does not, however, mean that J&J’s statements were untrue.

J&J’s statements about parallel pathing Verb and iPlatform are relatively less vague. They include:

- that iPlatform and Verb would be developed in “parallel”;⁶¹⁸ and
- that J&J planned to launch both iPlatform and Verb, meaning that it had the funds to develop both.⁶¹⁹

Fortis contends that J&J “never intended” to develop the two systems in parallel, as evidenced by Project Manhattan and the Ashley Management Decision.⁶²⁰

These are statements of future intent rather than present fact.⁶²¹ The record demonstrates that pre-merger, J&J was considering different options for the

⁶¹⁸ Pl.’s Opening Post-trial Br. 24 (quoting Moll Tr. 40).

⁶¹⁹ *Id.* (citing Morano Tr. 1474).

⁶²⁰ *Id.* at 25.

⁶²¹ *See Great Lakes Chem. Corp. v. Pharmacia Corp.*, 788 A.2d 544, 554 (Del. Ch. 2001) (“Predictions about the future cannot give rise to actionable common law fraud. Nor can expression of opinion.” (citation omitted)); *MicroStrategy Inc. v. Acacia Rsch. Corp.*, 2010 WL 5550455, at *15 (Del. Ch. Dec. 30, 2010) (“Generally, prior oral promises or statements of future intent do not constitute ‘false representation[s] of fact’ that would satisfy the first element of fraudulent misrepresentation.”); *Winner Acceptance*, 2008 WL 5352063, at *10 (“This Court looks with particular disfavor at allegations of fraud when the underlying utterances take the form of unfulfilled promises of future performance.”); *Carrow v. Arnold*, 2006 WL 3289582, at *9 (Del. Ch. Oct. 31, 2006) (“Generally, prior oral promises or statements of future intent do not constitute ‘false representation[s] of

respective programs. J&J viewed iPlatform as a potential a backup for Verb—Shen’s so-called “bullet proof strategy.”⁶²² Before closing, J&J evaluated developing both systems and launching them as complementary offerings focused on different indications or markets.⁶²³ I cannot conclude that J&J’s statements about parallel pathing were made without any intention of performing.⁶²⁴

Project Manhattan was contrary to J&J’s promise to devote commercially reasonable efforts to iPlatform. But the contours of Project Manhattan as a direct comparison between iPlatform and Verb were set after closing. J&J had the funds to develop and launch both robots, even if the Ashley Management Decision made

fact’ that would satisfy the first element of fraudulent misrepresentation.”), *aff’d*, 933 A.2d 1249 (Del. 2007).

⁶²² JX 1630; *see supra* note 218 and accompanying text.

⁶²³ *E.g.*, JX 1363 at 9 (J&J in February 2019 projecting launches for iPlatform and Verb); JX 664 at 4 (Shen in September 2018 describing “a potential segmentation play” of Verb and iPlatform, stating that the programs “can be complementary,” and that having both would be a “‘Fail Safe’ plan for [J&J’s] robotic[s] strategy”); *see also* JX 1557 at 2 (J&J telling the FTC post-closing that the systems were “complementary” because “Verb will pursue laparoscopic procedures with a focus on those that benefit from advanced instrumentation, and iPlatform will pursue complex procedures that benefit from concomitant endoscopic and laparoscopic techniques”).

⁶²⁴ *See Grunstein v. Silva*, 2009 WL 4698541, at *13 (Del. Ch. Dec. 8, 2009) (“Courts . . . will convert an unfulfilled promise of future performance into a fraud claim if particularized facts are alleged that collectively allow the inference that, at the time the promise was made, the speaker had no intention of performing.”); *see also Stevanov v. O’Connor*, 2009 WL 1059640, at *12 (Del. Ch. Apr. 21, 2009).

this a less likely outcome.⁶²⁵ Parallel pathing was one of the three outcomes of Project Manhattan contemplated by Shen.⁶²⁶

J&J ultimately chose to use iPlatform to prop up Verb. Some J&J officers, like Gorsky, may have viewed “meshing” the robots as an upside of the merger. As of closing, though, it was just a scenario under consideration. The final decision to merge iPlatform with Verb was made only after Project Manhattan when the J&J Board approved it. Although J&J’s conduct regarding iPlatform fell short of its contractual efforts obligations, Fortis did not prove that J&J’s pre-closing statements about parallel pathing constitute fraud.

3. “Light Touch” Integration

Fortis also avers that J&J defrauded it by making representations about Auris’s anticipated place within the overall J&J organization. These statements include:

- that J&J would “[p]reserve [Auris’s] entrepreneurial innovation culture”;⁶²⁷

⁶²⁵ See Shen Tr. 1247-48 (explaining that despite the budget challenge by McEvoy, J&J was financially able to develop both systems in parallel if the business decision was made to do so).

⁶²⁶ JX 1702 at 3 (“Develop both systems in parallel and the[n] make the final commercialization decision.”).

⁶²⁷ Pl.’s Opening Post-trial Br. 31 (quoting JX 838 at 6); see also *id.* (quoting Moll. Tr. 38).

- that J&J would “retain [Auris’s] leadership / team by creating a semi-autonomous model”;⁶²⁸
- that J&J would be “deferential” to Moll;⁶²⁹ and
- that, unlike in prior mergers, it was going to “do[] Silicon Valley well . . . this time.”⁶³⁰

Fortis did not prove that these statements were fraudulent. Several are the sort of fluffy platitudes made during negotiations that “no rational prospective investor . . . would find material.”⁶³¹ J&J’s integration of Auris might not have had the “light touch” Auris anticipated, but it seems that Auris had a different subjective view of lightness than J&J.⁶³²

Other statements are not false. Auris personnel were kept in some key leadership positions and maintained a measure of control over certain functions, as J&J intended.⁶³³ In many other ways, Auris’s autonomy was understandably lost.

⁶²⁸ *Id.* (quoting JX 838 at 6).

⁶²⁹ *Id.* (quoting DeFonzo Tr. 328).

⁶³⁰ *Id.*

⁶³¹ *Lazard Debt Recovery GP, LLC. v. Weinstock*, 864 A.2d 955, 971 (Del. Ch. 2004) (finding that statements touting an “ideal work environment” and “unique resources” were “at best enthusiastic puffery”); *Squid Soap*, 2010 WL 2836391, at *8 (explaining that statements of “corporate optimism” cannot support a fraud claim); *see supra* note 615 and accompanying text.

⁶³² *E.g.*, JX 1299 at 8 (J&J talking points explaining to Auris “some aspects that will need to be integrated into J&J post-close such as financial reporting, and HR”).

⁶³³ *E.g.*, McEvoy Tr. 2597; Pl.’s Dem. 7; *cf. Trifecta*, 318 A.3d at 458, 464-65 (holding that it was reasonably conceivable an explicit promise that a target could “operate independently (including all local corporate functions)” was fraud where the acquirer

Auris could not justifiably expect that it would retain the same culture and independence it enjoyed as a startup after being acquired by a multi-billion-dollar global company like J&J. Nor did J&J represent as much.

4. Certainty of the Soft Tissue Ablation Milestone

Fortis's third fraud theory is markedly different than the others. On January 24, 2019, while working to convince Auris to sell, Gorsky (with the guidance of Morano and Kozak) offered the \$100 million Soft Tissue Ablation Milestone to Moll. Gorsky told Moll that there was such a "high certainty" of achieving the milestone that J&J viewed it as an "effective" up front" payment.⁶³⁴ This representation was false because the milestone was not remotely certain to be met.⁶³⁵

prevented the target's personnel from speaking with potential customers immediately after closing).

⁶³⁴ JX 1228 at 5 (Gorsky talking points delivered to Moll on January 24, 2019, referencing the milestone as part of the total up front consideration); *id.* at 6 (explaining that J&J had included the milestone "to be responsive to [Auris's] request" and that J&J thought Auris would "view [it] as relatively certain and near-term"); *see also* Kozak Tr. 1572-73; Moll Tr. 51 (testifying that Gorsky described "a highly likely target for achievement by the team because it was a very simple integration" between Monarch and the FLEX device).

⁶³⁵ Kozak testified that J&J viewed the milestone as "achievable." Kozak Tr. 1618; *see also* JX 1239 at 3 (discussing the achievability of the milestone by end of July 2022). That is very different from being "effective" up-front consideration." JX 1228 at 5.

Whether Gorsky’s statement is an “overt misrepresentation” is borderline.⁶³⁶ But it is undoubtedly “active concealment of material facts.”⁶³⁷ When J&J’s representation about the milestone’s certainty was made, J&J knew that a patient in its NeuWave clinical study had recently died.⁶³⁸ A for-cause, on-site investigation had been launched by the FDA.⁶³⁹ On January 24—two weeks before Gorsky and Moll spoke—J&J’s point of contact for the study “briefed” J&J’s Auris deal team (including Kozak) on the “patient death that [wa]s currently under investigation.”⁶⁴⁰ The investigation risked substantial delay.⁶⁴¹ Yet J&J waited until after closing to tell Auris.

Gorsky’s statement was intended to induce Auris to agree to a contingent payment and Auris justifiably relied on it.⁶⁴² Auris was damaged as a result of its

⁶³⁶ *In re Am. Int’l Grp., Inc., Consol. Deriv. Litig.*, 965 A.2d 763, 804 (Del. Ch. 2009), *aff’d sub nom. Teachers.’ Ret. Sys. Of La. v. PricewaterhouseCoopers LLP*, 11 A.3d 228 (Del. 2011) (TABLE).

⁶³⁷ *Id.*

⁶³⁸ *See* JX 1901 at 30.

⁶³⁹ *See* JX 1673; Bryant Tr. 2519-20; *supra* note 172 and accompanying text.

⁶⁴⁰ JX 1182 (Kozak updating Morano in January 2019, discussing that “a sensitivity [analysis] will be run to understand impact to valuation” from the patient death under investigation); *see also* JX 1171; JX 1673.

⁶⁴¹ *See* Wittwer Rep. ¶¶ 95-101; Wittwer Tr. 1966-68; *see also* JX 1213.

⁶⁴² *See* Hebert Tr. 1400-01; Kerrey Tr. 1428-29; Royan Tr. 1378-79; *see also* JX 1249 at 3 (Moll on Jan. 24, 2019 calling the Monarch milestone a “chip shot”). J&J argues that “[t]here is no document that corroborates” the Auris directors’ testimony that they relied on J&J’s representations. Defs.’ Answering Post-trial Br. 121 n.9. It is unclear why J&J feels that the directors’ credible testimony is insufficient. The parties’ negotiating history

reliance.⁶⁴³ Destroying the value of the milestone was a direct and proximate result of J&J's fraud.⁶⁴⁴ Auris never would have agreed to this milestone had it known about the patient death, since uncertainty persisted over the safety of FLEX and the timeline to clear regulatory hurdles.⁶⁴⁵ It would have demanded a higher upfront payment instead.⁶⁴⁶

III. REMEDY

Fortis is entitled to damages for J&J's breaches of the efforts provision in the Merger Agreement as they relate to the iPlatform regulatory milestones and GI Milestone. It is also entitled to damages for J&J's fraud as it relates to the Soft

further supports that the \$100 million milestone as "up front" consideration was important in Auris's decision to merge. *See* Moll Tr. 51-52; DeFonzo Tr. 390-392.

J&J has asked for adverse inferences on the Auris board's reliance since two members (Salehizadeh and Hebert) failed to preserve text messages. Defs.' Mot. for Spoliation Sanctions (Dkt. 328). On June 5, 2023, I ordered the directors' remaining responsive texts to be produced and reserved decision on whether they recklessly spoliated evidence. After reviewing the trial record, I decline to issue sanctions. I see no basis to conclude that either individual recklessly (much less intentionally) spoliated evidence.

⁶⁴³ At some point, the fact of the patient death became public. *See* JX 976. A report dated December 3, 2018 is on the FDA's website. *Id.* at 3. This does not excuse J&J's fraud. It is unknown when the report was posted. Even if it were made public pre-merger, Auris would have had no reason to search the FDA's website for information about problems with the NeuWave study.

⁶⁴⁴ *See Maverick*, 2021 WL 1592473, at *9.

⁶⁴⁵ *See* DeFonzo Tr. 391-92 ("[I]f we were aware of that, I don't think we would have accepted that milestone."); Moll Tr. 177 (testifying the FLEX complications put in doubt whether the "milestone was even relevant"); *see also* JX 2339; Leparmetier Tr. 996-97.

⁶⁴⁶ *See* Moll Tr. 51-52; DeFonzo Tr. 391-92; *see also supra* note 642.

Tissue Ablation Milestone. Once liability is established, “this court has broad discretion to tailor a remedy to suit the situation as it exists.”⁶⁴⁷

Under Delaware law, the standard remedy for breach of contract “is based upon the reasonable expectations of the parties *ex ante*.”⁶⁴⁸ Damages for fraud are similar. “[T]he recipient of a fraudulent misrepresentation is entitled to recover as damages . . . the pecuniary loss to [it] of which the misrepresentation is a legal cause.”⁶⁴⁹ “Such expectation—or benefit-of-the-bargain—damages are measured by the amount of money that would put the plaintiff in the position it would have held if the defendant’s representations were true” or if the defendant had performed as promised.⁶⁵⁰

A. Contract Damages

J&J must indemnify Fortis for losses “arising from or relating to” any “breach of or failure to perform” under the Merger Agreement.⁶⁵¹ Fortis proved that J&J

⁶⁴⁷ *Gilliland v. Motorola, Inc.*, 873 A.2d 305, 312 (Del. Ch. 2005) (citation omitted).

⁶⁴⁸ *Siga II*, 132 A.3d at 1111 (quoting *Duncan v. Theratx, Inc.*, 775 A.2d 1019, 1022 (Del. 2001)).

⁶⁴⁹ *NetApp, Inc. v. Cinelli*, 2023 WL 4925910, at *17 (Del. Ch. Aug. 2, 2023) (quoting Restatement (Second) of Torts § 549(1)).

⁶⁵⁰ *Id.* at *17 (citing *Siga II*, 132 A.3d at 1130); *see also Comrie v. Enterasys Networks, Inc.*, 837 A.2d 1, 17 (Del. Ch. 2003) (“Th[e] principle of expectation damages is measured by the amount of money that would put the promisee in the same position as if the promisor had performed the contract.” (citing *Duncan*, 775 A.2d at 1022)).

⁶⁵¹ Merger Agreement § 8.02. Although Section 8.02(c) caps damages at \$170,000,000 except for intra-contractual fraud, Section 8.05(b) carves out the “right to Earnout

breached the Merger Agreement and the implied covenant of good faith and fair dealing, leading it to miss the iPlatform and GI regulatory milestones. Fortis has put forward two measures of calculating its damages from these breaches.

First, it requests monetary damages equivalent to the full amount of each milestone. The milestones for which Fortis is entitled to damages and the associated payments are:

| <u>Milestone</u> | <u>Payment</u> |
|---------------------------|----------------|
| General Surgery Milestone | \$400,000,000 |
| Upper Abdominal Milestone | \$150,000,000 |
| Lower Abdominal Milestone | \$150,000,000 |
| Urologic Milestone | \$150,000,000 |
| Gynecologic Milestone | \$150,000,000 |
| GI Milestone | \$150,000,000 |

Together, these milestones total \$1,150,000,000.⁶⁵²

In the alternative, Fortis proposes an approach to damages in which each milestone payment is weighted by the parties' estimated probability of achievement at the time of the merger. It offers the expert opinion of Dr. Richard Manning, an economist, in support.⁶⁵³ Manning opined that the court can reasonably measure

payments and the rights and obligations of the parties pursuant to Section 2.07.” *Id.* §§ 8.02(c), 8.05(b). Fortis’s contract claims are under Section 2.07.

⁶⁵² Fortis seeks a total of \$2,350,000,000 in breach of contract damages, which is the amount of potential earnout payments. *See* Pl.’s Opening Post-trial Br. 101.

⁶⁵³ Manning is a managing director at Intensity, LLC, where he works as an economist. He earned his M.A. and Ph. D. degrees in economics from the University of Chicago. He regularly provides consulting and expert services on breach of contract, economic

what Auris expected to gain using the probability-weighted milestone values assigned by the parties.⁶⁵⁴ Auris’s estimated probabilities of success are from a February 2019 valuation prepared by its financial advisor Centerview Partners, which reflects input from Auris management.⁶⁵⁵ J&J’s estimates are from a January 2019 valuation model prepared by J&J and presented to its Board.⁶⁵⁶ Manning also calculated a blended approach by averaging the parties’ probability assignments.⁶⁵⁷

Manning’s alternative approach is warranted here. Contract damages should “put the promisee in the same position as if the promisor had performed the contract.”⁶⁵⁸ At the time of the merger, neither party anticipated that the milestone payments were a certainty. They separately assigned each iPlatform regulatory milestone a probability of achievement. The risk-adjusted probabilities assessed by the parties and their advisors reasonably reflect the likelihood that the milestones would have been achieved if J&J complied with its efforts obligation.

valuation, competition economics and antitrust, intellectual property, business strategy, and public policy. *See* JX 4493 (“Manning Rep.”) 11.

⁶⁵⁴ Manning Tr. 2051-52; Manning Rep. ¶ 115; *see* Pl.’s Dem. 15 at 14.

⁶⁵⁵ Manning Rep. ¶¶ 115(a), 177; JX 1413 (Centerview Feb. 12, 2019 presentation).

⁶⁵⁶ Manning Rep. ¶¶ 115(b), 173-74; JX 2873 (J&J Jan. 2019 “BoD model” with native Excel attachment).

⁶⁵⁷ Manning Rep. ¶ 115(c); *see* Pl.’s Dem. 15 at 14.

⁶⁵⁸ *Comrie*, 837 A.2d at 17 (citation omitted).

The best evidence of how the milestones would have fared absent J&J's breaches of the Merger Agreement is the parties' contemporaneous risk-adjusted probabilities of success.⁶⁵⁹ These estimates provide a credible, responsible basis to calculate Fortis's damages.⁶⁶⁰ Auris had deep knowledge of its own ability to reach the milestones. J&J's independent estimate came after (or during) multiple rounds of due diligence and was remarkably close to Auris's predictions.⁶⁶¹ These probabilities are:⁶⁶²

| <u>Milestone</u> | <u>Auris Probability</u> | <u>J&J Probability</u> | <u>Blended Probability</u> |
|---------------------------|--------------------------|----------------------------|----------------------------|
| General Surgery Milestone | 65% | 85% | 75% |
| Upper Abdominal Milestone | 85% | 75% | 80% |
| Lower Abdominal Milestone | 85% | 75% | 80% |
| Urologic Milestone | 85% | 75% | 80% |
| Gynecologic Milestone | 85% | 75% | 80% |
| GI Milestone | 85% | 75% | 80% |

J&J did not offer a separate approach to calculating damages, other than to argue that Fortis is entitled to none. Its rebuttal expert, Dr. James E. Malackowski,

⁶⁵⁹ JX 3139 (J&J's Apr. 3, 2020 estimate); JX 1413 (Centerview's Feb. 12, 2019 estimates based on Auris management).

⁶⁶⁰ See *Beard Rsch., Inc. v. Kates*, 8 A.3d 573, 613 (Del. Ch. 2010) (explaining that mathematical certainty in damages is not required "where a wrong has been proven and injury established"), *aff'd*, 11 A.3d 749 (Del. 2010); see also *SIGA Techs., Inc. v. PharmAthene, Inc.*, 67 A.3d 330, 351 n.99 (Del. 2013).

⁶⁶¹ See Grennan Tr. 2560-61.

⁶⁶² JX 1413; JX 3139; see Manning Rep. at Attachments B-2, B-3, B-4.

criticized Manning’s approach.⁶⁶³ Malackowski opined that Manning’s analysis used an outdated pre-diligence model created by J&J, which relied on inaccurate projections from Auris and did not account for “undisclosed risks” negatively affecting Auris’s value.⁶⁶⁴

None of these points are persuasive. J&J’s own communications state that the differences between the pre-diligence model presented to its Board (that Manning relied on) and a updated post-diligence updated model (that Malackowski addressed) are “slight.”⁶⁶⁵ The changes have no meaningful effect on Fortis’s damages.⁶⁶⁶ The probabilities of success J&J assigned to the relevant milestones remained the same.⁶⁶⁷ J&J’s projections were based on extensive due diligence and reliance on an outside advisor. These estimates supported an essential part of the deal.⁶⁶⁸ And

⁶⁶³ Malackowski is the co-founder and senior managing director of Ocean Tomo, LLC, which provides financial expert, management consulting, and advisory services. He is an experienced testifying expert on subjects including valuation, lost profits, and venture financing including expected risk / return. He has a bachelor’s degree in accounting from the University of Notre Dame and is a registered Certified Public Accountant. Malackowski Rep. 5-6.

⁶⁶⁴ *Id.* at 37-58.

⁶⁶⁵ JX 2873 (“The overall EBIT differences are slight – only about \$200MM cumulative.”).

⁶⁶⁶ *Compare* Malackowski Rep. Figure 12, *with id.* at Figure 13.

⁶⁶⁷ *Compare id.* at Figure 13, *with* Pl.’s Dem. 15 at 14.

⁶⁶⁸ *See* Manning Tr. 2061-62 (opining that it was reasonable to conclude that the parties’ estimates of success were reliable since they were “an essential part of the transaction they were engaged in”).

there is also no credible basis in the record to find that material risks affecting iPlatform were hidden from J&J by Auris.⁶⁶⁹

Based upon the parties’ contemporaneous valuations, Fortis’s potential damages can be calculated using (1) J&J’s assessment; (2) Fortis’s assessment; or (3) a blended probability. I believe that the third approach is appropriate. It considers the plaintiff’s view of damages at the time of the breach, while accounting for J&J’s more conservative view of the 2023 milestones.⁶⁷⁰

Fortis’s damages for breach of contract, by milestone and based upon a blend of the probabilities contemporaneously assigned by the parties, are:

| <u>Milestone</u> | <u>Payment</u> | <u>Blended Probability</u> | <u>Damages</u> |
|---------------------------|----------------|----------------------------|----------------------|
| General Surgery Milestone | \$400,000,000 | 75% | \$300,000,000 |
| Upper Abdominal Milestone | \$150,000,000 | 80% | \$120,000,000 |
| Lower Abdominal Milestone | \$150,000,000 | 80% | \$120,000,000 |
| Urologic Milestone | \$150,000,000 | 80% | \$120,000,000 |
| Gynecologic Milestone | \$150,000,000 | 80% | \$120,000,000 |
| GI Milestone | \$150,000,000 | 80% | \$120,000,000 |
| TOTAL | | | \$900,000,000 |

⁶⁶⁹ See *supra* notes 104, 109, 118-19, 471-72 and accompanying text.

⁶⁷⁰ *NetApp*, 2023 WL 4925910, at *17 (citing *Stephenson*, 462 A.2d at 1076).

B. Fraud Damages

Fortis proved that J&J committed fraud with respect to the Soft Tissue Ablation Milestone.⁶⁷¹ Fortis has the burden to present a reasonable method to calculate fraud damages.⁶⁷²

Fortis offers two measures of damages for its fraud claim: (1) rescissory damages or (2) benefit of the bargain (i.e., expectation) damages.⁶⁷³ Rescissory damages are “the monetary equivalent of rescission” and intended to restore parties to the economic positions they would have held had the challenged transaction not occurred.⁶⁷⁴ Benefit of the bargain damages “are equal to ‘the difference between the actual and the represented values of the object of the transaction.’”⁶⁷⁵ Since J&J’s fraud concerns a single milestone, I believe that the benefit of the bargain approach is more suitable to compensate Fortis than the “exceptional” remedy of rescissory damages.⁶⁷⁶

⁶⁷¹ See JX 1215 at 5; *supra* Section II.B.4.

⁶⁷² See, e.g., *Maverick*, 2021 WL 1592473, at *9.

⁶⁷³ Pl.’s Opening Post-trial Br. 97.

⁶⁷⁴ *Lynch v. Vickers Energy Corp.*, 429 A.2d 497, 501 (Del. 1981), *overruled in part on other grounds*, *Weinberger v. UOP, Inc.*, 457 A.2d 701, 714 (Del. 1983).

⁶⁷⁵ *LCT Cap., LLC v. NGL Energy P’rs LP*, 249 A.3d 77, 91 (Del. 2021) (quoting *Stephenson*, 462 A.2d at 1076).

⁶⁷⁶ See *Universal Enters. Grp., L.P. v. Duncan Petroleum Corp.*, 2013 WL 3353743, at *15-16 (Del. Ch. July 1, 2013) (explaining that Delaware courts are reluctant to award rescissory damages, particularly for transactions occurring years prior where intervening events have occurred) (citations omitted).

The purpose of expectation damages is to put Fortis “in the position it would have held if [J&J’s representations] were true.”⁶⁷⁷ Unlike rescissory damages, which are based on undoing a fraudulent transaction, expectation damages remit to Fortis the value of the object it was fraudulently promised.⁶⁷⁸ Damages are equal to the difference between the actual and represented values of the object of the fraudulent transaction—here, the Soft Tissue Ablation Milestone.

The actual value of the milestone is the reduced probability of reaching it due to the material information J&J kept from Fortis. Manning treated the actual value as \$0, on the assumption that J&J’s misrepresentation made the earnout payment associated with the milestone unattainable. I adopt this value. Fortis has proven that the milestone became unattainable due to the cumulative effect of J&J’s fraud.

The represented value of the milestone is based on Auris’s reasonable expectation of its value at the time of the breach—i.e., the risk-adjusted probability of reaching the milestone. Manning calculated this figure using the expected net present value (eNPV) of the milestone at the time of the merger.⁶⁷⁹ He considered

⁶⁷⁷ *NetApp*, 2023 WL 4925910, at *17 (citing *Siga II*, 132 A.3d at 1130); *Strassburger v. Earley*, 752 A.2d 557, 579 (Del. Ch. 2000) (explaining that expectations are measured at the time of the transaction).

⁶⁷⁸ *See Maverick*, 2021 WL 1592473, at *9 (“Benefit of the bargain damages are equal to the difference between the actual and represented values of the object of the fraudulent transaction. This method should put the plaintiff in the same position that the plaintiff would have been in if the defendant’s representations had been true.” (citation omitted)).

⁶⁷⁹ Manning Rep. ¶¶ 181-85.

three valuation scenarios representing Auris's reasonable expectation of the contingent payment. First, he assessed an eNPV for the milestone using Centerview's February 2019 valuation.⁶⁸⁰ Second, he assessed an eNPV for the milestone using J&J's January 2019 model as presented to its Board.⁶⁸¹ Finally, he calculated an eNPV for the milestone using a blended average of Centerview and J&J's risk-adjusted values.⁶⁸²

Centerview derived a present value of the contingent payments based on an estimated probability of success for each milestone.⁶⁸³ The estimated probability of successful results multiplied by the contingent payment amount results in an expected payment for each milestone. To calculate the present value of each milestone, Centerview discounted each expected payment back to March 31, 2019 using a 10.5% discount rate.⁶⁸⁴ Centerview's risk-adjusted eNPV for the Soft Tissue Ablation Milestone is \$58,000,000 using an 85% probability of achievement.⁶⁸⁵

⁶⁸⁰ *Id.* ¶ 183; *see id.* ¶¶ 161, 177; JX 1413.

⁶⁸¹ Manning Rep. ¶ 184; *see id.* ¶¶ 173-74; JX 2873.

⁶⁸² Manning Rep. ¶ 182.

⁶⁸³ JX 1413; *see* Manning Rep. ¶¶ 177-79.

⁶⁸⁴ JX 1413 (“Valuation as of 3/31/19 based on 10.5% discount rate using mid-year convention.”); Manning Rep. ¶ 177.

⁶⁸⁵ Manning Rep. Attachment D-2; *see* JX 1413.

Like Centerview, J&J assessed the present value of the contingent payments using an estimated probability of success for each milestone.⁶⁸⁶ The expected payment amount was calculated by multiplying the estimated probability of success by the contingent payment amount. J&J discounted each expected payment back to April 1, 2019 using a 9.5% discount rate.⁶⁸⁷ The risk-adjusted eNPV for the Soft Tissue Ablation Milestone using J&J's model is \$63,731,495 based on an 85% probability of achievement.⁶⁸⁸

Manning's blended average of the Centerview and J&J risk-adjusted eNPVs is \$60,865,748.⁶⁸⁹ The difference between the represented value of the Monarch Soft Tissue Ablation Milestone and the actual value (\$0) is \$60,865,748. I adopt this figure as the most responsible estimate of Auris's reasonable expectation of the Monarch Soft Tissue Ablation Milestone's value at the time of the merger. Consistent with my approach to contract damages, the blended value strikes a responsible balance.

⁶⁸⁶ JX 2873 (Tab: "Contingent Consideration"); Manning Rep. ¶¶ 174-75.

⁶⁸⁷ Manning Rep. ¶ 174; JX 2873 (Tab: "Corporate Model (Stock)").

⁶⁸⁸ Manning Rep. ¶ 192; *id.* at Attachment D-3; JX 2873 (Tabs: "Input," "Contingent Consideration").

⁶⁸⁹ Manning Rep. ¶ 190; *id.* at Attachment D-1.

C. Pre-judgment Interest

“In Delaware, pre-judgment interest is awarded as a matter of right.”⁶⁹⁰

“Prejudgment interest serves two purposes: first, it compensates the plaintiff for the loss of the use of [its] money; and second, it forces the defendant to relinquish any benefit that it has received by retaining the plaintiff’s money in the interim.”⁶⁹¹

1. Contract Damages

The Merger Agreement states that, for any earnout payment not paid within 10 days of J&J delivering notice of a milestone’s achievement:

interest shall accrue on such unpaid amount at a rate per annum equal to the prime rate of interest reported from time to time in *The Wall Street Journal*, calculated on the basis of the actual number of days elapsed over three hundred sixty (360), from the date such amount should have been paid pursuant to the terms of this Agreement . . . to the date of actual payment in full of such amount.⁶⁹²

The Merger Agreement also states that J&J will “notify the Stockholders’ Representative in writing within fifteen (15) days after the achievement” of any regulatory milestone.⁶⁹³ J&J “shall, or shall cause the Surviving Corporation or the Paying Agent to, pay the applicable Earnout Payment . . . within ten (10) days after such notice is delivered.”⁶⁹⁴

⁶⁹⁰ *Citadel Hldg. Corp. v. Roven*, 603 A.2d 818, 826 (Del. 1992).

⁶⁹¹ *Brandywine Smyrna, Inc. v. Millennium Builders, LLC*, 34 A.3d 482, 486 (Del. 2011).

⁶⁹² Merger Agreement § 2.07(d)(vii).

⁶⁹³ *Id.* § 2.07(c).

⁶⁹⁴ *Id.* § 2.07(c).

Guided by these provisions, Manning calculated pre-judgment interest on Fortis’s breach of contract damages using per-quarter averages of daily prime rates as reported in *The Wall Street Journal*, adjusted to reflect one quarter of a 360-day year.⁶⁹⁵ He conservatively assumed that the milestone payments would have been received 25 business days after the last day of the milestone period.⁶⁹⁶ He calculated pre-judgment interest through May 18, 2023 (the date through which he was asked to calculate damages), applying a floating interest rate that compounds quarterly.⁶⁹⁷

I adopt Manning’s approach as both fair and consistent with the Merger Agreement. The prime rate was not only agreed upon by the parties, but also considered the best measure of the commercial lending rate used by banks for loans to creditworthy customers.⁶⁹⁸ Using a variable rate accounts for the economic realities during the relevant period, which saw significant swings in interest rates.⁶⁹⁹ Whether to award compound or simple interest is a discretionary matter for this

⁶⁹⁵ Manning Rep. ¶ 87.

⁶⁹⁶ *Id.*

⁶⁹⁷ *Id.*

⁶⁹⁸ *Id.* ¶ 87 n. 202 (citing Federal Reserve Website, *FAQs*, “What is the Prime Rate, and Does the Federal Reserve Set the Prime Rate?” https://www.federalreserve.gov/faqs/credit_12846.htm).

⁶⁹⁹ *See Gentile v. Rossette*, 2010 WL 3582453, at *2 (Del. Ch. Sept. 10, 2010) (“In departing from a legal rate of interest fixed at the time of the wrongdoing, our courts have considered concepts such as ‘the realities of the relationship’ between the parties, whether a particular party was the primary cause for a delay in the litigation, as well as general ‘fundamental economic realit[ies].’” (citation omitted)).

court.⁷⁰⁰ J&J's sophistication, plus the years that it benefitted from non-payment of the earnout, support compound rather than simple interest.⁷⁰¹

The only applicable milestones that expired before May 18, 2023 are the General Surgery Milestone and the Soft Tissue Ablation Milestone. A further interest calculation from May 19, 2023 through the date of judgment will be needed for these milestones, as well as the four iPlatform umbrella milestones for which Fortis proved its entitlement to damages.

For the General Surgery Milestone, Manning computed pre-judgment interest from (1) the milestone end date plus 25 business days through (2) May 18, 2023. For the first quarter of this period, for each milestone, he multiplied the damages by the quarterly average prime rate and by the number of days in the quarter divided by 360 to determine interest. For each of the remaining quarters, for each milestone, he multiplied the sum of the expected payment and cumulative interest by the number of days in the quarter divided by 360 and by the quarter's average prime rate.⁷⁰² The resulting calculation is:⁷⁰³

⁷⁰⁰ *NGL Energy P'rs LP v. LCT Cap., LLC*, --- A.3d ---, 2024 WL 2716005, at *4 (Del. May 28, 2024).

⁷⁰¹ *See Valeant Pharms. Int'l v. Jerney*, 2007 WL 2813789, at *8 (Del. Ch. Mar. 1, 2007).

⁷⁰² Manning Rep. ¶ 93.

⁷⁰³ *Id.* at Attachment B-20 (calculating interest for the General Surgery Milestone by quarter beginning in Q1 2022 based upon the average prime rate assuming a cumulative payment of \$300,000,000).

| <u>Quarter</u> | <u>Cumulative Payment</u> | <u>Days</u> | <u>Years</u> | <u>Average Prime Rate</u> | <u>Interest in Quarter</u> | <u>Cumulative Interest</u> |
|----------------|---------------------------|-------------|--------------|---------------------------|----------------------------|----------------------------|
| 2022 – Q1 | \$300,000,000 | 56 | 0.16 | 3.29% | \$1,537,366 | \$1,537,366 |
| 2022 – Q2 | \$300,000,000 | 91 | 0.25 | 3.93% | \$2,994,434 | \$4,531,799 |
| 2022 – Q3 | \$300,000,000 | 92 | 0.26 | 5.37% | \$4,181,586 | \$8,713,385 |
| 2022 – Q4 | \$300,000,000 | 92 | 0.26 | 6.82% | \$5,380,273 | \$14,093,658 |
| 2023 – Q1 | \$300,000,000 | 90 | 0.25 | 7.69% | \$6,041,237 | \$20,134,895 |
| 2023 – Q2 | \$300,000,000 | 47 | 0.13 | 8.06% | \$3,370,596 | \$23,505,491 |
| Total | n/a | n/a | n/a | n/a | \$23,505,491 | \$23,505,491 |

2. Fraud Damages

In assessing pre-judgment interest for Fortis’s fraud damages, Manning considered the period from April 1, 2019 (the merger date) through May 18, 2023.⁷⁰⁴ “The Court of Chancery generally looks to the legal rate of interest, as set forth in 6 *Del. C.* § 2301, as the ‘benchmark’ for the appropriate rate of pre-[judgment] interest.”⁷⁰⁵ Manning followed this approach and applied a floating rate that compounds four times a year. As with his interest calculation for Fortis’s contract damages,⁷⁰⁶ this is reasonable.

Manning determined the average Federal Reserve discount rate for each quarter during the relevant period and added 5% to these averages, consistent with the statutory rate. He calculated interest by multiplying the difference in the eNPV

⁷⁰⁴ *Id.* ¶ 186.

⁷⁰⁵ *Murphy Marine Servs. of Del., Inc. v. GT USA Wilm., LLC*, 2022 WL 4296495, at *24 (Del. Ch. Sept. 19, 2022) (citation omitted).

⁷⁰⁶ *See supra* note 700 and accompanying text.

and the actual value by the quarterly interest rate and the days in each quarter divided by 365, while compounding on a quarterly basis.

The resulting calculation is:⁷⁰⁷

| <u>Quarter</u> | <u>Cumulative Payment</u> | <u>Days</u> | <u>Years</u> | <u>Interest Rate</u> ⁷⁰⁸ | <u>Interest In Quarter</u> | <u>Cumulative Interest</u> |
|----------------|---------------------------|-------------|--------------|-------------------------------------|----------------------------|----------------------------|
| 2019 – Q2 | \$60,865,748 | 91 | 0.25 | 8.00% | \$1,213,980 | \$1,213,980 |
| 2019 – Q3 | \$60,865,748 | 92 | 0.25 | 7.81% | \$1,221,571 | \$2,435,551 |
| 2019 – Q4 | \$60,865,748 | 92 | 0.25 | 7.33% | \$1,170,062 | \$3,605,614 |
| 2020 – Q1 | \$60,865,748 | 91 | 0.25 | 6.82% | \$1,096,101 | \$4,701,715 |
| 2020 – Q2 | \$60,865,748 | 91 | 0.25 | 5.25% | \$858,215 | \$5,559,930 |
| 2020 – Q3 | \$60,865,748 | 92 | 0.25 | 5.25% | \$879,003 | \$6,438,933 |
| 2020 – Q4 | \$60,865,748 | 92 | 0.25 | 5.25% | \$890,635 | \$7,329,568 |
| 2021 – Q1 | \$60,865,748 | 90 | 0.25 | 5.25% | \$882,802 | \$8,212,370 |
| 2021 – Q2 | \$60,865,748 | 91 | 0.25 | 5.25% | \$904,166 | \$9,116,536 |
| 2021 – Q3 | \$60,865,748 | 92 | 0.25 | 5.25% | \$926,067 | \$10,042,603 |
| 2021 – Q4 | \$60,865,748 | 92 | 0.25 | 5.25% | \$938,321 | \$10,980,925 |
| 2022 – Q1 | \$60,865,748 | 90 | 0.25 | 5.29% | \$937,682 | \$11,918,607 |
| 2022 – Q2 | \$60,865,748 | 91 | 0.25 | 5.94% | \$1,078,305 | \$12,996,912 |
| 2022 – Q3 | \$60,865,748 | 92 | 0.25 | 7.36% | \$1,370,920 | \$14,367,832 |
| 2022 – Q4 | \$60,865,748 | 92 | 0.25 | 8.83% | \$1,673,848 | \$16,041,680 |
| 2023 – Q1 | \$60,865,748 | 90 | 0.25 | 9.69% | \$1,837,269 | \$17,878,949 |
| 2023 – Q2 | \$60,865,748 | 47 | 0.13 | 10.07% | \$1,021,102 | \$18,900,052 |
| Total | n/a | n/a | n/a | n/a | \$18,900,052 | \$18,900,052 |

D. Attorneys' Fees

In addition to damages, Fortis invokes Section 8.02 of the Merger Agreement to request the reimbursement of its attorneys' fees from this lawsuit. Section 8.02

⁷⁰⁷ Manning Rep. at Attachment D-6 (calculating interest for the Soft Tissue Ablation Milestone by quarter beginning in Q2 2019 based upon the legal rate of interest assuming a cumulative payment of \$60,865,748).

⁷⁰⁸ This column reflects the Federal Reserve discount rate plus 5%. See 6 Del. C. § 2301(a).

states that J&J will indemnify Auris for “any and all Losses suffered or incurred by any such Seller Indemnified Party arising from or relating to . . . any breach of or failure to perform any covenant, agreement or obligation . . . contained in this Agreement.”⁷⁰⁹ “Losses” are defined as:

any and all debts, obligations, losses, liabilities, damages, [t]axes, costs of investigation and other third party costs and expenses, in each case, whether known or unknown, absolute or contingent, liquidated or unliquidated, direct or indirect, due or to become due, accrued or not accrued, asserted or unasserted, related or not related to a Third Party Claim or otherwise (in each case excluding (x) incidental consequential and lost profits (in each case to the extent not reasonably foreseeable) and (y) punitive damages or damages based upon a financial metric multiple (except, in each case, to the extent awarded in a final non-appealable judgment and actually paid to a third party as part of a Third Party Claim)).⁷¹⁰

There is no language in this provision, or elsewhere in the Merger Agreement, contemplating an award of attorneys’ fees for litigation. Granting Fortis’s request would force me to “interpret the provision in an expansive way that would be inconsistent with the American Rule,” which requires each party to bear its own attorneys’ fees.⁷¹¹ I decline Fortis’s invitation to do so.

⁷⁰⁹ Merger Agreement § 8.02(ii).

⁷¹⁰ *Id.* § 8.01.

⁷¹¹ *Senior Housing Cap., LLC v. SHP Senior Housing Fund, LLC*, 2013 WL 1955012, at *45 (Del. Ch. May 13, 2012).

E. Total Damages

Fortis has proven its entitlement to contract damages in connection with five iPlatform regulatory milestones. It has also proven its entitlement to fraud damages in connection with the Soft Tissue Ablation Milestone. Pre-judgment interest, as set forth above, will be applied to these figures. Interest through May 18, 2023 is included in the total below for applicable milestones, though interest will also be awarded from that date through the date of judgment for the rest. In addition, Fortis will be entitled to post-judgment interest.

Fortis's total damages, based upon the available interest calculations, are:

| <u>Milestone</u> | <u>Damages</u> | <u>Interest</u> ⁷¹² | <u>Total</u> |
|--------------------------------|----------------|--------------------------------|------------------------|
| Breach of Contract | | | |
| General Surgery Milestone | \$300,000,000 | \$23,505,491 | \$323,505,491 |
| Upper Abdominal Milestone | \$120,000,000 | | \$120,000,000 |
| Lower Abdominal Milestone | \$120,000,000 | | \$120,000,000 |
| Urologic Milestone | \$120,000,000 | | \$120,000,000 |
| Gynecologic Milestone | \$120,000,000 | | \$120,000,000 |
| GI Milestone | \$120,000,000 | | \$120,000,000 |
| Fraud | | | |
| Soft Tissue Ablation Milestone | \$60,865,748 | \$18,900,052 | \$79,765,799 |
| Total Damages | | | |
| | \$960,865,748 | \$42,405,543 | \$1,011,271,291 |

IV. CONCLUSION

J&J breached Section 2.07(e) of the Merger Agreement and the implied covenant of good faith of fair dealing. These breaches led iPlatform to miss the

⁷¹² This column does not include pre-judgment interest from May 19, 2023 through the date of judgment or post-judgment interest.

General Surgery, Upper Abdominal, Lower Abdominal, Urologic, Gynecologic, and GI Milestones. J&J also committed fraud relating to the Soft Tissue Ablation Milestone. Fortis is entitled to damages, plus pre- and post-judgment interest, as outlined above.

Within 14 days, Fortis is asked to file an updated interest calculation consistent with the methodology adopted above. The parties are asked to confer on and file a proposed final order within 10 days of Fortis's interest submission.